

(Formerly Sernova Corp.)

MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE AND SIX MONTHS ENDED

APRIL 30, 2025 AND 2024

Dated June 13, 2025

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MANAGEMENT'S DISCUSSION AND ANALYSIS

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The following MD&A is prepared as of June 13, 2025 for Sernova Biotherapeutics Inc. ("Sernova" or the "Company") for the three and six months ended April 30, 2025 and 2024, and should be read in conjunction with the interim condensed consolidated financial statements and accompanying notes for the three and six months ended April 30, 2025 and 2024, which have been prepared by management in accordance with IFRS Accounting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our IFRS material accounting policies are set out in note 3 of the consolidated financial statements for the years ended October 31, 2024 and 2023. This MD&A should also be read in conjunction with the Company's Annual Information Form dated December 23, 2024. Effective February 4, 2025, the corporation's name changed from Sernova Corp. to Sernova Biotherapeutics Inc.

All amounts are in Canadian dollars, unless otherwise indicated.

#### FORWARD-LOOKING STATEMENTS

This MD&A 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 MD&A 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<sup>TM</sup> 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 Bio-hybrid Organ<sup>TM</sup>;
- 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<sup>TM</sup> in conjunction with the Evotec Collaboration (defined below);
- the protection of therapeutic cells within Cell Pouch™ from immune system attack using local immune protection technologies, or using a systemic anti-rejection regimen or a combination thereof, and the expected benefits;

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- our intention and ability to use human autograft cells or tissues or human donor allograft cells or xenogeneic (non-human) cells for treatment, coupled with the expectation that the use of ethically derived stem cell-derived cells (i.e., iPSCs) could provide a virtually unlimited cell supply for Cell Pouch to treat various diseases;
- our expectation that insulin independence can be achieved in our planned future trial with the iPSC derived ILCs transplanted into our Cell Pouch without the need for a portal vein top up;
- 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 Bio-hybrid Organ;
- securing cGMP manufacturing facilities for our cell therapy programs; and
- the benefits of developing next-generation Cell Pouch or Cell Pouch Bio-hybrid Organ 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 Bio-hybrid 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;

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- 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<sup>TM</sup> 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, the impact of any tariffs or international trade action, 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 MD&A and in our most recently filed Annual Information Form available on our profile at <a href="https://www.sedarplus.ca">www.sedarplus.ca</a>.

Although the forward-looking statements contained in this MD&A 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.

#### ITEM 1. BUSINESS

#### **OVERVIEW**

## About Sernova

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 Bio-hybrid Organ 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.

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Currently, Sernova's Cell Pouch Bio-hybrid Organ 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 or pursuing immune protection technologies, to jointly develop and commercialize our products. We have 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 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 detrimental 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).

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Figure 1

**Cell Pouch** 



Cell Pouch Bio-Hybrid Organ



*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*.

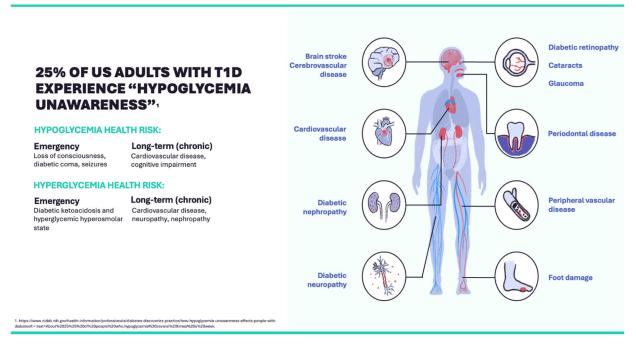
The lack of pancreatic beta cells in T1D patients also leads to the dysfunction of glucagon-producing alpha cells and somatostatin-producing delta cells. Glucagon is responsible for triggering the release of glycogen, which is a form of glucose that is stored in the liver and skeletal muscles. The stored glucose provides a continuous source of energy for the body during periods such as fasting 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.

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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. 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 three cohorts. Cohort A involved six patients who received the first-generation 8-channel Cell Pouch. Cohort B is expected to evaluate eight patients, seven of which have been transplanted to date, 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

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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

Interim data from 12 patients with transplanted human donor islet cells in Cohort A and ongoing Cohort B show patients achieving insulin independence, islet cell engraftment in Cell Pouch, islet function, islet survival, improved glycemic control, improved patient reported quality of life (QOL) and improved awareness of hypoglycemia and increased sensitivity to severe hypoglycemic symptoms. Improvement in patient outcomes was correlated with a cumulative increase in the quantity of transplanted islets. Based on these findings, the study is on track to meet its primary and secondary endpoints, and the confirmatory Cohort C is expected to initiate in H2 2025.

These interim findings show 8 of 12 patients achieving insulin independence so far, with the first patient treated in the trial having experienced sustained insulin independence for more than 4 years. These data support the thesis that Sernova's high volume ten channel Cell Pouch, used in Cohort B, has the potential to achieve insulin independence, without portal vein transplant, in our planned clinical trial with Evotec's high quality iPSC islet-like clusters.

C-peptide is a biomarker that measures the amount of insulin produced by the transplanted islets. For successful islet transplantation, a C-peptide level of 0.3 ng/mL (0.1 nmol/L) is generally considered a threshold for graft function. 7 of 12 patients showed C-peptide levels of 0.3 ng/mL or greater, indicating successful islet cell engraftment and insulin production by islets transplanted to the Cell Pouch alone. The interim data as analyzed using industry standard composite BETA and BETA-2 scores, as well as histology of explanted Cell Pouches provide further evidence of engraftment and function of islet cells after transplantation into the Cell Pouch alone.

Measured HbA1c (a blood test that estimates the average blood sugar levels over the past 2-3 months) in patients with Cell Pouch alone, showed that 9 of 12 patients had reduced values within the American Diabetes Association (ADA) recommended range of <7.0%. Of the remaining 3 patients, 1 experienced a 24% reduction in HbA1c from 10.3% to 7.8% and the other 2 maintained a normal HbA1c value of <7% as measured at baseline. Published clinical studies found that each 1% reduction in A1c was associated with a 14 % reduced risk of myocardial infarction in patients with diabetes. A single portal vein transplant resulted in all patients having a recommended HbA1c of <7.0% that was maintained for the duration of the study.

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## Additional Programs - Hypothyroidism and Hemophilia A

In February 2025, we received FDA authorization for an Investigational New Drug (IND) application to evaluate the Company's Cell Pouch with auto-transplanted thyroid cells to prevent hypothyroidism in patients undergoing total thyroidectomy for nodular thyroid disease. Hypothyroidism, a condition characterized by insufficient production of thyroid hormones, affects millions of people worldwide, often requiring lifelong daily hormone replacement therapy. 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).

In pre-clinical studies we have also been exploring the use of our bio-hybrid organ system in hemophilia A. 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 and hypothyroidism, hemophilia A is a chronic and life-limiting condition that requires lifelong monitoring and multiple daily treatments. 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 autoimmune destruction of islets that is a feature of type 1 diabetes and also occurs after islet transplantation due to the immune system's response to foreign cells.

#### **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 islet-like clusters (ILCs) 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.

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## Development Pipeline

| Indication                       | Cell Source                           | Immune Protection       | Discovery | Pre-clinical | Phase 1/2 | Phase 3 |
|----------------------------------|---------------------------------------|-------------------------|-----------|--------------|-----------|---------|
|                                  | Human donor islet cells               | Immunosuppressives      |           |              |           |         |
| Insulin-dependent Diabetes       | iPSC islets from Evotec               | Immunosuppressives      |           |              |           |         |
|                                  | iPSC islets from Evotec               | Local immune protection |           |              |           |         |
| Thyroid Disease / Hypothyroidism | Thyroid cells                         | Autologous cells        |           |              |           |         |
| myrod bisedse / nypodnyrodasii   | 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 |           |              |           |         |

## 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 glucoseresponsive, 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.

## 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

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today's most effective options. We believe our bio-hybrid organ 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 Biohybrid Organ as a potentially curative solution by providing a fully contained and retrievable, organlike 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.

## Human Capital

As of April 30, 2025, Sernova had 16 full-time employees based in the United States and Canada with employees operating remotely as well as in our facilities 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.

On May 22, 2025, we announced the formation of our clinical advisory board. The board consists of five members and is chaired by Dr. Robert Gabbay. This group of experts will provide guidance as we advance clinical development of our Cell Pouch Bio-hybrid Organ with islet cells in patients with T1D.

On June 2, 2025, we announced that Jonathan Rigby resumed the role of Board Chair on the resignation of Mr. Ross Haghighat.

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 Cell Pouch Bio-hybrid Organ with Evotec iPSC islet-like clusters as a functional cure for type 1 diabetes.

## **ITEM 1B. Unresolved Staff Comments**

Not applicable.

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## **ITEM 2. Properties**

We have separate laboratory and office leases in London, Ontario comprising approximately 2,300 square feet and 550 square feet, respectively, with lease terms expiring on December 31, 2026. We have the right to further extend the 20 month 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.

## **ITEM 3. Legal Proceedings**

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently subject to any material legal proceedings regarding our operations. The outcome of future litigation cannot be predicted with certainty and some lawsuits, claims or proceedings may be disposed of unfavorably to us, which could materially affect our financial condition or results of operations.

## **ITEM 4. Mine Safety Disclosures**

Not applicable.

# ITEM 5. Market for Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock is listed on the Toronto Stock Exchange under the symbol "SVA", on the OTCQB Venture Market under the symbol SEOVF and on the Xetra Exchange under the symbol PSH.

#### **Dividend Policy**

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our Board of Directors.

#### **Recent Sales of Prospectus Exempt Securities**

On April 16, 2025, we secured a term loan in the amount of \$4,000,000 from Navigate Private Yield Fund LP III, a fund managed by Fraser Mackenzie Private Credit Inc. The loan has minimum fixed interest of \$400,000 for the first six months and bears interest at 14.25% per annum thereafter. The loan principal is due on the maturity date which is the earlier of April 16, 2026, or the later of 120 days from the closing of the loan and ten days following the occurrence of certain specified monetization transactions. The loan is secured against the assets of the Company and our U.S. subsidiary as well as against the assets of a member of our Board of Directors. In consideration of the guarantee provided by the board member and assumption of liability, we granted 9,000,000 common share purchase warrants. Each compensation warrant is exercisable, once vested, at a price of \$0.20 per share for a term of 36 months. Upon closing of the loan, 4,000,000 warrants were vested and the remaining 5,000,000 will vest in monthly increments of 833,333 beginning after six months only while the loan remains outstanding.

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On March 4, 2025, we issued \$1,000,000 of convertible debentures to a Director of Sernova. The convertible debentures are repayable in 24 months, on March 4, 2027, unless earlier converted or redeemed and bear interest at a rate of 15% per annum payable annually in arrears, in cash or common shares at the option of the Company. The holder has the right to convert the principal amount into common shares of the Company at a conversion price of \$0.20 per share. The Company has an option to redeem and repay the convertible debt at any time after 12 months following the issue date at a redemption premium equal to 2% of the principal amount called for redemption. In conjunction with the issuance of debentures, 5,000,000 non-transferable share purchase warrants were issued with each warrant being exercisable into one common share at a price of \$0.20 per share, exercisable up to March 4, 2028.

On September 3, 2024, we issued 20,852,100 units at \$0.25 per unit for gross proceeds of \$5,213,025, before deducting cash offering costs of \$253,519 in a non-brokered private placement. Each unit comprises one common share of the Company and one common share purchase warrant. Each common share purchase warrant will be exercisable for one common share at a price of \$0.30 per common share for 18 months and 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 the Company's common shares exceeds \$0.50 per share. Non-cash offering costs include the issuance of 404,950 compensation warrants with a fair value of \$34,421.

## Repurchases of Shares or of Company Equity Securities

None.

#### Item 6. [Reserved]

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our interim condensed consolidated financial statements for the three and six months ended April 30, 2025 and 2024 filed on sedarplus.ca. This discussion and other parts of this report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

## **Financial Operations Overview**

## Research and Development Expenses

The largest component of our operating expenses is our investment in research and development activities, including the clinical development of our product candidates. Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates, as well as the development of product candidates pursuant to our collaboration, license and option to license agreements. Research and development costs include employee-related costs; research and clinical development; manufacturing; intellectual property costs; and other costs which includes facility costs,

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licensing costs, materials and supplies, and other expenses incurred to advance our research and development activities. We recognize all research and development costs as they are incurred. Clinical trial costs, contract manufacturing and other development costs incurred by third parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we advance our product candidates into and through clinical trials and pursue regulatory approval of our product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The probability of success for our product candidates and technologies may be affected by a variety of factors including: the quality of our product candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never succeed in obtaining regulatory approval for any of our product candidates. As a result of these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates.

## General and Administrative Expenses

General and administrative expenses include employee-related costs, expenses for outside professional services, directors fees, investor relations and corporate communications, public company expenses and insurance costs. Employee-related costs consist of salaries, bonuses, severance and benefits. Consulting and professional fees consist primarily of legal, accounting and audit services. Public company expenses consist of listing fees, stock exchange costs and shareholder-related expenses.

## Other expense (income)

Other expenses (income) consist of interest income generated on our cash and cash equivalents, interest expense on accounts payable, convertible debentures and loans payable and foreign exchange gains and losses.

#### Income taxes

We incur taxes in our U.S. subsidiary based on services it provides to the Canadian parent company.

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MANAGEMENT'S DISCUSSION AND ANALYSIS

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## **Results of Operations**

## Comparison of the three months ended April 30, 2025 and 2024 (unaudited)

|   | Three months ended April 30, |           |    |           |    |             |
|---|------------------------------|-----------|----|-----------|----|-------------|
|   | 2025                         |           |    | 2024      |    | Change      |
| Operating expenses                      |                              |           |    |           |    |             |
| Research and development                | \$                           | 2,362,761 | \$ | 7,709,017 | \$ | (5,346,256) |
| General and administrative              |                              | 1,963,901 |    | 2,089,500 |    | (125,599)   |
| Total operating expenses                |                              | 4,326,662 |    | 9,798,517 |    | (5,471,855) |
| Other expense (income)                  |                              |           |    |           |    |             |
| Interest income                         |                              | (2,027)   |    | (115,332) |    | 113,305     |
| Finance costs                           |                              | 238,728   |    | 21,186    |    | 217,542     |
| Foreign exchange loss (gain)            |                              | (823,078) |    | 239,113   |    | (1,062,191) |
| Net other expenses (income)             |                              | (586,377) |    | 144,967   |    | (731,344)   |
| Net loss before income taxes            |                              | 3,740,285 |    | 9,943,484 |    | (6,203,199) |
| Current income tax expense              |                              | 36,878    |    | -         |    | 36,878      |
| Net loss and comprehensive loss         | \$                           | 3,777,163 | \$ | 9,943,484 | \$ | (6,166,321) |
| Basic and diluted loss per common share | \$                           | 0.01      | \$ | 0.03      | \$ | (0.02)      |

For the three months ended April 30, 2025, we recorded a loss of \$3,777,163, a decrease of \$6,166,321 compared to the same period in the prior year. The decrease was driven mainly by a decrease in R&D expenses related to our iPSC program, consulting and professional fees and foreign exchange gains. The overall decrease was partially offset by an increase in finance costs related to interest expense on outstanding amounts payable.

## Research and Development Expenses

For the three months ended April 30, 2025, we incurred net R&D expenses of \$2,362,761, a \$5,346,256 decrease from the comparative period. The decrease reflects temporary reductions in resource allocation to the iPSC program as interim cost saving initiatives, a decrease in preclinical animal studies, personnel costs and lower non-cash share-based compensation. Personnel costs and share-based compensation decreased due to a combination of lower headcount throughout the current period over the prior period as well as higher separation payments incurred upon the retirement of a senior officer and reduction of workforce which occurred in the prior period.

#### General and Administrative Expenses

For the three months ended April 30, 2025, total G&A expenses of \$1,963,901 decreased by \$125,599 from the comparative period. The decrease was due primarily to lower legal and professional fees and public company expenses due to cost saving initiatives implemented throughout the prior fiscal year and the timing of annual general meeting of shareholders which took place during the first quarter of the current fiscal year compared to the second quarter of the prior fiscal year. The overall decrease was partially offset by an increase in personnel costs and non-cash share-based compensation. The increase in non-cash share-based compensation is primarily due to options granted in the fourth quarter of the

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prior fiscal year and the prior year comparative period including expense reversals upon the termination of certain employees.

#### Other expense (income)

Interest income for the three months ended April 30, 2025 decreased by \$113,305 from the comparable prior period. The decrease was due mainly to the use of our cash and marketable securities balances used to finance operations and therefore we had less cash than in the prior period with which to earn interest income.

Finance costs for the three months ended April 30, 2025 increased by \$217,542 from the comparable prior period. The increase is due mainly to contractual accrued interest on our accounts payable balance with one vendor where we have established a repayment plan and accrued and accreted interest on convertible debentures and loan payable. The foreign exchange loss (gain) results mainly from currency revaluation of U.S. dollar denominated balance sheet amounts into Canadian dollars each quarter. As our accounts payable balance to a significant vendor is denominated in U.S. dollars, our U.S. dollar currency exposure will vary throughout the year due to changes in exchange rate. A strengthened Canadian dollar against the U.S. dollar resulted in a net foreign exchange gain for the three months ended April 30, 2025.

## Comparison of the six months ended April 30, 2025 and 2024 (unaudited)

|  |      | Six months er |     |            |    |              |
|--|------|---------------|-----|------------|----|--------------|
|  | 2025 |               |     | 2024       |    | Change       |
| Operating expenses                         |      |               |     |            |    |              |
| Research and development                   | \$   | 4,951,167     | \$  | 14,950,021 | \$ | (9,998,854)  |
| General and administrative                 |      | 4,175,755     |     | 4,876,178  |    | (700,423)    |
| Total operating expenses                   |      | 9,126,922     |     | 19,826,199 |    | (10,699,277) |
| Other expense (income)                     |      |               |     |            |    |              |
| Interest income                            |      | (25,476)      |     | (281,659)  |    | 256,183      |
| Finance costs                              |      | 473,706       |     | 31,644     |    | 442,062      |
| Foreign exchange loss (gain)               |      | (145,950)     |     | 129,261    |    | (275,211)    |
| Gain on disposal of right-of-use asset and |      |               |     |            |    |              |
| lease liabilities                          |      | -             |     | (18,862)   |    | 18,862       |
| Net other expenses (income)                |      | 302,280       |     | (139,616)  |    | 441,896      |
| Net loss before income taxes               |      | 9,429,202     |     | 19,686,583 |    | (10,257,381) |
| Current income tax expense                 |      | 43,278        |     | -          |    | 43,278       |
| Net loss and comprehensive loss            | \$_  | 9,472,480     | \$_ | 19,686,583 | \$ | (10,214,103) |
| Basic and diluted loss per common share    | \$   | 0.03          | \$  | 0.06       | \$ | (0.03)       |

For the six months ended April 30, 2025, we recorded a loss of \$9,472,480, a decrease of \$10,214,103 compared to the same period in the prior year. The decrease was driven mainly by a decrease in R&D expenses related to our iPSC program, consulting and professional fees, personnel costs and non-cash share-based compensation, and an increase the foreign exchange gain. The overall decrease was partially offset by an increase in finance costs related to interest expense on outstanding amounts payable and lower interest income.

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## Research and Development Expenses

For the six months ended April 30, 2025, we incurred net R&D expenses of \$4,951,167, a \$9,998,854 decrease from the comparative period. The factors driving the decrease are largely the same as the factors mentioned above in the three-month analysis.

## General and Administrative Expenses

For the six months ended April 30, 2025, total G&A expenses of \$4,175,755 decreased by \$700,423 from the comparative period. The decrease was due primarily to lower legal and professional fees, investor relations and corporate communications and travel expenses due to cost saving initiatives implemented throughout the prior fiscal year. The overall decrease was partially offset by an increase in personnel costs and non-cash share-based compensation.

## Other expense (income)

Interest income for the six months ended April 30, 2025 decreased by \$256,183 from the comparable prior period and finance costs for the six months ended April 30, 2025 increased by \$442,062 from the comparable period. The factors driving the changes in interest income and finance costs are largely the same as the factors mentioned in the three-month analysis.

The foreign exchange loss (gain) results mainly from currency revaluation of U.S. dollar denominated balance sheet amounts into Canadian dollars each quarter. As our accounts payable balance is denominated mainly in U.S. dollars, our U.S. dollar currency exposure fluctuates throughout the year with changes in exchange rates. A strengthening of the Canadian dollar against the U.S. dollar resulted in a net foreign exchange gain for the six months ended April 30, 2025.

## LIQUIDITY AND CAPITAL RESOURCES

The Company's interim condensed consolidated financial statements have been prepared assuming we will continue as a going concern. The Company has incurred losses and generated negative cashflows since inception. A net loss and comprehensive loss of \$9,472,480 was incurred during the six months ended April 30, 2025 (2024 – \$19,686,583). As at April 30, 2025, the Company had an accumulated deficit of \$159,831,622 and a working capital deficit (current liabilities in excess of current assets) of \$20,406,294. As at April 30, 2025, the working capital deficit included \$12,685,553 (US\$9,184,443) in arrears included in accounts payable to one vendor for which the Company has negotiated a payment plan to be paid in full by the end of December 2025, which includes a contractual minimum monthly payment of US\$250,000 (approximately \$345,300). For the six months ended April 30, 2025, the Company generated negative cashflow from operations of \$8,664,530 (2024 – \$11,486,963).

Until the Company's products are approved and available for sale and profitable operations are developed, the Company's liquidity requirements will be dependent on its ability to continue to secure additional funding to meet its financial obligations and to fund research and development expenditures. Failure to do so could have a material adverse effect on the Company's financial condition. As a result, material uncertainty exists which may cast significant doubt on the Company's ability to continue as a going concern and realize its assets and discharge its liabilities in the normal course of business.

The Company expects to incur further losses in the development and commercialization of its proprietary Cell Pouch Bio-hybrid Organ platform and associated technologies for the foreseeable

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future and forecasts that it will need to successfully complete certain strategic financing initiatives before the end of June 2025 to continue as a going concern and cover its planned research and development expenditures and financial obligations. During the year ended October 31, 2024, we received \$5.0 million of net proceeds from a private placement of common shares (2023 – \$nil) to support our R&D operations. During the six months ended April 30, 2025, the Company secured a \$1 million debenture financing with a director and shareholder for net proceeds of \$967,555 and a \$4 million loan payable financing with Navigate Private Yield Fund LP III for net proceeds of \$3,703,323. At this time, no assurance can be given that new funding will be available or can be obtained on favorable terms. Management is working towards securing additional funding from lenders and investors, but there can be no assurance as to when or whether the Company will succeed in establishing such funding. Raising additional equity capital in the future is subject to market conditions and is not within the Company's control. Refer to sections "RISKS FACTORS" and "CAPITAL MANAGEMENT, FINANCIAL INSTRUMENTS AND RISKS" in this MD&A.

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

## Cash flows

The following table summarizes our cash flows for the periods indicated:

|                                   | <br>Six months ended April 30 |    |              |  |  |
|-----------------------------------|-------------------------------|----|--------------|--|--|
|                                   | 2025                          |    | 2024         |  |  |
| Cash flows provided by (used in): |                               |    |              |  |  |
| Operating activities              | \$<br>(8,664,530)             | \$ | (11,486,963) |  |  |
| Investing activities              | -                             |    | 6,079,304    |  |  |
| Financing activities              | <br>4,649,963                 |    | 123,618      |  |  |
| Net increase (decrease) in cash   | \$<br>(4,014,567)             | \$ | (5,284,041)  |  |  |

#### **Operating Activities**

Net cash used in operating activities was \$8.7 million for the six months ended April 30, 2025, a decrease of \$2.8 million compared to \$11.5 million for the six months ended April 30, 2024. The decrease was primarily due to lower cash used for operations partially offset by the impact of changes in non-cash working capital balances in the comparative period.

#### Investing Activities

Net cash provided by investing activities was \$nil for the six months ended April 30, 2025 compared to \$6.1 million for the six months ended April 30, 2024. The decrease was primarily due to net redemptions of marketable securities in the prior year.

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## Financing Activities

Net cash provided by financing activities was \$4.6 million for the six months ended April 30, 2025, an increase of \$4.5 million compared to net cash used in financing activities of \$0.1 million for the six months ended April 30, 2024. The increase was due mainly to proceeds from a loan payable and convertible debentures issued in the current period.

## Common share activity is set out below:

|  | Number of     |
|--|---------------|
|  | common shares |
| Balance outstanding as at October 31, 2024                         | 325,324,786   |
| Issued on settlement of deferred share units                       | 3,160,000     |
| Balance outstanding as at April 30, 2025 and the date of this MD&A | 328,484,786   |

## Warrant activity is set out below:

|  | Number of warrants | Weighted average ercise price |
|--|--------------------|-------------------------------|
| Balance outstanding as at October 31, 2024                         | 21,257,050         | \$<br>0.30                    |
| Issued with convertible debenture                                  | 5,000,000          | 0.20                          |
| Issued in conjunction with loan payable guarantee                  | 9,000,000          | 0.20                          |
| Balance outstanding as at April 30, 2025 and the date of this MD&A | 35,257,050         | \$<br>0.25                    |

## **Incentive plan**

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

## Incentive plan activity is set out below:

|   | Number of options | Weighted average exercise price |
|---|-------------------|---------------------------------|
| Balance outstanding as at October 31, 2024      | 43,080,158        | \$ 0.53                         |
| Granted   | 2,520,000         | 0.25                            |
| Forfeited                                       | (44,039)          | (0.50)                          |
| Expired   | (15,973,818)      | (0.84)                          |
| Balance outstanding as at April 30, 2025        | 29,582,301        | 0.34                            |
| Granted   | 50,000            | 0.25                            |
| Expired   | (200,000)         | (0.80)                          |
| Balance outstanding as at the date of this MD&A | 29,432,301        | \$ 0.35                         |

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|  | Number of deferred |
|--|--------------------|
|  | share units        |
| Balance outstanding as at October 31, 2024                         | 4,445,001          |
| Equity settlement  | (3,160,000)        |
| Balance outstanding as at April 30, 2025 and the date of this MD&A | 1,285,001          |

Under the Incentive Plan, the Board of Directors may grant stock options to directors, officers, employees or consultants of the Company and deferred share units to directors and officers of the Company up to an aggregate fixed maximum of 55,510,001 of the Company's issued and outstanding common shares, representing approximately 16.9% of the common shares outstanding as at April 30, 2025. The remaining balance available for grant under the Incentive Plan as of April 30, 2025 is 18,175,434 which is reserved for the issuance of stock options.

#### **COMMITMENTS AND CONTINGENCIES**

The Company was previously awarded a US\$2.45 million (\$3.39 million) grant under an agreement with Breakthrough T1D (formerly JDRF) that supports its Phase 1/2 clinical trial of Sernova's Cell Pouch for treatment of patients with type 1 diabetes. Pursuant to the agreement, the Company has committed to perform certain clinical trial activities and to use commercially reasonable efforts to introduce a diabetes product into the US market. All milestone achievements under this agreement have been reached and the full amount of the grant has been earned, The Company is required to pay royalties to Breakthrough T1D as a percentage of any future net sales received from such diabetes product or in certain future license or disposition transactions up to a maximum of four times the aggregate amount of Breakthrough T1D grant funding received. A bonus amount equal to the total amount of grant funding received is also payable to Breakthrough T1D on two aggregate net sales thresholds if they are achieved. Given the early and inconclusive stage of development of the diabetes product, the royalty is not probable at this time and therefore no liability has been recorded.

The Company has a strategic partnership with Evotec for the development and commercialization of an iPSC-based beta cell replacement therapy ("iPSC Program") with the goal to provide an unlimited insulin-producing cell source to treat patients with insulin-dependent diabetes. The Company has committed to make future development milestone and royalty payments to Evotec contingent on the occurrence of certain events, including the Company's exercise of the option, as set forth in the collaboration agreement (the "Evotec Agreement"). Under the terms of the Evotec Agreement, the preclinical development program will be jointly funded up to IND submission with the Company's share of costs being 75% and Evotec's share being 25%. There are significant future development costs expected under the agreement. The Evotec agreement is cancellable by the Company with notice, subject to certain terms and conditions. The amount of joint iPSC Program costs originally incurred by Evotec and subsequently recharged to the Company was recorded in research and development expenses and the reimbursement of iPSC Program costs originally incurred by the Company was recorded as a reduction of research and development expenses.

The Company enters into contracts in the normal course of business, including for research and development activities, consulting and other services. As at April 30, 2025, the Company has commitments totaling approximately \$4.4 million, of which approximately \$1.3 million is expected to be paid over the next twelve months. The majority of these contracts are cancellable by the Company with notice. The Company has committed to use 10% of future financings to pay certain accounts

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payable and accrued liabilities. In addition, the Company has minimum annual royalty payment obligations of approximately \$34,000 for third party licensing agreements.

Effective January 1, 2024, the Company entered into a three-year lease for office premises and lab space at a rate of \$14,010 per month, with a 3% increase on the anniversary of the lease agreement. Under the terms of the lease, the Company has two option periods to extend the lease term for an additional twelve months each, up to December 31, 2028. As of April 30, 2025, remaining undiscounted lease payment obligations total \$666,720 assuming the Company exercises both options, of which \$174,892 is payable over the next twelve months and \$491,828 is payable in the following two to five years. On May 1, 2025, the Company entered into a new lease for reduced office space with the same landlord and terms as the January 1, 2024 lease at a rate of \$6,754 per month with a 3% increase on the first day of January each year.

The Company has entered into research collaboration agreements with strategic partners in the ordinary course of operations that may include contractual milestone payments related to the achievement of prespecified research, development, regulatory and commercialization events and indemnification provisions, which are common in such agreements. Pursuant to the agreements, the Company is obligated to make research and development and regulatory milestone payments upon the occurrence of certain events and royalty payments based on net sales. The maximum amount of potential future indemnification could be unlimited, however, the Company currently holds commercial and product liability insurance that limits the Company's liability and may enable it to recover a portion of any future amounts paid. Historically, the Company has not made any indemnification payments under such agreements and believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to indemnification obligations.

The following table summarizes our significant future contractual obligations as at April 30, 2025:

|                                     | Payment due by period |              |              |           |               |  |  |
|-------------------------------------|-----------------------|--------------|--------------|-----------|---------------|--|--|
| (1)(2)                              |                       | Less than 1  |              |           |               |  |  |
| Contractual Obligations (1)(2)      | Total                 | year         | 1-3 years    | 4-5 years | After 5 years |  |  |
| Lease Obligations <sup>(3)</sup> \$ | 666,720 \$            | 174,892 \$   | 491,828 \$   | - \$      | -             |  |  |
| Purchase Obligations (4)            | 3,689,946             | 1,143,004    | 2,546,942    | -         | -             |  |  |
| Total \$                            | 4,356,666 \$          | 1,317,896 \$ | 3,038,770 \$ | - \$      | -             |  |  |

#### Notes:

- (1) Contractual obligations in the above table do not include amounts in accounts payable and accrued liabilities on our statement of financial position as at April 30, 2025.
- (2) Contingent milestone and royalty payments under collaboration agreements noted above are not included in the table.
- (3) Includes operating lease obligations for office and laboratory facilities.
- (4) Purchase obligations include cancellable and non-cancellable contracts including agreements related to the conduct of our clinical trial, preclinical studies, and manufacturing activities.

## RELATED PARTY TRANSACTIONS

During the six months ended April 30, 2025, we issued convertible debentures to a Director of the Company and the same Director guaranteed a loan to the Company. All other related party transactions were for the payment of and accruals for compensation to key management personnel of the Company in the ordinary course of business for the six months ended April 30, 2025. Refer to Note 7 – *Related Party Transactions* in our interim condensed consolidated financial statements for further information.

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## **SUMMARY OF QUARTERLY RESULTS**

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

|                                 | Q2 2025   | Q1 2025   | Q4 2024    | Q3 2024   |
|---------------------------------|-----------|-----------|------------|-----------|
|                                 | \$        | \$        | \$         | \$        |
| Net loss and comprehensive loss | 3,777,163 | 5,695,317 | 4,968,112  | 7,537,440 |
| Net loss per share              | 0.01      | 0.02      | 0.02       | 0.02      |
|                                 | Q2 2024   | Q1 2024   | Q4 2023    | Q3 2023   |
|                                 | \$        | \$        | \$         | \$        |
| Net loss and comprehensive loss | 9,943,484 | 9,743,099 | 11,703,658 | 9,931,704 |
| Net loss per share              | 0.03      | 0.03      | 0.04       | 0.03      |

For fiscal year 2023 through the second quarter of Fiscal 2024, quarterly losses were fairly stable reflecting the steady advancement of our R&D programs, including our iPSC Program research collaboration with Evotec and study patient activities for our Phase 1/2 T1D clinical trial. From Q3 2024 to Q2 2025, our expenses decreased on a net basis as we took measures to reduce our costs with a staff reduction, focus on our T1D clinical trial and thyroid program, and stretch our cash resources pending new financing, while increasing some costs with the hiring of new senior management. The loss for the second quarter of 2025 was also impacted by foreign exchange gains on outstanding amounts payable due to a strengthening Canadian dollar against the U.S. dollar.

Our costs can vary significantly between reporting periods due to differences in timing of expenditures as well as the level and status of specific R&D and corporate activities being undertaken.

## **OFF-BALANCE SHEET ARRANGEMENTS**

The Company does not have any off-balance sheet arrangements.

#### CAPITAL MANAGEMENT, FINANCIAL INSTRUMENTS AND RISKS

This section provides disclosures relating to the nature and extent of our exposure to risks arising from financial instruments, including credit risk, liquidity risk, interest rate risk and foreign currency risk, and how we manage those risks.

#### Credit risk

Credit risk is the risk of loss to the Company if a counterparty to a financial instrument fails to meet its contractual obligations. The Company's credit risk is primarily attributable to cash, in excess of insured amounts, held or invested at financial institutions including Canadian chartered banks and financial service firms. Management actively reviews the risk of the financial institutions and or the counterparty to the underlying financial instruments held failing to meet its obligations and adjusts expected credit losses if and when any undue risk is identified. Amounts receivable at April 30, 2025 are composed primarily of amounts due from Canadian federal government agencies with full collection expected.

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## Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company is a development stage company and is reliant on external fundraising to support its operations. Once funds have been raised, the Company manages its liquidity risk by investing its cash resources in high interest savings accounts or marketable securities to provide regular cash flow for its operations and monitoring actual and projected cash flows. As at April 30, 2025, the Company had a working capital deficit of \$20,406,294 with accounts payable and accrued liabilities payable within the next twelve months. Additional financing is required for the Company to meet its short-term financial obligations. Refer to the *Liquidity and Capital Resources* section of this MD&A for more information.

#### Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company holds its cash in bank accounts and manages its interest rate risk by holding cash in high yield savings accounts or highly liquid short-term investments. Interest income is not significant to the Company's projected operational budget and rate fluctuations are not significant to the Company's risk assessment. Amounts in arrears due to a vendor accrue interest at Euribor plus one percent. Refer to the *Liquidity and Capital Resources* section of this MD&A for more information.

## Foreign currency risk

Foreign currency risk is the risk that future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. The Company is exposed to foreign currency risk on fluctuations in foreign exchange rates for any cash, amounts receivable, accounts payable and accrued liabilities and grant contributions that are denominated in foreign currencies. The Company's foreign currency risk is primarily related to US dollar denominated expenses and accounts payable. Fluctuations in the US dollar exchange rate could have a significant impact on the Company's results. Assuming all other variables remain constant, a 10% depreciation or appreciation of the Canadian dollar against the US dollar would result in an increase or decrease in loss and comprehensive loss for the six months ended April 30, 2025 of \$1,821,910 (2024 – \$963,902). Note 11(d) to the interim condensed consolidated financial statements for the three and six months ended April 30, 2025 provides information on our significant foreign exchange currency exposures as at that date.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

Refer to the Company's audited consolidated financial statements for the years ended October 31, 2024 and 2023 for discussions on our material accounting policies and significant estimates that are most important in assessing, understanding and evaluating our interim condensed consolidated financial statements.

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## INTERNAL CONTROLS OVER FINANCIAL REPORTING

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

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

There have been no changes in the Company's ICFR during the three months ended April 30, 2025, that have materially affected, or are reasonably likely to materially affect, the Company's ICFR.

## **RISKS 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, and in the Company's most recently filed Annual Information Form available on www.sedarplus.ca, as well as other information contained in this MD&A. 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.

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 Bio-hybrid Organ 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 Biohybrid Organ in T1D, we have not yet completed later stage clinical trials for any of our product candidates.

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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.

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 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 April 30, 2025 of \$2.0 million will enable us to fund our current operating plan requirements through June 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.

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# 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. Deterioration in international trade relations, new legislation and tariffs may also adversely impact our operations and/or financial condition by limiting or preventing the activities of third parties that we engage, increasing import costs or increasing the cost of our operations. 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, which 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.

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 April 30, 2025, we had 328,484,786 common shares issued and outstanding, outstanding DSUs convertible into an additional 1,285,001 common shares, outstanding options to purchase 29,582,301 common shares, and outstanding warrants to purchase 35,257,050 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.

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## ADDITIONAL INFORMATION

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