



## **SERNOVA CORP.**

### **MANAGEMENT'S DISCUSSION AND ANALYSIS**

**FOR THE THREE AND NINE MONTHS ENDED JULY 31, 2014 AND 2013**

Dated September 26, 2014

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## **INTRODUCTION**

The following management's discussion and analysis ("MD&A") explains the variations in the consolidated operating results and financial position and cash flows of the Company for the three and nine months ended July 31, 2014 and 2013. This analysis should be read in conjunction with the unaudited interim condensed consolidated financial statements for the three and nine months ended July 31, 2014 and the audited consolidated financial statements of the Company and related notes as at and for the years ended October 31, 2013 and 2012, which have been prepared by management reflecting the adoption of International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The Company's IFRS accounting policies are set out in Note 3 of the consolidated financial statements for the year ended October 31, 2013.

The information in this report is dated as of September 26, 2014.

## **FORWARD-LOOKING STATEMENTS**

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

The Company's statements of "belief" with respect to its product candidates are based primarily upon results derived to date from its preclinical and initial clinical research and development and the Company's research and development programs. The company also uses the term "demonstrated" in this MD&A to describe certain findings that it makes arising from its research and development including any preclinical and clinical studies that the Company has conducted to date.

Specifically, this MD&A may contain forward-looking statements which include, but are not limited to, statements regarding:

- The Company's corporate strategies and objectives;
- General business and economic events;
- The availability of various forms of financing;
- The initiation and completion of clinical trials of our Cell Pouch™ for the treatment of insulin-dependent diabetes and other diseases;
- The intention to protect therapeutic cells within the Cell Pouch™ from immune attack using either systemic antirejection regimens or local immune protection such as Sertolin™ or encapsulation technologies or a combination thereof;
- The intention to use human donor cells, xenogeneic cells and stem cells in our Cell Pouch™ for the potential treatment of chronic diseases;
- The intention to receive regulatory approval and commercialize the Cell Pouch™ for the treatment of insulin-dependent diabetes and other potential indications;

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- Expectations with respect to the cost of Sernova's products, clinical trials and commercialization of our products;
- Sales and marketing strategy;
- Sernova's intentions to secure academic and industrial collaborations and to develop and implement partnering strategies; and,
- Intentions regarding the protection of Sernova's intellectual property;

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

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

The MD&A has been prepared to help investors understand the financial performance of Sernova in the broader context of the Company's strategic direction, the risks and opportunities as understood by management, and some of the key metrics that are relevant to the Company's performance. This discussion and analysis has been reviewed and approved by the Audit Committee and the Board of Directors. The Audit Committee of the Company includes three Directors who are financially knowledgeable.

### **ABOUT SERNOVA**

Sernova Corp. is a Canadian-based regenerative medicine company, focused on commercializing the proprietary Cell Pouch™, and therapeutic cells protected locally from immune system attack with its proprietary technologies. The Cell Pouch™ is a scalable, implantable, medical device for the transplantation and survival of therapeutic cells, which then release proteins and/or hormones for the long-term treatment of a number of serious, chronic, debilitating diseases such as diabetes and haemophilia. Our proprietary local immune protection technology is being developed to create an immune privileged environment to protect the Cell Pouch™ transplant from rejection with the goal to eliminate the need for daily antirejection drugs. Our initial studies have focused on the treatment of insulin-dependent diabetes through the transplantation of pancreatic islets, which control blood glucose levels. To date, we have successfully transplanted autologous islets (self-islets) and donor islets in our Cell Pouch™ to treat insulin-dependent diabetes in multiple animal models, and a proof of concept clinical trial for the treatment of human subjects with diabetes receiving an islet transplant, protected by the standard of care antirejection drug regimen, is underway in Canada at the University of Alberta with Dr. James Shapiro as principal investigator. The primary endpoint of this study is Cell Pouch™ safety. Interim results of this study have demonstrated the Cell Pouch™ to be biocompatible and safe following implantation and to provide a suitable environment for the survival and engraftment of islets. With these interim safety results in humans, the company is committed to securing an unlimited supply of cells to treat diabetes and to expand its clinical programs into additional suitable disease indications.

### **Research and Development**

Sernova is a development stage company. Our research and development efforts are focused principally on the development of the Cell Pouch™, our medical device for transplantation and treatment of chronic diseases, and on local immune protection technologies such as Sertolin™. We have not been profitable since inception, and we expect to continue to incur substantial losses as we continue our research and development

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efforts. We do not expect to realize material revenues until, if and when, our medical technologies become commercially viable.

Our objective is to advance our medical technologies through the various stages required to develop a commercial product. To achieve this goal, our primary activities include the following:

1. Conducting clinical trials required to gain marketing approval for the Cell Pouch™ device in countries that have a significant market opportunity. Our first clinical trial is currently underway in Canada, evaluating as a primary endpoint, safety and secondary endpoint, efficacy of the Cell Pouch™ transplanted with human donor islets, protected using the standard of care antirejection drug regimen, in subjects with insulin-dependent diabetes. These programs may involve third party collaborations and corporate partnerships in addition to our internal clinical development activities;
2. Conducting preclinical and clinical research programs to examine a range of therapeutic indications for our platform Cell Pouch™ technology including, but not limited to: chronic pancreatitis, haemophilia, parathyroid gland replacement, and other chronic diseases that require a hormone or protein which is missing or in short supply in the body. These programs may involve third party collaborations in addition to our internal R&D efforts;
3. Identification and development of complementary technologies which may improve the safety and efficacy of our Cell Pouch™, including local immune protection technologies such as Sertolin™. These programs may involve third party collaborations in addition to our internal R&D efforts;
4. Identification and development of alternative sources of therapeutic cells for transplantation within our Cell Pouch™, including autologous, allogeneic, donor, xenogeneic differentiated cells and stem cells. These programs may involve third party collaborations in addition to our internal R&D efforts;
5. Manufacturing and supply of Cell Pouches™; and,
6. Generation and/or licensing of Intellectual Property.

#### **Corporate Update for the period ended July 31, 2014 and to the date of this MD&A**

##### **The following is a summary of highlights in 2014 to date:**

- Sernova released encouraging interim results from a patient cohort in the Cell Pouch™ diabetes clinical study demonstrating Cell Pouch™ biocompatibility and safety and four key points regarding islets transplanted into the Cell Pouch™: 1.) transplanted islets are well-incorporated with blood vessels, important for islet survival and function 2.) the islets are housed within a natural tissue matrix, 3.) the islets are making insulin, glucagon and somatostatin – the key hormones to control diabetes, and 4.) there is no evidence of immune rejection of the islets;
- Sernova agreed on key terms with the University Health Network of Toronto for an exclusive license to stem cell technologies as an unlimited source of cells for the treatment of insulin-dependent diabetes;
- Sernova appointed David Garland CPA-CA, CPA-CMA, MAcc as Sernova's interim CFO;
- Sernova expanded its business development team with the appointment seasoned experts, Kevin Egan and Nick Borrelly;
- Sernova appointed Frank Holler to Sernova's board of directors.

In July 2014, we signed a term sheet agreeing on key terms with the University Health Network of Toronto ("UHN") for the granting of an exclusive license to the Company covering patent rights relating to the UHN stem cell technologies including for the treatment of diabetes. We believe the proprietary product – insulin

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producing stem cells, protected locally from immune system attack and placed within Sernova's prevascularized Cell Pouch™ - has the potential to provide a significant break-through in the quality of treatment for the millions of people suffering from insulin-dependent diabetes, following successful preclinical and clinical testing. Sernova's rights to the UHN stem cell technologies are subject to negotiation and execution of a definitive license agreement with UHN based on the signed term sheet

In June 2014, we appointed Mr. David Garland, CPA-CA, CPA-CMA, MAcc as interim CFO to replace Ms. Cathy Steiner, who has moved on to pursue other business interests. Mr. Garland has extensive public company experience and has been CFO of Mash Media Solutions Inc. and Wi-LAN V-Chip Corp (formerly Tri Vision International) and has worked as VP Finance and/or Controller at Pathways to Education, Certicom Corp., and Delano Technology Corporation.

In May 2014, we expanded our business development team with Mr. Kevin Egan and Mr. Nick Borelly to establish corporate partners for Senova's programs and to further develop our proprietary technologies through academic and corporate partnerships. Mr. Egan, President, Borealis Biotechnology LLC, an international biotechnology consulting company is a Washington-based entrepreneur and investor. Mr. Egan brings over 25 years' experience in biopharma, and commercialization & partnering expertise to Sernova. Mr. Borelly has over 25 years' experience in corporate/business development as well as marketing and sales in the pharmaceutical (Ciba-Geigy, Novartis and Sanofi-Aventis) and biopharma industries. As President of Camargue Consulting, Mr. Borelly specializes in development, evaluation and in-licensing of technologies, initiation of strategic alliances with multi-national corporate partners and leading sales and marketing teams for commercial stage products.

In February 2014, we appointed Frank Holler to our Board of Directors. Mr. Holler brings 25 years of experience in the biopharma and technology sectors to Sernova's board. Mr. Holler previously served as President & CEO of Xenon Pharmaceuticals, Inc., President & CEO of ID Biomedical Corporation, and was a founding director of Angiotech Pharmaceuticals, a TSX/NASDAQ-listed biotechnology company. He was also an investment banker with Merrill Lynch Canada and Wood Gundy, Inc. (now CIBC World Markets) and former director of the British Columbia Biotechnology Association (now LifeSciences BC). Sernova also announced that it granted an aggregate of 150,000 incentive stock options to a director of the Company to purchase common shares in the capital stock of the Company. Each option entitles the holder to purchase one common share of the Company, once vested, at an exercise price of \$0.15, for a period of 5 years.

In January 2014, the Board of Directors granted an aggregate of 2,910,000 incentive stock options to certain directors, officers, employees and consultants of the Company which, once vested, are exercisable at \$0.15 for a period of five years.

In November 2013, we engaged Carson Seabolt and Network IR to work with us to develop and execute a comprehensive investor communications program to raise awareness of the Company within North America and international investment communities. Under the terms of our agreement with Network IR, Sernova is providing a cash payment of \$6,000 per month. In addition, we granted Network IR 300,000 incentive stock options to purchase common shares of the Company which, once vested, are exercisable at \$0.15 for a period of two years.

### **Research and Development Outlook for the 2014 Calendar Year**

Our product development program for the remaining 2014 includes the following:

- Anticipated further follow up on the Cell Pouch™ diabetes clinical study;

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- Anticipated preclinical results from our collaboration with Dr. James Shapiro;
- Anticipated preclinical results from our studies of local immune protection within the Cell Pouch™, based on the NRC-IRAP contribution agreement;
- Anticipated preclinical results from the collaborative agreement with Medicyte GMBH evaluating feasibility of the use of Medicyte's upcyte® cells in Sernova's Cell Pouch™;
- Anticipated selection of another disease indication for product development and future human evaluation in a clinical trial to assess the safety and efficacy of the Cell Pouch™ in this indication; and,
- Ongoing assessment of complementary immune protection technologies and alternative sources of cells, which may result in additional academic and /or corporate relationships to further develop and expand Sernova's technologies towards commercialization.

We anticipate the total cash requirements to fund our planned activities for 2014 will be in the range of \$2 to \$2.5 million. Our actual cash requirements for 2014 will depend on the actual clinical, pre-clinical, and collaborative activities that we ultimately undertake.

### **Cell Pouch™ Clinical Development**

Sernova's lead program is the clinical development of the Cell Pouch™ for treatment of patients with insulin-dependent diabetes. In August 2012, the Company and the University of Alberta announced the treatment of the first patient with insulin-producing islets transplanted into the Cell Pouch™. Dr. James Shapiro, pioneer of the Edmonton Protocol, and his team at the University of Alberta are conducting this human clinical study to assess the safety as primary endpoint and efficacy as secondary endpoint of the Cell Pouch™ with donor islets, in insulin-dependent diabetic subjects who are receiving islet transplantation.

The Edmonton Protocol is a treatment for insulin-dependent diabetes that involves infusing donor pancreatic islets, often from multiple donors, into a patient's portal vein of the liver, followed by life-long administration of immunosuppressive drugs to prevent rejection of the transplant. Overall, benefits of the Edmonton Protocol may include a reduction in the incidence of hypoglycemia unawareness, a reduced requirement for exogenous insulin and reduced diabetes-induced microvascular damage. The Edmonton Protocol has been proven to reduce the incidence of hypoglycemia-unawareness and its devastating consequences and with enough islet transplants may lead to a period of insulin-independence. It is believed, however, following islet infusion, there is an initial significant reduction in surviving islets due to an immediate blood mediated inflammatory reaction, which may damage and destroy a significant proportion of the islets infused into the portal vein. In addition, the proportion of patients with insulin-independence decreases over time, likely due to continued islet destruction with multiple etiologies. There is a need for an improved environment in which to place therapeutic cells that more closely mimics the natural environment of cells which are in close proximity to microvessels but not actually bathed in blood. Furthermore, the portal vein is not a suitable location for alternative but virtually unlimited sources of cells such as insulin producing stem cells or xenogeneic cells that could be used to treat large numbers of patients.

We believe our Cell Pouch™ will offer significant benefits over the Edmonton Protocol, the current standard of care protocol for islet transplantation, to restore the body's insulin production and glucose control in insulin-dependent diabetic patients. The Cell Pouch™ was designed to take into consideration the biological requirements of therapeutic cells. A tissue matrix rich in microvessels forms within the Cell Pouch™ when implanted subcutaneously prior to islet transplantation, providing an ideal environment for placement of therapeutic cells, including insulin-producing islets. We have demonstrated in a series of ISO10993

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biocompatibility studies and multiple animal studies that the Cell Pouch™ is biocompatible and safe. Long-term studies in multiple animal models have demonstrated that the islets become well-supported with microvessels and even infiltrated with microvessels as in their natural pancreatic environment following islet transplantation into the Cell Pouch™.

Benefits of the Cell Pouch™ are anticipated to be enhanced long-term islet graft survival and function. It is important for islets to have close contact with microvessels to monitor blood glucose levels and produce the appropriate amount of insulin throughout the day and night and after meals. The Cell Pouch™ achieves this ideal islet/microvessel connection and should allow for improved glucose control. Our studies have shown that the Cell Pouch™ with islets can control glucose levels in small and large animal models of diabetes over extended periods.

We believe the immediate blood-mediated inflammatory reaction will also be prevented, as the therapeutic cells are surrounded by microvessels similar to the islets' natural microenvironment in the pancreas rather than being bathed in a constant flow of blood. This reduced inflammatory response should enable improved islet survival and potentially lead to the need to implant fewer islets. In the case of donor islets, this could potentially enable patients with diabetes to be treated with fewer donor pancreata than are currently being used. Currently, it can take up to three pancreata to treat a single patient and achieve a reduction in insulin injections using the Edmonton Protocol.

The Cell Pouch™ enables islets to be transplanted in the subcutaneous space, which we believe will offer significant advantages over portal vein delivery as it can be monitored, imaged and if required, retrieved and replaced. Known side effects such as portal vein hypertension, thrombosis, and liver steatosis (fatty liver), along with the costs of treating them, should be eliminated.

The Cell Pouch™ may allow for local immunoprotection rather than the need for lifelong systemic antirejection drug treatment. Local immune protection of islets could result in a significant reduction in the need for antirejection drugs and their ongoing prohibitive costs, as well as associated healthcare costs related to side effects of these drugs. In addition, local immunoprotection may provide a safer environment for the transplanted islets.

Finally, the Cell Pouch™ could be used with a variety of sources of cells, such as insulin-producing stem cells and xenogeneic cells, addressing the limited availability of donors and allowing the widespread treatment of insulin-dependent diabetes. Thus, we believe our approach offers substantial benefit over the currently-used Edmonton Protocol, and its ease of use may provide an opportunity for the Cell Pouch™ to become the standard of care in islet transplantation, if it proves to be safe and effective in clinical trials.

In our human clinical trial, subjects who meet the entry criteria are implanted with the Cell Pouch™, which is allowed to incorporate with tissue and microvessels prior to transplantation of donor human islets. In this "first-in-human" study, to prevent islet graft rejection, patients are treated with the state of the art standard of care Alemtuzumab-induction protocol and provided maintenance immunosuppression. This regimen has been shown to be a substantial improvement over previous antirejection protocols when assessed for portal vein delivery of islets.

In September 2013, encouraging interim safety and biocompatibility results for the implanted Cell Pouch™ and proof of islet survival within the Cell Pouch™ following islet transplant in the first two patients was released. Dr. Shapiro presented these results in a podium session at the XIV World Congress of the International Pancreas and Islet Transplantation Association in Monterey California. In this initial assessment, the Cell Pouches™ were shown to meet the primary endpoint of safety after implantation. The Cell Pouches™ were then transplanted with human donor islets, followed by removal up to 30 days post-transplant

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for assessment of islet survival and function. The Cell Pouches™ were prepared for comprehensive histological analysis and assessed by experts in an independent, blinded analysis for key features including device biocompatibility, tissue and microvessel development into the device, islet survival and the presence of important hormones produced by islets in the control of glucose (i.e. insulin, glucagon, and somatostatin) as well as protection of islets from immune attack.

The results showed device-tissue biocompatibility, tissue and microvessel development within the Cell Pouch™, proof of islet cell survival with microvessels at and within islets, and importantly, the presence of islet insulin, glucagon, and somatostatin. The identification of these three hormones indicates that the islets within the Cell Pouch™ are able to produce the required hormones that regulate blood sugar levels. There was also no evidence of immune cell attack of the islets within the Cell Pouch™. Based on these encouraging initial results, which support the positive results of our multiple preclinical models, we are encouraged that the Cell Pouch™ continues to provide a safe and suitable environment for therapeutic cells, and the clinical study is ongoing.

Importantly, in longer-term assessment, the Cell Pouch™ has continued to demonstrate consistent clinical biocompatibility and safety at the 6 month time point. These ongoing results continue to support that the Cell Pouch™ is both safe and provides a suitable environment for therapeutic cells.

Further interim safety and efficacy results will be released as the clinical trial advances and sufficient data have been accumulated to make definitive statements. It is anticipated that these results will be presented to the scientific community at relevant scientific conferences.

With the positive results to date, the Company is committed to gaining access to sources of cells to treat the available patients and to expanding clinical assessment of the Cell Pouch™ in additional disease indications and will provide updates as these developments progress.

### **Collaborations to Advance the Cell Pouch™ for Therapeutic Cells**

#### *Collaboration with Medicyte GmbH: Cell Pouch™ for Haemophilia*

As part of our strategy to develop the Cell Pouch™ for different therapeutic indications, in September 2013 we announced a material transfer agreement with Medicyte GmbH to jointly evaluate the use of Medicyte's upcyte® cell technology in Sernova's Cell Pouch™ for the treatment of patients with haemophilia A. Both parties have also entered into a non-binding term sheet describing the general terms of a collaboration, outlining the preclinical and clinical development of the novel Cell Pouch™/upcyte® product for the treatment of haemophilia A. While preclinical proof of concept work is underway under the terms of the MTA, the parties intend to complete negotiations of a definitive agreement. We anticipate that positive results in the proof of concept studies will lead to the initiation of a formal development program towards entry into clinical trials.

#### *University of Alberta: Cell Pouch™ and Diabetes*

In addition to the clinical evaluation of the Cell Pouch™ in subjects receiving an islet transplant, the Company has an ongoing preclinical collaboration with Dr. Shapiro of the University of Alberta with the goal to increase the number of subjects that can be treated with the Cell Pouch™ and associated technologies through approaches which provide improved health of islets prior to and after being placed into the Cell Pouch™.

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

When transplanted into a recipient, Sertoli cells ("Sertolin™") provide an immune privileged environment for therapeutic cells. Sernova is currently conducting preclinical investigations of Cell Pouch™ and Sertolin™ transplantation, with the goal to reduce or eliminate the need for anti-rejection medications.

In March 2013, we were awarded a third non-repayable financial contribution of up to \$254,300 from the National Research Council of Canada for the optimization of our Sertolin™ technology within our Cell Pouch™ to treat chronic diseases. This financial contribution is being used for a series of studies to optimize the safety and efficacy of Sertolin™ with insulin-producing islets in the Cell Pouch™. We continue to evaluate various local immune protection technologies.

### **Alternative Sources of Cells**

Our transplantation technologies may incorporate autologous cells, donor cells or other sources of cells including xenogeneic or stem cells, depending on the clinical indication under evaluation and the need for expanded numbers of cells for treatment of larger populations. As such, we are working with academic collaborators and industry partners to identify and secure the required cells for our therapeutic indications.

### **Manufacturing**

Our contract manufacturer has the required expertise to manufacture both our Cell Pouch™ and mini-Cell Pouch™ for preclinical and clinical evaluation in a number of clinical indications. Device specifications were set, a semi-automated manufacturing process developed and the product manufactured, packaged and sterilized under strict regulatory guidelines (ISO 13485:2003) suitable for testing in clinical trials in North America and Europe. Sterilization verification studies have been completed and the product has been released for assessment in human clinical trials by Health Canada and for potential clinical trials in other regulatory jurisdictions.

### **Intellectual Property**

At July 31, 2014 our patent portfolio consisted of 25 issued and 27 pending patents in nine families covering our enabling platforms. We strive to receive broad claims in our patents, to have exclusivity using our Cell Pouch™ and Sertolin™ in combination with a wide range of therapeutic cell types and to treat a number of chronic diseases. We intend to continue to expand our patent and licensing portfolio through proprietary internal inventions as well as strategic in-licensing, to maximize the commercial potential for our platform technologies.

### **Financing Activity**

For the nine months ended July 31, 2014, 1,634,195 stock options were exercised for gross proceeds of \$210,180 and 100,000 warrants were exercised for gross proceeds of \$20,000.

In February, 2013 the Company completed a non-brokered private placement in the amount of \$2.0 million. The offering consisted of 10 million units sold at a price of \$0.20 per unit. Each unit consists of one common share and one common share purchase warrant, with each warrant entitling the holder thereto to purchase one

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common share of the Company for a period of 36 months from closing of the offering at a price of \$0.35 per share for the first 24 months and at a price of \$0.40 per share for the last 12 months. The warrants were ascribed a value of \$250,000 representing the difference between the issue price of the unit and the fair market value of the shares at the time received as part of the offering.

Costs associated with the private placement totaled \$228,383 including a finder's commission of \$140,000 and the issue of 985,931 finder's warrants valued at \$60,240, which costs have been deducted from the gross proceeds.

## RESULTS OF OPERATIONS

### Selected Annual Information

Selected financial information from the statements of loss and comprehensive loss for the three and nine months ended July 31, 2014 and 2013 follows:

<i>(all amounts in Cdn\$)</i>	Three months ended		Nine months ended	
	July 31, 2014	July 31, 2013	July 31, 2014	July 31, 2013
Research and development costs	\$ 546,570	\$ 309,494	\$ 1,413,451	\$ 1,140,871
General and administrative costs	209,579	87,760	692,888	369,443
Loss and comprehensive loss for the period	745,839	382,393	2,067,879	1,465,478

For the three and nine months ended July 31, 2014, the Company recorded a loss of \$745,839 and \$2,067,879 respectively compared to \$382,393 and \$1,465,478 respectively for the same period in the prior year. The increase in the current period loss of \$363,446 and \$602,401 respectively was attributable mainly to an increase in general and administrative costs and research and development expenses, as more fully described below.

### Research and Development Expenses

Research and development expenditures for the three and nine months ended July 31, 2014 and 2013 were as follows:

<i>(all amounts in Cdn\$)</i>	Three months ended		Nine months ended	
	July 31, 2014	July 31, 2013	July 31, 2014	July 31, 2013
Salaries, supplies and contract payments	\$ 358,193	\$ 237,286	\$ 852,832	\$ 647,174
Patent fees and costs	35,168	40,411	130,177	125,227
Depreciation of equipment and furniture	1,189	734	3,567	1,337
Amortization of intangible assets	126,939	177,401	489,903	526,223
Share-based compensation	51,159	13,140	86,677	65,673
Contributions and tax credits	(26,078)	(159,478)	(149,705)	(224,763)
Total research and development expense	\$ 546,570	\$ 309,494	\$ 1,413,451	\$ 1,140,871

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Research and development expenses for the three and nine months ended July 31, 2014 was higher by \$237,076 and \$272,580, respectively, compared to the same period of the prior year. Our preclinical and clinical research efforts increased during the three and nine months ended July 31, 2014, with salaries, supplies and contract payments increasing \$120,907 and \$205,658 compared to the same period of the prior year.

Patent fees and costs for the nine months ended July 31, 2014 were marginally higher by \$4,950 compared to the same period of the prior year due to legal expenses related to the renewal and maintenance of the patent portfolio and to the prosecution of patents in various countries.

Share-based compensation increased by \$38,019 and \$21,004 in the three and nine months ended July 31, 2014 because options were granted on January 27, 2014 resulting in an increase of share-based compensation compared to the same period of the prior year which did not have options granted.

Our contribution agreement from the National Research Council of Canada Industrial Research Assistance Program to optimize our Sertolin™ technology within the Cell Pouch™ and treat chronic disease had a balance of \$17,519 claimed during the quarter.

We are committed to the payment of certain costs under the Cell Pouch™ clinical trial with Dr. Shapiro, under a clinical trial agreement with the University of Alberta which includes but is not limited to clinical trial insurance, expenses typical of an ongoing clinical trial related to required procedures, patient care, regulatory filings, administrative costs and overhead. We anticipate our financial commitment through the duration of the trial to be approximately \$2,000,000; however, this amount may be positively or negatively impacted by various factors related to the conduct of the clinical study.

#### General and administrative expenses

General and administrative costs for the three and nine months ended July 31, 2014 and 2013 were as follows:

<i>(all amounts in Cdn \$)</i>	Three months ended		Nine months ended	
	July 31, 2014	July 31, 2013	July 31, 2014	July 31, 2013
Consulting fees	\$ 85,513	\$ 25,450	\$ 128,661	\$ 78,427
Professional fees	15,493	15,394	86,756	77,902
Director fees and expenses	29,725	-	69,258	-
Investor relations	35,385	27,807	119,340	85,435
Other costs	3,151	17,480	114,351	88,354
Depreciation of equipment and furniture	31	82	93	149
Share-based compensation	40,281	1,547	174,429	39,176
Total general and administrative expense	\$ 209,579	\$ 87,760	\$ 692,888	\$ 369,443

General and administrative expenses consist mainly of professional fees, personnel costs related to corporate activities, costs for shareholder-related activities including investor relations, directors' fees, stock exchange fees and share-based compensation. Total general and administrative expenses for the three and nine months ended July 31, 2014 was higher by \$121,819 and \$323,445, respectively, compared to the same period in the prior year.

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Consulting fees increased \$60,063 and \$50,234 in the three and nine months ended July 31, 2014, compared to the same period in the prior year. The increase primarily related to additional consulting used for the transition to a new interim CFO plus consulting for market research and business planning.

Professional fees were flat and increased by \$8,854 for the three and nine months ended July 31, 2014 compared to the same period in the prior year primarily due to an increase in corporate legal fees.

Director fees and expenses increased \$29,725 and \$69,258 in the three and nine months ended July 31, 2014 compared to the same period in the prior year as these are a new expenditure.

Other costs increased \$25,997 in the nine months ended July 31, 2014 compared to the same period in the prior year primarily related to travel and other expenses associated with strategic planning meetings and business development activities.

Investor relations expense increased \$7,578 and \$33,905 in the three and nine months ended July 31, 2014, compared to the same period in the prior year. We believe that investor relations are important for the Company to continue to be able to access capital and we outsource this work to specialized firms. At this time, we have retained appropriate firms to assist us with the development and execution of a comprehensive investor communications program to raise awareness of the Company in the capital markets.

Share-based compensation for the three and nine months ended July 31, 2014 increased by \$39,274 and \$135,253 because options were granted on January 27, 2014 resulting in a larger expense being recognized in this period.

#### Finance Income

Finance income, representing mainly interest income earned on the Company's term deposits, was \$11,578 and \$40,957 respectively during the three and nine months ended July 31, 2014, compared to \$17,401 and \$46,515 respectively for the same period in the prior year. This decrease of \$5,823 and \$5,558, respectively, was due to the prior period having larger average holdings of cash and short-term investments resulting from the additional capital secured through completion of a financing.

#### LIQUIDITY AND CAPITAL RESOURCES

Selected financial information from the statements of financial position as at July 31, 2014 and October 31, 2013 follows:

	July 31, 2014	October 31, 2013
Cash and short-term investments	\$ 3,879,313	\$ 4,975,906
Total assets	4,665,816	6,243,771
Current liabilities	223,786	225,148
Share capital and warrants	27,649,433	27,244,296
Deficit	(26,115,447)	(24,047,568)

As at July 31, 2014, the Company had cash and short-term investments of \$3,879,313 compared to \$4,975,906 at the prior year end date. Management believes working capital is sufficient to meet the cost of our research and development programs for at least the next twelve months.

The Company does not have any debt or credit facilities.

For the nine months ended July 31, 2014, various stock options and warrants were exercised for gross proceeds of \$230,180.

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Historically, funding requirements have been met through the issuance of common shares from treasury and common share purchase warrants that are converted to common shares upon exercise. Management regularly monitors the capital markets and attempts to balance timing of new equity issues with the progress of our research and clinical development plan, general market conditions, and availability of capital. In addition, management actively targets additional sources of financing such as grants and contributions, as well as collaborative partners which would assist in progressing our operations and research and clinical development programs.

The interim condensed consolidated financial statements have been prepared using IFRS that are applicable to a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business for the foreseeable future. The Company has experienced operating losses and cash outflows from operations since inception, it will require ongoing financing in order to continue its research and development activities, and it has not earned significant revenue or reached successful commercialization of its products. The company will seek new funding from additional equity financings and/or licensing agreements and collaboration arrangements with development partners; however, there is no assurance that these funding initiatives will be successful.

#### Common Shares

Changes in the number of issued common shares from the most recent year ended October 31, 2013 to the date of this report are as follows:

	Number of Common Shares
<b>Balance as at October 31, 2013</b>	<b>129,643,636</b>
Shares issued under warrant exercise	100,000
Shares issued under stock option exercise	1,634,195
<b>Balance as at July 31, 2014</b>	<b>131,377,831</b>
Shares issued under stock option exercise	100,000
<b>Balance as at September 26, 2014</b>	<b>131,477,831</b>

#### Performance Escrow Shares

Included in the number of issued common shares as at July 31, 2014 are 3,472,500 (2013 – 3,472,500) performance escrow shares related to the licensing of the Sertolin™ technology. These common shares will not be released, transferred or assigned without the consent of the regulatory authorities, and are subject to performance-based release terms as follows:

- 1,736,250 common shares on the date the Company receives approval from authorities for the initiation of human trials for a licensed product involving Sertolin™;
- 1,736,250 common shares on the date the Company enrolls the first patient in a Phase 3 human clinical efficacy trial for a licensed product involving Sertolin™.

Any remaining performance-based escrow shares will be cancelled and returned to treasury upon the earlier of (i) August 2016, and (ii) the Company ceasing to hold an interest in the intellectual property, or (iii) the mutual agreement of the Company and the shareholders.

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### Warrants

The following table reflects the activity of the warrants from the most recent year ended October 31, 2013 to the date of this report:

	Number of Warrants	Weighted Average Exercise Price
Balance outstanding October 31, 2013	31,153,263	\$0.35
Exercised	(100,000)	\$0.20
<b>Balance outstanding July 31, 2014 and September 26, 2014</b>	<b>31,053,263</b>	<b>\$0.35</b>

The warrants outstanding as at July 31, 2014 are detailed in note 8 to the interim condensed consolidated financial statements.

### Incentive Stock Options

The Company has an incentive stock option plan, the current terms of which were approved by shareholders of the Company on April 26, 2013. There have been no cancellations or modifications to the plan during the year. Details of the incentive stock option plan are provided in note 8 to the interim condensed consolidated financial statements.

The following table reflects the activity from the most recent year ended October 31, 2013 to the date of this Management Discussion and Analysis:

	Number of Options	Weighted Average Exercise Price
Balance outstanding October 31, 2013	7,675,445	\$0.16
Granted	3,360,000	\$0.15
Expired	(143,250)	\$0.14
Cancelled	(1,044,250)	\$0.15
Exercised	(1,634,195)	\$0.13
<b>Balance outstanding July 31, 2014</b>	<b>8,213,750</b>	<b>\$0.16</b>
Exercised	(100,000)	\$0.13
<b>Balance outstanding September 26, 2014</b>	<b>8,113,750</b>	<b>\$0.16</b>

### COMMITMENTS AND CONTINGENCIES

The Company is committed to the payment of certain costs under the clinical trial which commenced in the third quarter of the previous fiscal year. The study is a Phase I/II study with a primary endpoint of safety and a secondary endpoint of efficacy. The study is designed to allow for interim analyses at various points as sufficient data are collected. In this study patients will also be followed for a minimum of three years to assess longer-term safety and efficacy of the Cell Pouch™ with transplanted islets. The commitment under the agreement includes the cost of clinical staff and overhead thereon, trial insurance, and may include travel and

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a portion of drug-or procedure –related expenses or transplantation expenses not covered by insurance. The total commitment over the duration of the trial is expected to be approximately \$2,000,000 but will be impacted by such factors as the rate of enrollment, the province in which the patient resides and the specifics of patient insurance.

The Company has an annual commitment of \$40,000 for the rental of laboratory space.

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### TRANSACTIONS WITH RELATED PARTIES

The key management personnel of the company are the Directors, Chief Executive Officer and President and the Chief Financial Officer.

Amounts due to related parties, including amounts due to key management personnel, at the period-end are unsecured, interest free and settlement occurs in cash. There have been no guarantees provided or received for any related party receivables or payables.

Compensation for key management personnel of the company and the Directors for the period ended July 31 was as follows:

	Three months ended		Nine months ended	
	2014	2013	2014	2013
	\$	\$	\$	\$
Salaries, benefits and consulting fees	95,596	176,844	305,215	496,085
Director fees and expenses	29,725	-	69,258	-
Share-based compensation	60,907	14,687	174,428	92,383
Total expenses	186,228	191,531	548,901	588,468

Executive officers and directors participate in the stock option plan and officers participate in the Company's health plan. Key management personnel control 3.0% of the issued common shares of the Company as at July 31, 2014.

During the three and nine months ended July 31, 2014 the Company paid \$13,750 and \$34,809 respectively (2013- \$20,625 and \$41,250) in consulting fees for the services of a chief financial officer.

### SUMMARY OF QUARTERLY RESULTS

Selected quarterly data with respect to the statement of loss and comprehensive loss is set out below:

		1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter
2014	Net loss	\$590,905	\$727,935	\$745,839	
	Net loss per share	0.00	0.01	0.01	
2013	Net loss	\$531,380	\$551,705	\$382,393	\$537,443
	Net loss per share	0.01	0.01	0.01	0.00
2012	Net loss	\$625,833	\$677,974	\$574,489	689,732
	Net loss per share	0.01	0.00	0.01	0.00

It is important to note that historical patterns of expenditures cannot be taken as an indication of future expenditures. The amount and timing of expenditures, and therefore liquidity and capital resources, may vary substantially from period to period depending on the business and research activities being undertaken at any one time and the availability of funding from investors and prospective collaborative partners.

### OFF-BALANCE SHEET ARRANGEMENTS

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

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The preparation of financial statements in conformity with IFRS requires the Company to select from possible alternative accounting principles and to make estimates and assumptions that determine the reported amounts of assets and liabilities at the balance sheet date, and reported costs and expenditures during the reporting period. Management believes that the estimates and assumptions upon which the Company relies are reasonable based upon information available at the time these estimates and assumptions are made. Estimates and assumptions may be revised as new information is acquired, and are subject to change. A summary of the Company's significant accounting policies and estimates under IFRS is found in Note 3 of the Company's audited consolidated financial statements for the year ended October 31, 2013.

Significant assumptions about the future and other sources of estimation uncertainty, in addition to the going concern assumption described above, that management has made at the statement of financial position date that could result in a material adjustment to the carrying amounts of assets and liabilities, in the event that actual results differ from assumptions that have been made relate to the following key estimates:

i. Intangible assets – impairment

The application of the Company's accounting policy for intangible assets expenditures requires judgment in determining whether it is likely that future economic benefits will flow to the Company, which may be based on assumptions about future events or circumstances. Estimates and assumptions may change if new information becomes available. If, after expenditures are capitalized, information becomes available suggesting that the recovery of expenditures is unlikely, the amount capitalized is written off in profit or loss in the period the new information becomes available.

ii. Intangible assets – useful lives

Following initial recognition, the Company carries the value of intangible assets at cost less accumulated amortization and any accumulated impairment losses. Amortization is recorded on a straight-line basis based upon management's estimate of the useful life and residual value. The estimates are reviewed at least annually and are updated if expectations change as a result of technical obsolescence or legal and other limits to use. A change in the useful life or residual value will impact the reported carrying value of the intangible assets resulting in a change in related amortization expense.

iii. Share-based compensation

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them. The assumptions and models used for estimating fair value for share-based payment transactions are discussed in Note 8 of the interim condensed consolidated financial statements.

## **INTERNAL CONTROLS OVER FINANCIAL REPORTING**

As a result of the Company's limited administrative staffing levels, internal controls which rely on segregation of duties in many cases are not possible. Due to resource constraints and the present stage of the Company's development, the Company does not have sufficient size and scale to warrant the hiring of additional staff to address this potential weakness at this time. To help mitigate the impact of this, the

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Company is highly reliant on the performance of compensating procedures and senior management's review and approval.

As a venture issuer, the Company is not required to certify the design and evaluation of the Company's disclosure controls and procedure ("DC&P") and internal controls over financial reporting ("ICFR"), and as such has not completed such an evaluation. Investors should be aware that inherent limitations on the ability of certifying officers of a venture issuer to design and implement on a cost effective basis DC&P and ICFR as defined in NI 52-109 may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

### **CHANGES IN ACCOUNTING POLICIES**

#### **New standards and interpretations not yet effective**

Standards issued but not yet effective up to the date of issuance of the Company's consolidated financial statements are listed below. This listing is of standards and interpretations issued, which the Company reasonably expects to be applicable at a future date. The Company intends to adopt those standards when they become effective.

Certain pronouncements were issued by the IASB or International Financial Reporting Interpretation Committee that are mandatory for annual periods beginning after January 1, 2012 or later periods. Many of these updates are not applicable or are inconsequential to the Company and have been excluded from the discussion below. The remaining pronouncements are being assessed to determine their impact on the Company's results and financial position.

#### *IFRS 9, Financial Instruments: Classification and Measurement*

IFRS 9 (2010) reflects the first phase of the IASB's work on the replacement of IAS 39, Financial instruments: Recognition and Measurement and deals with the classification and measurement of financial assets and financial liabilities. This standard establishes two primary measurement categories for financial assets, amortized cost and fair value, and eliminates the existing categories of held to maturity, available for sale, and loans and receivables. The new classification will depend on the entity's business model and the contractual cash flow characteristics of the financial asset. The standard effective date is unknown due to postponement. The Company does not expect IFRS 9 (2010) to have a material impact on the financial statements. The classification and measurement of the Company's financial assets is not expected to change under IFRS 9 (2010) because of the nature of the Company's operations and the types of financial assets that it holds.

#### *IFRS 10, Consolidated Financial Statements*

This amendment provides a single model to be applied in the control analysis for all investees. The amendments issued in June 2012 simplify the process of adopting IFRS 10 and provide additional relief from certain disclosures. The standard is effective for annual periods beginning on or after January 1, 2013. The Company is currently assessing the impact of the standard on the consolidated financial statements.

#### *IFRS 12, Disclosure of involvement with Other Entities*

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IFRS 12 includes all of the disclosures that were previously in IAS 27, Consolidated and Separate Financial Statements related to consolidated financial statements, as well as all of the disclosures that were previously included in IAS 31, Investment in Associates. These disclosures relate to an entity's interests in subsidiaries, joint arrangements, associates and structured entities. A number of new disclosures are also required. The standard is effective for annual periods beginning on or after January 1, 2013. The Company is currently assessing the impact of the standard on the consolidated financial statements.

#### *IFRS 13, Fair Value Measurement*

In May 2011, the IASB published IFRS 13 Fair Value Measurement, which is effective prospectively for annual periods beginning on or after January 1, 2013. The disclosure requirements of IFRS 13 need not be applied in comparative information for periods before initial application. IFRS 13 replaces the fair value measurement guidance contained in individual IFRSs with a single source of fair value measurement guidance. It defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, i.e. an exit price. The standard also establishes a framework for measuring fair value and sets out disclosure requirements for fair value measurements to provide information that enables financial statement users to assess the methods and inputs used to develop fair value measurements and, for recurring fair value measurements that use significant unobservable inputs (Level 3), the effect of the measurements on profit or loss or other comprehensive income. IFRS 13 explains 'how' to measure fair value when it is required or permitted by other IFRSs. IFRS 13 does not introduce new requirements to measure assets or liabilities at fair value, nor does it eliminate the practicability exceptions to fair value measurements that currently exist in certain standards. The Company intends to adopt IFRS 13 prospectively in its financial statements for the annual period beginning on November 1, 2013. The Company does not expect IFRS 13 to have a material impact on the financial statements.

#### Annual Improvements to IFRS (2010 – 2012) and (2011-2013) cycles

In December 2013, the IASB issued narrow-scope amendments to a number of standards as part of its annual improvements process. The IASB uses the annual improvements process to make non-urgent but necessary amendments to IFRS. Amendments were made to clarify the following in their respective standards.

IFRS version that a first-time adopter can apply in IFRS 1 *First-time Adoption of International Financial Reporting Standards*;

Definition of "vesting condition" in IFRS 2 *Share-based payment*;

Classification and measurement of contingent consideration; and scope exclusion for the formation of joint arrangements in IFRS 3 *Business Combinations*;

Disclosures on the aggregation of operating segments in IFRS 8 *Operating segments*;

Measurement of short-term receivables and payables; and scope of portfolio exception in IFRS 13 *Fair Value Measurement*;

Restatement of accumulated depreciation (amortization) on revaluation in IAS 16 *Property, Plant and Equipment* and IAS 38 *Intangible Assets*;

Definition of "related party" in IAS 24 *Related Party Disclosures*; and

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Inter-relationship of IFRS 3 and IAS 40 in IAS 40 *Investment Property*.

Special transitional requirements have been set for amendments to IFRS 2, IAS 16, IAS 38 and IAS 40.

Most amendments will apply prospectively for annual periods beginning on or after July 1, 2014; earlier application is permitted, in which case, the related consequential amendments to other IFRSs would also apply. The Company intends to adopt these amendments in its financial statements for the annual period beginning on November 1, 2014. The extent of the impact of adoption of the amendments has not yet been determined.

**ADDITIONAL INFORMATION**

Additional information relating to the Company can be found on SEDAR at [www.sedar.com](http://www.sedar.com).