

# SERNOVA CORP.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

# FOR THE THREE MONTHS ENDED JANUARY 31, 2015 AND 2014

Dated March 26, 2015

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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 months ended January 31, 2015 and 2014. This analysis should be read in conjunction with the unaudited interim condensed consolidated financial statements for the three months ended January 31, 2015 and the audited consolidated financial statements of the Company and related notes as at and for the years ended October 31, 2014 and 2013, which have been prepared under 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, 2014.

The information in this report is dated as of March 26, 2015.

## 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 "may", identified bv the use of words such as or hv 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 pre-clinical 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 pre-clinical 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 pre-clinical studies and clinical trials of our Cell Pouch<sup>™</sup> for the treatment of insulin-dependent diabetes and other diseases;
- The expected benefit of the Cell Pouch<sup>TM</sup> with therapeutic cells versus the Edmonton Protocol;
- The intention to protect therapeutic cells within the Cell Pouch<sup>TM</sup> from immune attack using local immune protection such as Sertolin<sup>TM</sup> or microencapsulation, or systemic antirejection regimens and/or a combination thereof;
- The intention to use human autograft cells or human donor cells, or human stem cells or xenogeneic cells as virtually unlimited cell sources for our Cell Pouch<sup>TM</sup> for the potential treatment of chronic diseases;

- The intention to receive regulatory approval and commercialize the Cell Pouch<sup>TM</sup> for the treatment of insulin-dependent diabetes and other potential indications such as hemophilia and thyroid disease;
- Expectations with respect to the cost of Sernova's products, clinical trials and commercialization of our products;
- Sales and marketing strategy;
- Expectation to secure the UHN technology;
- Sernova's intentions to secure academic and industrial collaborations and to develop and implement partnering strategies; and,
- Intentions regarding the development and 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 described 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<sup>TM</sup>, 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, hemophilia and thyroid disease. Our patented Sertolin<sup>TM</sup> and other local immune protection technologies are being developed to create an immune privileged environment and protect the Cell Pouch<sup>TM</sup> transplant from rejection.

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 donor islets in our Cell Pouch<sup>TM</sup> to treat insulin-dependent diabetes in multiple animal models, and a proof of principle clinical trial for the treatment of human subjects with diabetes receiving an islet transplant, protected by the standard of care antirejection drug regimen is ongoing in Canada at the University of Alberta with Dr. James Shapiro as principal investigator. In this study, interim results in a small cohort of patients have shown the Cell Pouch<sup>TM</sup> to be safe alone and with donor islets. With these encouraging results, in addition to its ongoing clinical work, the Company is now seeking to secure an unlimited supply of cells which will be immune protected within the Cell

Pouch<sup>TM</sup> as a product to enable potential treatment of millions of people with diabetes, and is expanding into other therapeutic areas such as hemophilia.

#### **Research and Development**

Sernova has been a development stage company since inception. Our research and development efforts are focused principally on the development of the Cell Pouch<sup>TM</sup>, our medical device for transplantation of therapeutic cells for the treatment of chronic diseases, and on local immune protection technologies such as Sertolin<sup>TM</sup> that when placed within the Cell Pouch<sup>TM</sup> may protect the therapeutic cells from immune system attack. We have not been profitable since inception, and we expect to continue to incur substantial losses as we continue our research and development 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<sup>TM</sup> device in countries that have a significant market opportunity. Our first product is for the treatment of insulin-dependent diabetes. Our first clinical trial designed to demonstrate proof of concept of the Cell Pouch<sup>TM</sup> and therapeutic cells is currently ongoing in Canada. It is evaluating as a primary endpoint, safety and secondary endpoint, efficacy of the Cell Pouch<sup>TM</sup> transplanted with human donor islets, protected using the standard of care antirejection drug regimen, in subjects with insulin-dependent diabetes. Our goal is for the treatment of diabetes with the Cell Pouch<sup>TM</sup> transplanted with locally immune protected cells from an unlimited source of cells such as insulin- producing stem cells to treat the epidemic of people 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<sup>™</sup> technology which may include: diabetes, hemophilia, thyroid gland disease, 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 cells within the Cell Pouch<sup>TM</sup>, including local immune protection technologies such as Sertolin<sup>TM</sup> and/or microencapsulation. These programs may involve third party collaborations in addition to our internal R&D efforts;
- 4. Development of various sources of therapeutic cells for transplantation within our Cell Pouch<sup>TM</sup>, including, depending on the clinical application, autologous cells, allogeneic cells such as donor cells or stem cells that could be used to treat large numbers of patients and, xenogeneic cells. These programs may involve third party collaborations in addition to our internal R&D efforts;
- 5. Manufacturing and supply of Cell Pouches<sup>TM</sup> and processing and supply of cells; and,
- 6. Generation and/or licensing of Intellectual Property.

## Corporate Update for the three months ended January 31, 2015 and to the date of this MD&A

In November 2014 we announced an update of the clinical assessment of the Cell Pouch<sup>TM</sup> in diabetic patients with hypoglycemia unawareness who has received an islet transplant. In the first small

cohort of patients in interim analysis, the Cell Pouch<sup>TM</sup> was biocompatible and safe following implant and transplant with safety being the primary endpoint of the study. Initial data from the study have also shown that islets within the Cell Pouch<sup>TM</sup>, as shown by histological analysis, are wellvascularized, living within a natural tissue matrix and are able to make insulin, glucagon and somatostatin, key hormones in the control of blood glucose levels. We believe such revascularization of islets and islet metabolic function within an implantable medical device for therapeutic cells in humans in this patient population is a first in the regenerative medicine field. These findings also suggest that the Cell Pouch<sup>TM</sup> may form a suitable environment for the survival and function of multiple types of therapeutic cells including human stem cells which can represent a virtually unlimited supply of cells for treating disease.

In February, 2015 we announced that the patent offices in China, Israel, Singapore and New Zealand issued Notices of Allowance and issued patents to Sernova for its patent application entitled "Methods and Devices for Cellular Transplantation." These patents help protect Sernova's entire Cell Pouch<sup>TM</sup> system, including the Cell Pouch<sup>TM</sup> itself, as well as the Cell Pouch<sup>TM</sup> combined with therapeutic cells and surgical tools for cell transplantation. These issued patents, in addition to patent rights already granted or actively being pursued in other countries, provide Sernova with patent protection through 2030.

In March 2015, we announced that Frank Holler was appointed Chairman of the Board and that after a lengthy and productive term as Chairman, Dr. George Adams advised the board that he will be retiring as a director of Sernova at the end of his term and has stepped down as Chairman of the Board. Mr. Holler brings a wide-range of experience to his role as Sernova's Chairman of the Board as an active investor and successful entrepreneur. Mr. Holler is currently the CEO and fund manager for BC Advantage Funds. He previously served as President & CEO of Xenon Pharmaceuticals Inc., a NASDAQ listed genomics-based drug development company, from 1999 to 2003; as President & CEO of ID Biomedical Corporation, a NASDAQ listed vaccine development company sold to GlaxoSmithKline plc in 2005, from 1991 to 1998; and as a founding director of Angiotech Pharmaceuticals, a TSX/ NASDAQ listed medical device company which developed and partnered one of the world's first drug-eluting stents, from 1992 to 1997.

## **Research and Development Outlook for the 2015 Calendar Year**

Our product development program for 2015 includes the following:

- Anticipated further follow up on the Cell Pouch<sup>™</sup> diabetes clinical study;
- Anticipated follow up from the collaborative agreement with Medicyte GMBH evaluating feasibility of the use of Medicyte's upcyte<sup>®</sup> cells in Sernova's Cell Pouch<sup>TM</sup>;
- Anticipated selection and initiation of product development work of another disease indication such as thyroid disease in preparation for human evaluation in a clinical trial to assess the safety and efficacy of the Cell Pouch<sup>TM</sup>;
- Completion of a definitive license agreement and preclinical assessment of glucoseresponsive, insulin-producing, human-derived stem cells within Sernova's Cell Pouch<sup>TM</sup> for the treatment of insulin-dependent diabetes; and,
- Assessment of complementary immune protection technologies, which may result in additional academic and /or corporate relationships to further develop and expand Sernova's total solution for diabetes of immune protected cells within the Cell Pouch<sup>TM</sup>.

## Cell Pouch<sup>TM</sup> Clinical Development Program

Sernova's lead program is the clinical development of the Cell Pouch<sup>TM</sup> for treatment of patients with insulin-dependent diabetes. Dr. James Shapiro, pioneer of the Edmonton Protocol, and his team at the University of Alberta are conducting a proof of concept human clinical study to assess the safety and efficacy of the Cell Pouch<sup>TM</sup> 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 lifelong 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 surrounded by tissue matrix and in close proximity to microvessels but not actually bathed in blood. Furthermore, and of critical importance is the fact that 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 are locally immune protected that could be used to treat the large numbers of patients with insulin-dependent diabetes.

We believe our Cell Pouch<sup>TM</sup> will offer significant benefits over the Edmonton Protocol, the current standard-of care, to restore the body's insulin production and glucose control in insulin-dependent diabetic patients. The Cell Pouch<sup>TM</sup> was designed to take into consideration the biological requirements of therapeutic cells. A tissue matrix rich in microvessels forms within the Cell Pouch<sup>TM</sup> when implanted subcutaneously prior to islet transplantation, providing an ideal environment for placement of therapeutic cells, including insulin-producing islets. We believe these conditions are key for maintaining long term survival and function of therapeutic cells. We have demonstrated in a series of ISO10993 biocompatibility studies and multiple animal studies that the Cell Pouch<sup>TM</sup> 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<sup>TM</sup>.

Benefits of the Cell Pouch<sup>TM</sup> 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<sup>TM</sup> achieves this ideal islet/microvessel connection and should allow for improved glucose control. Our studies have shown that the Cell Pouch<sup>TM</sup> 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 or other sources of insulin producing cells. 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. 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<sup>TM</sup> enables islets to be transplanted subcutaneously, 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<sup>TM</sup> may accommodate local immunoprotection technologies rather than the need for lifelong systemic antirejection drug treatment. Local immune protection of islets could result in a significant reduction or even elimination 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<sup>TM</sup> 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<sup>TM</sup> to become the standard of care in therapeutic cell transplantation, if it proves to be safe and effective in clinical trials. In fact, Sernova believes it has the only such device technology of its kind in which therapeutic cells have been definitely proven to survive in a tissue matrix integrated with microvessels in close association with the therapeutic cells.

In our human clinical trial, subjects who meet the entry criteria are implanted with the Cell Pouch<sup>TM</sup>, 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.

In November 2014, the Company released additional encouraging results from the clinical study. To date, in a small cohort of patients in interim analysis, which Dr. Shapiro has presented in a number of international transplantation conferences, the Cell Pouch<sup>TM</sup> demonstrated biocompatibility and safety following implant and transplant. Safety is the primary endpoint of the study. These initial data from the study have shown the following three important findings:

- First, biocompatibility and a positive safety profile of the Cell Pouch<sup>TM</sup> have been shown in the first cohort of patients;
- Second, the islets within the Cell Pouch<sup>™</sup>, as shown by histological analysis, are wellvascularized, living within a natural tissue matrix and are able to make insulin, glucagon and somatostatin, key hormones in the control of blood glucose levels. We believe such revascularization of islets and islet metabolic function within an implantable medical device for therapeutic cells in humans in this patient population is a first in the regenerative medicine field; and,
- Third, these encouraging developments of the study suggest that Sernova's Cell Pouch<sup>™</sup> may form a suitable environment for the survival and function of multiple types of therapeutic

cells including human stem cells which can represent a virtually unlimited supply of cells for treating disease.

In addition to the clinical evaluation of the Cell Pouch<sup>TM</sup>, the Company has a preclinical collaboration with Dr. Shapiro of the University of Alberta with the goal to achieve long term efficacy with a minimal islet mass to increase the number of subjects that can be treated with the Cell Pouch<sup>TM</sup>. An independent pre-clinical study of the Cell Pouch<sup>TM</sup> with islets, demonstrated that the Cell Pouch<sup>TM</sup> provided insulin independence for 100 days, the length of the study, in a small animal model of diabetes using a marginal (minimal) transplanted islet mass. This study supports the concept that the Cell Pouch<sup>TM</sup> may require a smaller than anticipated number of cells to achieve efficacy, one of the parameters being considered to achieve glucose control in the current clinical trial.

## **Developing the Cell Pouch<sup>TM</sup> for Other Indications**

## Hemophilia

As part of our strategy to develop the Cell Pouch<sup>TM</sup> for different therapeutic indications, we announced a material transfer agreement with Medicyte GmbH to jointly evaluate the use of Medicyte's upcyte<sup>®</sup> cell technology in Sernova's Cell Pouch<sup>TM</sup> for the treatment of patients with hemophilia A. Both parties have also entered into a non-binding term sheet describing the general terms of a collaboration, outlining the pre-clinical and clinical development of the novel Cell Pouch<sup>TM</sup>/upcyte<sup>®</sup> product for the treatment of hemophilia A.

The research and development teams at Medicyte and Sernova are working to develop a product to treat Hemophilia A patients. This product involves taking a small blood sample from the patient, correcting the genetic defect in isolated cells and then using Medicyte's upcyte® technology to expand the cell numbers for placement into Sernova's Cell Pouch<sup>™</sup> for release of Factor VIII. The teams are currently conducting proof of concept studies which include cell isolation, processing and scale-up, product release and pilot studies for preclinical evaluation. With successful completion of these studies, the next steps will include production of cells and the required pre-clinical studies that will become part of a regulatory package in preparation for human clinical trials.

## *New Cell Pouch<sup>TM</sup> Indications for Metabolic Disorders*

As the Company continues its work on the diabetes and hemophilia indications, this year we are exploring new potential autograft (self-cell) and/or allograft (donor-cell) indications to further expand the application of our cell therapy platform technologies. For example, the Company is exploring the use of the Cell Pouch<sup>TM</sup> in the treatment of thyroid disease.

## Local Immune Protection & Other Complementary Technologies

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

On March 25, 2013, we announced our award of a third non-repayable financial contribution of up to \$254,300 from the National Research Council of Canada for the optimization of our Sertolin<sup>TM</sup> technology within our Cell Pouch<sup>TM</sup> to treat chronic diseases. This financial contribution was used to continue a series of studies to optimize the safety and efficacy of Sertolin<sup>TM</sup> with insulin-producing islets in the Cell Pouch<sup>TM</sup>. The analysis of the results of this study is ongoing.

To broaden Sernova's local immune protection technologies, we continue to evaluate additional advanced technologies such as microencapsulation. We believe that microencapsulation of therapeutic cells within the Cell Pouch<sup>TM</sup> may provide a means to contain therapeutic cells within the Cell Pouch<sup>TM</sup> while providing close association of therapeutic cells with the required microvessels and tissue matrix for long-term survival and function of cells for our disease indications.

## **Alternative Sources of Cells**

Our transplantation technologies may incorporate autologous cells, donor cells or other sources of cells including human-derived stem cells or xenogeneic cells, depending on the clinical indication under evaluation and the need for expanded numbers of cells for treatment of larger populations. As such, we will continue to work with academic collaborators and industry partners to identify and secure the required cells for our therapeutic indications. In this regard, Sernova has agreed on key terms with the University Health Network of Toronto (UHN) to gain access to worldwide, exclusive rights to certain patent-pending technologies developed by distinguished UHN researchers, Dr. Cristina Nostro and Dr. Gordon Keller, for the advancement of glucose-responsive insulin-producing stem cells for the treatment of patients with insulin-dependent diabetes. Sernova and UHN have entered into a non-binding Term Sheet with an exclusive negotiation period which outlines the terms of the definitive license agreement for the granting of an exclusive license to Sernova covering all patent rights relating to the UHN stem cell technologies including for the treatment of diabetes. A manufacture and product development program is also being developed. Sernova's rights to the UHN stem cell technologies are subject to negotiation and execution of a definitive license agreement with UHN.

#### Manufacturing

Our contract manufacturer has the required expertise to manufacture both our Cell Pouch<sup>TM</sup> and mini-Cell Pouch<sup>TM</sup> 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. A two-year packaging and product stability study has been successfully completed.

## **Intellectual Property**

Our patent portfolio consists of 27 issued and 25 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<sup>TM</sup> and Sertolin<sup>TM</sup> 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.

#### **Business Development**

Sernova is committed to business development activities to in-license complementary technologies to expand Sernova's product development portfolio, and intellectual property base that is of key importance for partnering activities. This work is also expected to result in corporate partnerships to

develop products with other Companies. Furthermore, Sernova is actively pursuing potential pharmaceutical and medical device corporate partners to develop and market its products.

#### **Financing Activity**

There was no financing activity for the three months ended January 31, 2015 and 2014.

## **RESULTS OF OPERATIONS**

#### **Selected Annual Information**

Selected financial information from the statements of loss and comprehensive loss for the three months ended January 31, 2015 and 2014 follows:

(all amounts in Cdn\$)	T Endeo	Three Months d January 31, 2015	End	Three Months ed January 31, 2014
Research and development costs	\$	461,854	\$	435,710
General and administrative costs		176,789		173,214
Loss and comprehensive loss for the period	\$	630,294	\$	594,105

For the three months ended January 31, 2015, the Company recorded a loss of \$630,294 compared to \$594,105 for the same period in the prior year. The increase in the current period loss of \$36,189 was attributable mainly to a decrease in contributions and tax credits, as more fully described below.

## **Research and Development Expenses**

Research and development expenditures for the three months ended January 31, 2015 and 2014 were as follows:

(all amounts in Cdn\$)	Three Months Ended January 31, 2015		Three Months Ended January 31, 2014	
Salaries, supplies and contract payments	\$	195,651	\$	237,651
Patent fees and costs		23,619		36,792
Depreciation of equipment and furniture		1,189		1,189
Amortization of intangible assets		224,425		181,399
Share-based compensation		16,971		2,979
Contributions and tax credits		-		(24,300)
Total research and development expense	\$	461,854	\$	435,710

Research and development expenses for the quarter were \$461,854, an increase of \$26,144 compared to expenses of \$435,710 in the same quarter of the prior year. This increase is mainly due to amortization of intangible assets and no contributions and tax credits for this quarter.

We are committed to the payment of certain costs under the Cell Pouch<sup>TM</sup> 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 a 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 \$1,000,000; 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 months ended January 31, 2015 and 2014 were as follows:

(all amounts in Cdn\$)	Three Months Ended January 31, 2015		En	Three Months Ended January 31, 2014	
Salaries, benefits and consulting fees	\$	51,717	\$	21,059	
Professional fees		23,481		22,620	
Directors fees and expenses		28,438		-	
Investor relations		24,735		42,491	
Travel and other costs		40,648		66,247	
Depreciation of equipment and furniture		31		31	
Share-based compensation		7,739		20,766	
Total general and administrative expense	\$	176,789	\$	173,214	

General and administrative expenses consist mainly of professional fees, personnel costs related to corporate activities, costs for shareholder-related activities including investor relations, stock exchange fees and share-based compensation. Total general and administrative expenses for the three months ended January 31, 2015 were \$176,789 compared to \$173,214 for the same period in the prior year. The period-over-period increase of \$3,575 was attributable to consulting fees and director fees, partially offset by decreases in investor relations and other costs.

## **Finance Income**

Finance income, representing mainly interest income earned on the Company's term deposits, was \$8,986 during the three months ended January 31, 2015, compared to \$15,461 for the same quarter in the prior year. This decrease of \$6,475 was due to the decrease in average holdings of cash and short-term investments.

## LIQUIDITY AND CAPITAL RESOURCES

Selected financial information from the statements of financial position as at January 31, 2015 and October 31, 2014 follows:

	January 31, 2015	October 31, 2014
Cash and short-term investments	\$ 3,050,449	\$ 3,416,710
Total assets	3,319,709	4,021,072
Current liabilities	144,308	240,087
Share capital and warrants	30,599,322	30,574,612
Deficit	(27,423,921)	(26,793,628)

As at January 31, 2015, the Company had cash and short-term investments of \$3,050,449 compared to \$3,416,710 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.

There was no financing activity in the three months ended January 31, 2015 and 2014.

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.

We anticipate the cash requirements to fund our planned activities for 2015 will increase over the previous year. Our actual cash requirements for 2015 will depend on the clinical, pre-clinical, and collaborative activities that we ultimately undertake and the ability to secure partners, and non-dilutive funding in the form of government grants.

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**

There were no changes in the number of issued common shares from the most recent year ended October 31, 2014 to the date of this report are as follows:

Performance Escrow Shares

Included in the number of issued common shares as at January 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:

a) 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<sup>TM</sup>;

b) 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  $\operatorname{Sertolin}^{TM}$ .

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.

## 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:

		Weighted Average
	Number of Warrants	Exercise Price
Balance outstanding October 31, 2014 and		
January 31, 2015	31,053,263	\$0.35
Warrants re-pricing	(10,000,000)	0.35
Warrants re-pricing	10,000,000	0.40
Expired	(885,931)	0.20
Expired	(19,395,110)	0.35
Balance outstanding March 26, 2015	10,772,222	\$0.40

## **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, 2014 to the date of this Management Discussion and Analysis:

	Number of Options	Weighted Average Exercise Price
Balance outstanding October 31, 2014,		
January 31, 2015 and March 26, 2015	7,988,750	\$0.16

## COMMITMENTS AND CONTINGENCIES

The Company is committed to the payment of certain costs under the clinical trial which commenced in fiscal year 2012. 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<sup>™</sup> with transplanted islets. The commitment under the agreement includes the cost of clinical staff and overhead thereon, trial insurance, and may include travel and 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 \$1,000,000 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 is committed to an estimated payment of approximately \$225,000 USD in fees to maintain the patents in good standing for the year ending October 31, 2015. Similar payments will be required for subsequent years.

The Company has an annual commitment of \$40,000 for the rental of laboratory space which is short-term in nature but essentially subject to an annual renewal.

## 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 periodend are unsecured, interest free and settlement occurs in cash. There have been no guarantees provided or received for any related party receivables or payables.

Included in accounts payable and accrued liabilities at January 31, 2015 is \$69,688 due to management personnel (2014 - \$74,477).

Compensation for key management personnel of the company other than directors for the three months ended January 31 was as follows:

	2015	2014
Salaries and consulting fees	86,625	91,982
Director fees	28,438	-
Share-based compensation	7,739	8,893
Total expenses	122,802	100,875

Executive officers and directors participate in the stock option plan and officers participate in the Company's health plan. Key management personnel control approximately 3.0% of the issued common shares of the Company as at January 31, 2015.

During the quarter ended January 31, 2014 the Company paid \$21,059 (2013- \$20,625) in consulting fees for the services of the chief financial officer.

## SUMMARY OF QUARTERLY RESULTS

1<sup>st</sup> Ouarter 2<sup>nd</sup> Ouarter 3<sup>rd</sup> Ouarter 4<sup>th</sup> Ouarter 2015 Net loss \$630.294 Net loss per share 0.00 2014 \$594,105 \$725,839 \$678,180 Net loss \$747.935 Net loss per share 0.01 0.01 0.01 0.01 2013 \$551,705 \$382,393 Net loss \$531,380 537,443 Net loss per share 0.01 0.00 0.01 0.00

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

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, 2014.

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 for the three months ended January 31, 2015.

## 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 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.

## 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 is effective for annual periods beginning on or after January 1, 2017. The Company is reviewing the standard to determine the impact that the adoption of the standard may have on the consolidated 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.

## **RISKS AND UNCERTAINTIES**

The following is a summary list of risks and uncertainties for the Company. For a detailed description of each risk and uncertainty, please refer to the annual Management's Discussion and Analysis for the year ended October 31, 2014 as filed on SEDAR.

## **Investment Risk**

• Volatility of Share Price, Absence of Dividends and Fluctuation of Operating Results.

#### **Issuer Risk**

- Early Stage Development and Scientific Uncertainty.
- Additional Financing Requirements and Access to Capital.
- Patents and Proprietary Technology.
- Dependence on Collaborative Partners, Licensors and Others.
- Clinical trials are long, expensive and uncertain processes and Health Canada or the FDA may ultimately not approve any of our products. We may never develop any commercial applications or products that generate revenues.
- *Reliance on Key Personnel.*
- Lack of Product Revenues and History of Losses. Conflict of Interest.

## **Industry Risk**

- Government Regulations.
- Hazardous Materials and Environmental Matters.
- *Rapid Technological Change. Competition.*
- Status of Healthcare Reimbursement. Potential Product Liability.

## **ADDITIONAL INFORMATION**

Additional information relating to the Company can be found on SEDAR at www.sedar.com.