

**SERNOVA CORP.**  
**MANAGEMENT'S DISCUSSION AND ANALYSIS**  
**For the three months ended January 31, 2013**

**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, 2013 and 2012. This analysis should be read in conjunction with the unaudited condensed consolidated interim financial statements for the three months ended January 31, 2013 and the audited consolidated financial statements and related notes for the year ended October 31, 2012 and 2011, 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, 2012.

The information in this report is dated as of March 26, 2013.

**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 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
- Clinical trials of the Cell Pouch™ with antirejection regimens, Sertolin™ or other local immune protection products for the treatment of insulin-dependent diabetes and other potential indications;
- The intention to use human donor cells, xenogeneic cells or stem cells in the Cell Pouch™ for the 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;
- 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 form academic and industrial collaborations and to develop and implement partnering strategies;
- 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, health sciences company focused on commercializing medical technologies. Sernova is currently developing a platform technology for a number of serious disease indications, starting with a novel treatment for insulin-dependent diabetes, using the Cell Pouch System™, a medical device for transplantation and long-term support of therapeutic cells and its patented Sertolin™ cell technology which provides local immune protection of therapeutic cells. The Company is focused on the manufacture and clinical evaluation of the Cell Pouch™ for insulin-dependent diabetes.

## **Corporate Objectives**

The overall corporate product development objectives for Sernova are:

1. to conduct the studies required to gain marketing approval for the Cell Pouch™ with human donor islets and the state of the art antirejection regimen for subjects with insulin-dependent diabetes;
2. to conduct studies to gain marketing approval for the addition of a local immune protection technology, i.e. Sertolin™;
3. to gain marketing approval for an unlimited source of therapeutic cells (insulin-producing stem cells, xenogeneic cells) within the Cell Pouch™ to treat insulin-dependent diabetes;
4. to expand into additional therapeutic indications including, but not limited to parathyroid cell replacement, treatment of hemophilia, and other diseases which require the production of a hormone or protein missing or in short supply in the body. The Company plans to work with academic institutions or other corporate entities to secure stem cell technologies, xenogeneic cell technologies or other cells sources for use within the Cell Pouch™. The Company may seek corporate development partners, or may develop certain products on its own for marketing purposes. The Company also may in-license or develop related technologies to expand its product capabilities.

## **PERFORMANCE SUMMARY AND UPDATE**

### **Current Operating Highlights for the Year Ending October 31, 2012**

#### **Approval to Initiate Human Clinical Trial**

On May 2, 2012, the Company advanced from a preclinical to a clinical stage company when it received Health Canada clearance to conduct human clinical studies assessing both the safety and efficacy of the Cell Pouch™ with transplanted insulin-producing islets in patients with insulin-dependent diabetes. Following further approvals including the Health Ethics Review Board of the University of Alberta, in August 2012, the Company and the University of Alberta announced the treatment of the first patient with insulin-producing islets transplanted into the Company's Cell Pouch™.

#### **Background and Product Rationale**

Insulin-dependent diabetic patients have lost the ability of their insulin-producing islets to function in the control of blood glucose levels. Patients with insulin-dependent diabetes take exogenous insulin to provide some control over their blood glucose levels; however, this is often not sufficient to prevent the serious diabetes side effects. In addition, about 25% of these patients have hypoglycemia (low blood glucose levels) unawareness. These are individuals who do not receive the typical signals of hypoglycemia after taking insulin and may fall into a coma and even die.

Islet transplantation to replace the non-functioning islets is a promising solution that under the right conditions could provide relief to patients, who are currently taking insulin injections and can significantly reduce the incidence of hypoglycemia-unawareness and its devastating consequences.

The current procedure for islet transplantation to treat diabetes, commonly known as the "Edmonton Protocol" involves infusing islets directly into a blood vessel (portal vein) of the liver followed by life-long anti-rejection therapy to help protect the donor islets from being attacked by the host immune system. Following transplantation, the islets lodge in the microvessels of the liver and the surviving islets react to elevated sugar levels in the blood flowing past and accordingly release insulin into the bloodstream to sometimes maintain normoglycemia. This treatment can decrease the incidence of hypoglycemia unawareness in those patients who have the procedure.

While this therapy has been beneficial there are a number of issues which prevent the Edmonton Protocol from being used widely. Principal among these is the need for two to four procedures to achieve glucose control. This may be related to an immediate blood-mediated inflammatory response which is thought to destroy a majority of the donor islets following infusion, as they are lodged in small vessels in a flowing stream of blood rather than residing naturally in a tissue matrix surrounded by microvessels. There is a limited supply of donor islets and it would be preferable to have a virtually unlimited supply of islets such as might occur with either insulin producing stem cells or xenogeneic islets; however, portal vein delivery of such cells is not practical. In addition, there may be liver morbidities that can arise from blocking microvessels with islets as well as portal hypertension that may develop. Other issues exist such as an inability to image the islets and the cost of the Edmonton Protocol is high. These issues suggest that a better site for islet transplantation is warranted.

Sernova views the replacement of insulin-producing cells as a way to potentially treat a significant number of people with insulin-dependent diabetes and has developed a tiered strategy to its product development approach to move from treating a subset of patients with hypoglycemia unawareness to a much larger population of patients with diabetes and other diseases.

In this regard, Sernova developed the Cell Pouch™, a subcutaneous implantable medical device, to solve a number of issues arising from portal vein delivery. For example, the Cell Pouch™ provides a natural setting for the islets where they reside in a tissue matrix with microvessels growing adjacent to and into the islets, which are then nourished naturally. Without the blood-mediated inflammatory response, the islets are expected to have an improved survival potential. Use of the Cell Pouch™ would also eliminate the concern of portal vein hypertension and thrombosis and potentially reduce the cost of

the procedure as the catheterization laboratory is not required for either implantation or transplantation of the Cell Pouch™. Importantly, the Company's preclinical studies of the Cell Pouch™ have consistently shown excellent safety and efficacy profiles with the use of fewer islets than for portal vein delivery. This could increase the number of recipients treated with the current donor pool. Furthermore, implantation of the Cell Pouch™ in the subcutaneous space allows for imaging of the islets and microvessels to monitor cell viability and for potential local immunoprotection of therapeutic cells rather than systemic antirejection drugs. Furthermore, the Cell Pouch™ may be an ideal environment in which to place insulin-producing stem cells and xenogeneic cells which could provide an unlimited source of insulin producing cells to treat millions of patients.

### **Preclinical Results**

The Cell Pouch™ is a scalable medical device providing a natural "organ-like" environment for therapeutic cells. Once implanted under the skin, the Cell Pouch™ develops endocrine-like function when transplanted with islets, controlling blood sugar levels as shown by published preclinical data. These data also suggest that the natural environment enables cell survival required for long-term therapy. The Company has conducted successful testing of prototype Cell Pouches™ in small animal models. The Company has also completed studies in large diabetic animals successfully demonstrating the safety and efficacy the Cell Pouch™ in both an autograft (self-tissue) and an allograft (donor tissue) transplant models. This is important because it demonstrates that the Cell Pouch™ is scalable and may be useful to treat human diabetes as well as other diseases.

Sernova has also completed biocompatibility studies (ISO 10993) of the Cell Pouch™ using product manufactured by Sernova's contract manufacturer. The Cell Pouch™ passed all the tests and the requirements for demonstrating biocompatibility in the body. These along with additional studies form the basis for which to evaluate the Cell Pouch™ in human clinical trials.

Health Canada has designated the Cell Pouch™ as a Class III Medical Device for regulatory purposes. Thus, the Cell Pouch™ and therapeutic cells will be regulated by separate Divisions allowing Sernova the opportunity to test different types of therapeutic cells in the Cell Pouch™ for commercial use.

The Company developed the Cell Pouch™ regulatory documentation and worked with Dr. James Shapiro's team at the University of Alberta in the preparation of the clinical documentation for submission to Health Canada. Dr. Shapiro is a well-recognized transplant surgeon who contributed to developing the Edmonton Protocol. These regulatory documents which include preclinical safety and efficacy studies, contract manufacturing results the clinical protocol and other documents were subsequently reviewed by Sernova's regulatory consultants and submitted to Health Canada and the Research Ethics Board (HREB) at the University of Alberta and the Cell Pouch™ has been cleared for clinical evaluation in humans with diabetes.

The human clinical study is a Phase I/II study assessing the safety and efficacy of the Cell Pouch™ with donor islets in up to 20 diabetic patients who are to receive islet transplantation. The study being conducted at the University of Alberta is an open label, non-randomized, single arm, Phase I/II safety and efficacy study in patients with insulin-dependent diabetes with insulin unawareness undergoing allograft pancreatic islet transplantation. Patients are implanted with the Cell Pouch™, which is allowed to incorporate with tissue and microvessels prior to transplantation of donor human islets. To prevent islet graft rejection, patients are treated with a best in class immunosuppression regimen approved by Health Canada. This is an Alemtuzumab induction protocol, which has been shown to be a significant improvement over the previously used immunosuppression protocols.

The primary endpoint of the study is to assess the safety of the Cell Pouch™ in adult participants with Type-1 diabetes with insulin unawareness and receiving islet transplantation for the first time. This endpoint is assessed just prior to islet transplantation and one month thereafter. The secondary endpoint of the study is efficacy in which the proportion of subjects implanted with the Cell Pouch™ and transplanted with islets that achieve and maintain insulin independence is measured three months post-final islet transplantation. Additional standard measure, such as HbA1c, arginine-stimulated C-peptide

response, and glucose response to a standard mixed meal test, etc. comprise the secondary efficacy endpoint.

In addition, the study provides preliminary data on the efficacy of the Cell Pouch™ to maintain adequate immunological protection against both allo- and autoimmunity of islet transplant recipients.

Following assessment of initial primary and secondary endpoints, patients are followed for a minimum of three years to assess long-term safety and efficacy of the Cell Pouch™. It should also be noted that the study allows for interim analysis of the data at various study time points.

With respect to manufacture of the clinical product, device specifications were set, a semi-automated manufacturing process developed and the product manufactured, packaged and sterilized by a contract manufacturer under regulatory guidelines (ISO 13485:2003), which will be suitable for testing in clinical trials in North America and Europe. Sterilization verification studies have been completed and the product has subsequently been released for assessment in human clinical trials by Health Canada.

In August 2012, the Company and the University of Alberta announced the treatment of the first patient with insulin-producing islets transplanted into the Company's Cell Pouch™. The implantation and transplantation processes are relatively simple, rapid, minimally-invasive procedures. This approach is anticipated to offer substantial potential benefit over the Edmonton protocol and the ease of use provides 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.

### **Plan to Expand the Market Reach of the Cell Pouch™**

In addition to the human clinical study of the Cell Pouch™, the Company has initiated a preclinical collaboration with the University of Alberta under the direction of Dr. Shapiro. This collaboration is focused on evaluating next generation products for the Cell Pouch™. The Company plans to initiate additional collaborations with other academic institutions and/or Corporations to expand its pipeline.

### **Cell Pouch™ Product Development Plan**

The Company is currently evaluating various uses for the Cell Pouch System™, in a tiered product development approach, including: (1) testing autograft islets (i.e., an individual's own islets) placed in the Cell Pouch™ in patients with chronic pancreatitis who are having their pancreas removed to alleviate severe pain; (2) testing donor islets with an anti-rejection drug regimen i.e. University of Alberta clinical study; (3) testing donor islets in patients using Sertolin™ or other local immune protection technology that may allow dose reduction or even elimination of anti-rejection drugs in patients; and (4) assessing insulin-producing stem cells and anti-rejection drugs or immune protective cells in diabetic patients. Management believes this tiered approach may allow the Company to explore multiple sources of revenue with its products. Under all of these settings, the Company is planning to focus on the use of human islets or human-derived cells for clinical testing and initial entry into the marketplace. While the current focus will be on human and or human-derived cells, additional testing may occur using xenotransplant-derived cells providing another virtually unlimited supply of cells. Furthermore, the Company is exploring its options for additional cell-based therapies for the Cell Pouch™ such as hemophilia, parathyroid gland transplant and Parkinson's disease.

### **Detailed Overview of Sernova's Technology**

The Company, through development of its novel products, is focused on improving the outcome and safety of therapeutic cell treatment for chronic debilitating diseases with the first clinical indication of insulin-dependent diabetes.

The Company is developing its proprietary Cell Pouch™ and Sertolin™ technologies using a tiered approach. As such, Sernova is first conducting human clinical trials of the Cell Pouch™ for therapeutic cell transplantation using allograft (donor human cells) with a state-of-the-art anti-rejection protocol. The Company may also initiate clinical studies in patients with chronic pancreatitis using an autograft (self-cells) transplant. In order to reduce the effects on patients of taking chronic antirejection drugs, the Company plans to advance the Sertolin™ technology as a means to protect therapeutic cells locally

within the Cell Pouch™. The allograft approach with state-of-the-art anti-rejection therapy being the first Sernova technology to enter human clinical evaluation is expected to be the first to gain marketing approval.

The Company is also exploring the possible use of human-derived stem cells, which can assess blood glucose levels and release insulin accordingly. Such a stem cell technology could be expanded allowing a very large number of patients with diabetes to be treated with these cells within the Cell Pouch™. Use of porcine islets from a clean herd is another opportunity the Company is exploring in the long-term as another source of cells providing a virtually unlimited supply of islets for patient treatment. The porcine islets may be encapsulated by a polymer to protect the islets from immune system attack. Thus, the Company is exploring a number of options to expand its technology in the marketplace.

In addition to the internal research and development activities and the current clinical evaluation at the University of Alberta, the Company is seeking academic collaborations with transplant centres that currently offer islet transplantation using the Edmonton Protocol. It is expected that the Cell Pouch™ may be used for autograft cellular transplants, for allograft cellular transplants with the use of immunosuppressive drugs or in conjunction with co-transplantation of islets and Sertolin™. In addition, methods to further increase the efficiency of cell transplantation within the Cell Pouch™ and to use alternative sources of therapeutic cells are also of interest. One or more of these options are expected to be explored under academic collaborations.

The Company has been in discussions with a number of transplant centres across North America with a view to establishing preclinical and potential future clinical collaborations to demonstrate proof of concept and commercialization of its proprietary technologies. In one such collaboration with the University of Illinois, the Cell Pouch™ has been evaluated in a preclinical study demonstrating its safety and confirming its function in preparing a natural environment for transplant of therapeutic cells. These collaborations may include studies to assess the various aspects of the Company's technology as well as additional preclinical safety and efficacy studies, which may contribute to the data sufficient for filing regulatory documents for future clinical evaluation as discussed above. It is the Company's position that by collaborating with leading transplant centres, the Company can conduct various studies in parallel, while still ensuring the highest quality of work to meet the standards of the FDA, Health Canada and the international scientific community. Similarly, the Company may also choose to conduct studies within its research and development department or may also seek corporate collaborations for such purposes.

While the initial primary focus of the Company's development efforts will be assessment of the Cell Pouch System™ for insulin-dependent diabetes, the Company is planning to develop partnerships with academic and corporate collaborators to develop the Cell Pouch™ for other chronic metabolic, hematologic and neurological diseases. Furthermore, the Company will be seeking to investigate the use of the device for transplantation of multiple cell types including natural cells, stem cells and genetically-engineered cells. The Company may also investigate different methods of protecting cells such as islets from attack by immune cells.

The Company has been conducting its own research and development at Western University, London, Ontario using the state of the art facilities and expertise of surgeons hired as contractors to work in conjunction with Sernova scientists. The Company has also hired contract laboratories to conduct some of its work including preclinical safety assessment, biocompatibility and histopathology analysis. The Company plans to continue to use external laboratories to conduct certain studies. In addition, the Company plans to work with academic centres under collaborative arrangements to conduct pre-clinical studies of the Cell Pouch™ for advanced next-generation applications.

In order to develop and commercialize the Cell Pouch System™, the Company will be seeking regulatory approval to conduct clinical studies in patients for the various clinical indications discussed above. This will then likely be followed by one or more pivotal studies to assess efficacy and safety in a larger population. It is expected that these studies will be used to gain regulatory approvals of the Cell Pouch™ for the various clinical indications discussed above. The Company is working closely with consultants and regulatory authorities in the development of the commercialization of its products.

## 2012 Accomplishments

The following 2012 key development objectives were achieved:

- Completed contract manufacture and sterilization of the Cell Pouch™ for human clinical evaluation;
- Completed and submitted regulatory documents to the University of Alberta Health Review Ethics Board to initiate a clinical study of the Cell Pouch™ for diabetes;
- Completed and submitted regulatory documents to Health Canada to initiate a clinical study of the Cell Pouch™ in diabetic patients;
- Gained clearance by Health Canada to initiate the Cell Pouch™ clinical study at the University of Alberta;
- Gained University of Alberta hospital and surgical approvals to begin the clinical study and completed Investigator's Meeting and initiated screening of patients;
- Initiated enrollment of patients to assess the safety and efficacy of the Cell Pouch™ with transplanted islets in patients with diabetes;
- Completed and submitted an application for an additional government grant support for work on local cell protector technology and for the collaboration with Dr. Shapiro to assess next generation products related to the Cell Pouch™.

In November 2011, the Company retained the services of Russo Partners LLC, a leading healthcare communications company to provide investor relations to the Company. This relationship was deemed important as the Company transitioned to a clinical stage company with an international presence. Russo Partners has been increasing the exposure of Sernova to international investors and industry experts.

In December 2011, the Company provided shareholders with an update of the accomplishments for the past fiscal year and the progress towards the human clinical trials, including confirmation from Health Canada that the Cell Pouch™ has been designated as a Class III Medical device for regulatory purposes. This announcement addressed the manufacturing of clinical Cell Pouch™ product, sterilization processes and the results of the ISO10993 biocompatibility studies, all of which were successful.

On April 19, 2012 the Company received the University of Alberta hospital ethics board approval to initiate the first clinical trial of the Cell Pouch™ pending Health Canada Clearance. The Company has also completed the manufacture and release of the Cell Pouch™ clinical product from its contract manufacturer.

In May 2012, the Company announced it received Health Canada approval to conduct its human clinical trial assessing both the safety and efficacy of Sernova's Cell Pouch™ with transplanted insulin-producing islets in 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 Sernova's Cell Pouch™ in a Phase I/II clinical study led by Dr. James Shapiro, principal investigator at the University of Alberta.

The following is the outlook for 2013:

- Continued enrolment of patients and release of interim clinical results from the Phase I/II study of the Cell Pouch™ in patients with diabetes receiving an islet transplant
- Development and confirmation of an international clinical, regulatory and commercialization strategy for the Cell Pouch™ for the treatment of insulin-dependent diabetes
- Conduct of preclinical proof of concept safety and efficacy of a local immune protection technology such as Sertolin™ within the Cell Pouch™ for diabetes through an NRC-IRAP contribution agreement
- Proof of concept safety and efficacy of an unlimited supply of cells (e.g. stem cells, xenogeneic cells) within the Cell Pouch™ for diabetes
- Development of a corporate partnership to begin development of a new product indication for the Cell Pouch™
- Preparation of regulatory documentation for initiation of a second clinical indication for the Cell Pouch™

### **Scientific Advisory Board**

To help guide the diabetes research and development efforts, the Company has a Scientific Advisory Board chaired by Dr. David White. He is a noted transplant immunologist, formerly a professor at Cambridge University in England and now Professor Emeritus at the Western University in Ontario.

The Scientific Advisory Board also includes the following individuals:

Dr. James Shapiro, a world renowned transplantation scientist and clinician who is currently Director of Clinical Islet Transplantation program at the University of Alberta, where he oversees the largest clinical islet transplant program in the world. Dr. Shapiro with a team at the University of Alberta was instrumental in developing the Edmonton protocol, the current standard of care for islet transplantation. Dr. Shapiro is the principal investigator for Sernova's clinical study assessing the safety and efficacy of the Cell Pouch™ and collaborator with Sernova on advanced Sernova technologies.

Dr. David Sutherland is a professor, Transplantation Scientist and Clinician in the Division of Transplantation, Director of the Schulze Institute and Dobbs Diabetes Research Chair within the Department of Surgery at the University of Minnesota where he oversees the largest clinical islet autotransplant program in the world. The addition of Dr. Sutherland to the Advisory Board represents another key component in the strategy of advancing the Cell Pouch System™ into multiple Human Clinical Trials for a number of clinical indications.

Dr. Stephen Paraskevas is highly respected in the islet transplant field and the new islet transplantation program at McGill University headed by Dr. Paraskevas is the third such centre in Canada and provides the potential to significantly increase the number of diabetic patients that can be treated with donor islets.

Dr. Norman Wong, co-founder of Resverlogix and a Professor in the Departments of Medicine and Biochemistry & Molecular Biology at the University of Calgary;

Dr. Jannette Dufour, an expert in Sertoli cells and Assistant Professor in the Department of Cell Biology and Biochemistry at Texas Tech University Health Sciences Center;

Dr. Clive Patience, a leading expert on biological safety of xenotransplants and currently Associate Director of Bioanalytical Quality Control at Biogen Idec. Inc.;

Dr. George King, an award winning diabetologist who is the Director of Research and Head of the Vascular Cell Biology Section at Joslin Diabetes Center, and a Professor of Medicine at Harvard Medical School.

### **Corporate Activity and Current Financings**

In January 2012, the Company announced that the Japan Patent office had issued a Notice of Allowance to the Company for a patent entitled “Compositions Containing Sertoli Cells and Myoid Cells and Use Thereof in Cellular Transplants”. Allowance in additional international jurisdictions including Canada, Europe and the United States is pending while allowance in Australia has been granted.

Details of the common shares and warrants issued in the February and March 2012 are fully described in note 8 to the annual audited Consolidated Financial Statements for the year ended October 31, 2012.

In March 2012, the Company granted incentive stock options to purchase 1,342,918 common shares of the Company to employees and consultants of the Company.

In April 2012, the Company granted incentive stock options to purchase up to 2,865,000 common shares of the Company to directors, officers, employees and consultants of the Company, of which 2,475,000 were granted to directors and officers of the Company.

The options are subject to the terms of the Company’s incentive stock option plan and are generally exercisable for a period of five years. Details of the options are set out in note 9 to the condensed consolidated interim financial statements for the three months ended January 31, 2013.

At the annual general meeting held April 19, 2012, Dr. George Adams, Dr. Philip Toleikis and Mr. Jeff Bacha were re-elected and Mr. Bruce Weber and Mr. James Parsons were elected to the Company’s Board of directors while Mr. Hans Mader did not stand for reelection to the Company board. The election of Mr. Weber and Mr. Parsons strengthens the Company board from a perspective in the international clinical, regulatory and corporate finance areas. With the launch of its first-in-man Canadian clinical trial of the Cell Pouch™, the Company is strategically focused on clinical validations. The board now has the seasoned Directors with operational and transactional experience to properly govern and guide the Company.

In June 2012, the Company announced that since mid-April 2012, it had received gross proceeds of \$772,182 on the exercise of 3,878,277 common share purchase warrants, of which 3,808,814 were exercisable at a price of \$0.20 and 69,463 were exercisable at a price of \$0.15 per share.

In September 2012, the Company presented at the New York Rodman and Renshaw Conference and provided an overview of the Company’s business strategy and the on-going Phase I/II clinical trial of the Cell Pouch™ with insulin-producing islets in patients with Type 1 diabetes.

On February 19, 2013, the Company closed its non-brokered private placement that was announced on January 21, 2013, consisting of 10,000,000 units at a price of \$0.20 per unit for gross proceeds of \$2,000,000. Each unit comprises one common share and one common share purchase warrant, with each warrant entitling the holder thereof to purchase one common share of the Company for 36 months 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. In connection with the closing of the offering, the Company paid a commission of \$140,000 and issued 700,000 finder’s warrants. Each warrant entitles the holder to purchase one common share of the Company at a price of \$0.20 for a period of 24 months.

## Results of Operations

A summary of the selected financial information from the statement of net loss and comprehensive loss includes the following:

	Three Months Ended January 31, 2013 \$	Three Months Ended January 31, 2012 \$
Research and development costs	421,687	501,348
General and administrative costs	121,856	126,363
Loss and comprehensive loss for the period	(531,380)	(625,833)

For the three months ended January 31, 2013, the Company recorded a net loss of \$531,380 or \$0.01 per share versus a loss of \$625,833 or \$0.01 per share for the corresponding period last year, a decrease of \$94,453 or 15%. The principal reason for the decrease in the loss for the current fiscal year were the research and development expenditures which were reduced by \$79,661 primarily due to the timing of costs for the pre-clinical and clinical trials and the timing of recognition of government assistance.

Research and development expenditures for the three months ended January 31 were as follows, reflecting a reduction of 16% year over year:

	Three Months Ended January 31, 2013 \$	Three Months Ended January 31, 2012 \$	Increase (decrease) \$
Supplies and contract payments	51,182	123,685	(72,503)
Salaries and benefits	130,792	116,242	14,550
Patent fees and costs	42,052	34,990	7,062
Depreciation of property & equipment	378	472	(94)
Amortization of intangible assets	174,565	217,601	(43,036)
Share-based compensation	31,712	8,603	23,109
Grants and tax credits	(8,994)	(245)	(8,749)
Total expense	421,687	501,348	(79,661)

Supplies and contract payments for the three months ended January 31, 2013 were \$51,182 which represented a decrease of \$72,503 or 59% from the same period in the prior year. This decrease can be attributed to expenditures in the prior year towards the costs to enable the Company to advance toward clinical trials of its Cell Pouch System™, including manufacturing and sterilization costs of the Cell Pouch™ and regulatory submissions.

Salaries and benefits were approximately \$14,550 higher in the current fiscal year as compared to the prior year due to one additional staff member and annual salary adjustments.

Patent fees and costs for the period ended January 31, 2013 were \$42,052 compared to \$34,990 for the same period in the prior year. The increase in the costs of \$7,062 reflects the costs involved in prosecution of an internally generated patent in a number of countries as the Company seeks to expand its patent portfolio.

The grants and tax credits for the three months ended January 31, 2013 represents the balance of the refundable provincial investment tax credits for the year ended October 31, 2011 upon finalization of the review of the claim, which amount compares to \$245 for the prior year.

General and administrative costs for the three month ended January 31 were as follows and reflected a decrease of \$4,507:

	Three Months	Three Months	
	Ended	Ended	
	January 31,	January 31,	Increase
	2013	2012	(decrease)
	\$	\$	\$
Other costs	39,196	47,293	(8,097)
Investor relations	28,971	49,860	(20,889)
Consulting fees	27,190	26,509	681
Depreciation of property & equipment	42	53	(11)
Share-based compensation	26,457	2,648	23,809
Total expense	121,856	126,363	(4,507)

General and administrative costs for the three months ended January 31, 2013 were comparable with the prior year at \$121,856 as compared to \$126,363.

The change year-over year in investor relations costs of \$20,889 driven by the new contract with Russo Partners LLC in fiscal 2012 which required an initial payment of \$25,000.

Other costs for the three months ended January 31, 2013 were \$39,196 compared to \$47,293 for the same period in the prior year representing a decrease of \$8,097. The main expenditure included in this caption includes professional fees of \$18,548 compared to professional fees of \$21,994 for the prior year.

Included in the general and administrative expenses for the three months ended January 31, 2013 were \$26,457 of non-cash share-based compensation expense compared to \$2,648 for the same period in the prior year and the higher compensation reflects the recognition of stock option awards that were granted in March and April of 2012.

Other finance income principally represents interest income earned on the Company's term deposits and was higher than the comparable period due to the larger average holdings of cash and short-term investments.

The basic and diluted loss per common share remained at \$0.01 per share.

Selected summary data with respect to the statement of operations is set out below:

**SUMMARY OF QUARTERLY RESULTS**

		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2011	Net loss	(569,772)	(570,284)	(423,220)	(465,002)
	Net loss per share	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.01)
2012	Net loss	(625,833)	(677,974)	(574,489)	(689,732)
	Net loss per share	(\$0.01)	(\$0.01)	(\$0.01)	(\$0.01)
2013	Net loss	(531,380)	-	-	-
	Net loss per share	(\$0.01)	\$0.00	\$0.00	0.00

The annual loss per share is not the sum of the quarterly loss per share reported.

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 resource, 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.

**CASH FLOWS**

Summary data with respect to the cash flows is presented below:

	Three Months Ended January 31, 2013	Three Months Ended January 31, 2012
	\$	\$
Cash used by operating activities	(311,556)	(329,567)
Cash provided by (used by) investing activities	(1,399,177)	134,496
Cash provided by financing activities	1,980,052	-

Cash flows used by the operating activities for the three months ended January 31, 2013 were \$311,556 compared with cash flows used by the operating activities of \$329,567 in the prior year, a decrease of \$18,011 or 5% over the prior year. The change can be attributed to the decrease in research and

development expenditures for the current period has been fully explained under the statement of operations commentary.

Within the cash used by operating activities, cash used by changes in working capital balances for the three months ended January 31, 2013 was \$854 compared with cash provided by changes in working capital of \$70,310 in the prior year. The net current assets remained relatively stable between October 31, 2012 and January 31, 2013. The change in the Three Months Ended January 31, 2012 arose principally from the collection of the amounts receivable of \$17,131 due under the contribution from the National Research Council, the collection of the sales tax and investment tax credit receivable, and an increase in accrued liabilities in the period of \$17,676.

Regarding financing activities, in the three months ended January 31, 2013 the Company received net subscriptions in advance amounting to \$1,980,052 resulting from the announcement in January 2013 of a non-brokered private placement. There were no financing activities in the three months ended January 31, 2012. The specific transaction is fully described in Note 9 to the condensed consolidated interim financial statements.

With respect to investing activities, the company invested \$3,549 in the acquisition of patent rights for the three months ended January 31, 2013 compared to \$19,595 for the same period in the prior year. The Company purchased a net of \$1,395,628 in short-term investments in the three months ended January 31, 2013 following receipt of the subscription funds compared to an inflow of \$155,878 from a reduction of short-term investments for the three months ended January 31, 2012 as funds were required to meet operating activities. Total investing activities for the three months ended January 31, 2013 amounted to \$1,399,177 as compared to a cash inflow of \$134,496 for the same period in the prior year.

Cash resources for the three months ended January 31, 2013 increased by \$269,319 from the balance of \$255,557 as at October 31, 2012 compared to a decrease of \$195,071 in cash resources for the same period in the prior year.

## **LIQUIDITY AND CAPITAL RESOURCES**

Since inception, the Company has principally financed its operations from the sale of equity, exercise of warrants, and tax credits. As at January 31, 2013, the Company has cash and short-term investments of \$6,037,144 compared to \$4,359,721 as at October 31, 2012.

As a result of subscriptions received in advance in the three months ended January 31, 2013, the Company has improved its working capital position by \$1,679,833 as compared to the working capital position as at October 31, 2012, and accordingly as at January 31, 2013 had working capital of \$6,002,392.

There are no significant commitments for equipment, although the Company expects some modest capital expenditures in the year ending October 31, 2013 related to additional personnel and the expansion of the research and development activities. Management will manage the investing activities related its patent portfolio and anticipates continuing expenditures on such assets. The Company invested \$14,349 in the three months ended January 31, 2013 in patent development compared to \$22,108 for the same period in the prior year.

The Company is committed to annual payments of rental space of approximately \$33,000 on a short-term arrangement. There are no other lease commitments. The Company is committed to annual maintenance fees on the patent portfolio of approximately \$66,000 USD.

While the Company does not have available credit facilities, and will not be impacted by the changing credit environment, it will require cash to fund continuing operations in the long-term, likely in the form of new capital or debt and new collaborations.

There are no defaults under operating agreements and management does not anticipate any significant risks that there will be such a default in the period to October 31, 2013.

### **Statement of Financial Position**

Selected financial data with respect to the statement of financial position as at January 31, 2013 and October 31, 2012 is as follows:

	<b>January 31,</b>	<b>October 31,</b>
	<b>2013</b>	<b>2012</b>
	<b>\$</b>	<b>\$</b>
Cash & short-term investments	6,037,144	4,359,721
Total assets	7,719,368	6,202,639
Current liabilities	143,838	133,950
Share capital & warrants	25,410,039	25,410,039
Subscription received in advance	1,980,052	-
Deficit	(22,576,027)	(22,044,647)

Total assets as at January 31, 2013 were \$7,719,368 compared with \$6,202,639 at the end of the Company's last year end, representing an increase of 24% or \$1,516,729. While cash and short-term investment resources have increased in the three month period by \$1,677,423 through the subscriptions received in advance noted elsewhere, substantially all of the net decrease is accounted for by the amortization of the intangible assets.

Total current assets of \$6,146,230 have increased from the balance of \$4,456,509 as at October 31, 2012, and reflect cash received from the subscriptions in advances, net of resources used to cover operations and resources used to invest in intangible assets. Other current assets were relatively unchanged.

The net book value of equipment of \$5,132 in the Company remains relatively unchanged from the balance as at October 31, 2012 and the change in value can be attributed to the depreciation of such assets.

The net book value of intangible assets as at January 31, 2013 declined to \$1,568,006 from \$1,740,578 as at the end of the prior year. Additions in the period ended January 31, 2013 amounted to \$1,993 compared to \$22,606 for the same period in the prior year. Amortization of \$174,565 for the three months ended January 31, 2013 compared to \$217,601 for the prior year which accounted for the

decrease in net book value. The reduction in the amortization charge for the current year results from an extension in the estimate of the useful life of the asset in 2013.

Accounts payable and accrued liabilities were \$143,838 at the January 31, 2013 compared to \$133,950 as at October 31, 2012, an increase of \$9,888. The change is the result of timing of receipt and settlement of invoices for services related to the continuing research and development, the cyclical nature of certain expenses and settlement payments with its trade creditors on a current basis. It is anticipated that substantially all accounts payable and accrued liabilities as at January 31, 2013 will be settled in the current fiscal year.

**Common shares issued – three months ended January 31, 2013**

On January 21, 2013 the Company announced that it had arranged a non-brokered private placement in the amount of \$2,000,000. The offering consisted of 10 million units each sold at a price of \$0.20 per unit.

Each unit will consist of one common share and one common share purchase warrant, with each warrant entitling the holder thereto to purchase one 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 Company received total net proceeds of \$1,980,052 before the end of the quarter, which has been classified as subscription received in advance on the statement of financial position.

**Common shares**

There was no change in the number of issued common shares between October 31, 2012 and January 31, 2013 and there are 119,623,636 common shares issued and outstanding at both dates.

Changes in the number of common shares to the date of this report are as follows and details of the common shares issued are detailed in note 17 to the condensed consolidated interim financial statements:

	Number of common shares
Balance outstanding, October 31, 2012 and January 31, 2013	119,623,636
Issued under private placement	10,000,000
Balance outstanding, as at March 26, 2013	129,623,636

Included in the common shares reported above are a number of performance escrow shares.

In May 2006, the Company entered into a Joint Venture to develop a commercially-viable treatment for insulin-dependent human diabetes using insulin producing islets. The licensed technology of the Joint Venture involves the use of sertoli cells to provide immune-protection within a local environment to reduce or eliminate the need for anti-rejection drugs in patients who have received donor therapeutic cells and is branded as “**Sertolin™**”.

In July 2007, the Company exercised its right under the Joint Venture to acquire the final one-third of the shares of Sertonex. Common shares issued under this Joint Venture arrangement have been subject to timed escrow release and earn out escrow provisions. All timed escrow release shares have been

released. As of the date of this MD&A, 3,472,500 common shares remain subject to a performance-based release as follows:

- (i) 1,736,250 common shares on the date that Sernova or an affiliate receives approval from the United States FDA (or its foreign equivalent in Canada, Europe or Japan) of an investigational new drug application or other appropriate regulatory application, as applicable, (or its foreign equivalent in Canada, Europe or Japan) for the initiation of human clinical trials using the licensed sertoli technology for transplantation;
- (ii) the balance of 1,736,250 common shares on the date that Sernova or an affiliate enrolls the first patient in a Phase III human clinical efficacy trial (or its foreign equivalent in Canada, Europe or Japan) using the licensed sertoli technology for transplantation; provided the Escrow Agent receives a declaration of the Company, in each instance that the conditions for the release have been met.

Any unreleased Performance Escrow Shares will be cancelled and returned to treasury upon the earlier of (i) August 2016, (ii) the Company ceasing to hold an interest in the intellectual property, or (iii) the mutual agreement of the Company and the shareholder.

### Stock Options

The Company has an incentive stock option plan and the current terms of the Plan were approved by the Company shareholders on April 19, 2012.

There have been no changes or activity in the number of stock options outstanding between October 31, 2012 and January 31, 2013 and there were 8,001,376 stock options outstanding at both dates. On March 19, 2013 a total of 285,931 stock options were surrendered and consent was given by the optionee for the cancellation of such options. Accordingly as at the date of this report, there were a total of 7,585,445 stock options outstanding.

Details of the stock options outstanding as at January 31, 2013 are provided in note 9 to the condensed consolidated interim financial statements. The following table reflects the activity to the date of this Management Discussion and Analysis:

					Weighted
					Average
			Number of		Exercise
			Options		Price
					\$
Balance outstanding, October 31, 2012 and January 31, 2013			8,001,376		\$0.16
	Surrendered and cancelled		(285,931)		\$0.18
	Expired		(130,000)		\$0.30
Balance outstanding, as at March 26, 2013			7,585,445		\$0.16

## Warrants

The following table reflects the activity of the warrants for the three months ended January 31, 2013 and to the date of this Management Discussion and Analysis:

			Weighted
			Average
		Number of	Exercise
		warrants	Price
Balance outstanding, October 31, 2012		29,161,942	\$0.23
	Expired	(2,350,284)	\$0.20
Balance outstanding, January 31, 2013		26,811,658	\$0.24
	Granted	10,985,931	\$0.34
Balance outstanding, March 26, 2013		<u>37,797,589</u>	<u>\$0.27</u>

Details of the warrants outstanding as at January 31, 2013 are provided in note 9 to the condensed consolidated interim financial statements.

On February 19, 2013 the Company closed its non-brokered private placement that was announced on January 21, 2013, consisting of 10,000,000 units at a price of \$0.20 per unit for gross proceeds of \$2,000,000. Each unit comprises one common share and one common share purchase warrant, with each warrant entitling the holder thereof to purchase one common share of the Company for 36 months 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.

In connection with this offering, the Company also granted 700,000 finder's warrants. Each warrant entitles the holder to purchase one common share of the Company at a price of \$0.20 for a period of 24 months.

On March 19, 2013, the Company granted an additional 285,931 finder's warrants in connection with the offering, subject to regulatory approval. Such warrants entitle the holder to purchase one common share of the Company at a price of \$0.20 for a period of 24 months.

## **GOING CONCERN**

These condensed consolidated interim financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") assuming the Company will continue on a going-concern basis. The Company has incurred losses and negative operating cash flows since inception. The ability of the Company to continue as a going-concern in the long-term depends upon its ability to develop profitable operations and to continue to raise adequate financing. Management is actively targeting sources of additional financing which would assure the long-term continuation of the Company's operations and research programs.

Management believes that the Company has sufficient working capital to maintain its operations for the next twelve months.

## **CONTRACTUAL OBLIGATIONS**

The Company has the following contractual obligations as at March 26, 2013 which are consistent with those contractual obligations reflected in the notes to the Company's audited Consolidated Financial Statements as at October 31, 2012.

The Company is committed to the payment of certain costs under the clinical trial which commenced in the third quarter of the current 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 analysis at various points during the study as sufficient data is 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, travel and a portion of drug-or procedure-related expenses or transplantation expenses not covered by insurance. The total commitment over the three years is expected to be in the range of \$2,000,000 to \$3,000,000 but the commitment 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 \$33,000 for the rental of laboratory space which is short-term in nature but essentially subject to an annual renewal.

The Company is committed to an estimated \$66,000 USD in fees to maintain its patent portfolio in good standing for the year ending October 31, 2013. It is anticipated that similar payments will be required subsequent years.

## **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. There are no amounts due to or due from related parties as at January 31, 2013 or October 31, 2012.

The following transactions in which the directors had an interest occurred in the three months ended January 31 is as follows:

	2013	2012
	\$	\$
Consulting fees	0	0
Director fees	0	0
Share-based compensation	20,426	0
Total expense	20,426	0

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

	2013	2012
	\$	\$
Salaries	114,121	101,465
Consulting fees	20,625	18,750
Benefits	16,672	14,778
Share-based compensation	28,571	11,251
<b>Total expense</b>	<b>179,989</b>	<b>146,244</b>

Executive officers and directors participate in the incentive stock option plan and officers participate in the Company’s health plan. Key management personnel control 2.4% of the issued common shares of the Company as at January 31, 2013.

During the three months ended January 31, 2013 the Company paid \$20,625 (2012- \$18,750) in consulting fees for the services of the Chief Financial Officer, to a company controlled by the officer.

**MANAGEMENT’S RESPONSIBILITY FOR INTERNAL CONTROL SYSTEMS AND DISCLOSURE CONTROLS**

In connection with National Instrument 52-109, certification of disclosure in issuer’s Annual and Interim Filings (“NI 52-109”) adopted in December 2008 by each of the securities commissions across Canada, the Chief Executive Officer and Chief Financial Officer of the Company will file a Venture Issuer Basic Certificate with respect to financial information contained in the unaudited Condensed Consolidated Interim Financial Statements and the audited annual consolidated financial statements and respective Management’s Discussion and Analysis. The Venture Issuer Basic Certification does not include representations relating to the establishment and maintenance of disclosure controls and procedures and internal control over financial reporting, as defined in NI 52-109. As a venture issuer, the company is not required to certify the design and evaluation of the Company’s disclosure controls and procedures and internal controls over financial reporting, and as such has not completed such an evaluation.

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 or scale to warrant hiring of additional staff to address this potential weakness at this time. To help mitigate the impact of this situation, the Company is highly reliant on the performance of compensating procedures, senior management’s review and approval and the Board of Directors oversight. During the three months ended January 31, 2013, the Company made no material changes to its system of internal controls over financial reporting.

Investors should be aware of the inherent limitations on the ability of the certifying officers of a venture issuer to design and implement on a cost effective basis disclosure controls and procedures and internal controls over financial reporting as defined in NI 52-109 which may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The preparation of the Consolidated Financial Statements in accordance with IFRS requires the use of estimates and assumptions to be made in applying the accounting policies that affect the application of accounting policies and reported amounts of assets, liabilities, expenses and the disclosure of contingent assets and liabilities. The estimates and related assumptions are based on previous experience and other factors considered reasonable under the circumstances, the results of which form the basis of making the assumptions about carrying values of assets and liabilities that are not readily apparent from other sources. A summary of the Company's significant accounting policies and estimates under IFRS are to be found in Note 3 to the Consolidated Financial Statements for the year ended October 31, 2012.

The estimates and underlying assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period or in the period of the revision and future periods if the revision affects both current and future periods. Judgments made by management in the application of IFRS that have significant effect on the Consolidated Financial Statements relate to the following areas:

### *Research and development costs*

Research expenditures are expensed as incurred. Development expenditures are capitalized only if development costs can be measured reliably, the product is technically and commercially feasible, future economic benefits are probable, and the Company intends to and has sufficient resources to complete development and to use or sell the asset. Government assistance and investment tax credits relating to research and development are recorded as a reduction of expenses. The cost incurred in maintaining patents for intellectual property are expensed in the period incurred.

### *Useful lives of key intangible assets*

Intangible assets that are acquired and have finite lives are measured at cost less accumulated amortization and accumulated impairment losses. Subsequent expenditures are capitalized when it increases future economic benefits embodied in the specific asset to which it relates. All other expenditures are recognized in profit and loss as incurred.

The amortization methods and estimates of useful lives reflect the pattern in which management expects the asset's future economic benefit to be consumed by the Company. Amortization of intangible assets is recognized in profit and loss on a straight-line basis over the estimated useful lives from the date they are available for use in the manner intended by management.

### *Impairment of long-lived assets*

The Company periodically reviews the useful lives and carrying value of its long-lived assets. Long-lived assets are reviewed for impairment upon the occurrence of events or change in circumstances indicating that the carrying value of the asset may not be recoverable.

The Company's impairment test is based upon value-in-use calculations that use a discounted cash flow model. The cash flows are derived from the projections for the period of the economic life of the asset and are sensitive to the discount rate used as well as the expected future cash inflows and the growth rate used for extrapolation purposes.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The Company evaluates impairment losses for potential reversals when events or circumstances warrant such consideration.

### *Share-based compensation*

The Company measures the cost of equity-settled transactions with officers, directors, employees and consultants by reference to the fair value of equity instruments at the date at which they are granted.

Estimating fair value for share-based payments requires determining the most appropriate valuation model for a grant of these instruments, which is dependent upon the terms and conditions of the grant. This also requires determining the most appropriate inputs for the valuation model, including the expected life of the option, volatility, dividend yield and forfeiture rates. Refer to note 8 of the Consolidated Financial Statements for the year ended October 31, 2012 and note 9 of the condensed consolidated interim financial statements for the three months ended January 31, 2013 for weighted average assumptions used to determine the fair value of Company warrants and options.

#### *Income tax valuation allowance*

The Company has a net tax benefit resulting from non-capital losses carried forward, and pools of scientific research and development expenditures and investment tax credits. The Company recognized no income taxes in the statement of loss and comprehensive loss, as it has been incurring losses since inception, and it is not probable that future taxable profits will be available against which the accumulated tax losses can be utilized.

### **CHANGES IN ACCOUNTING POLICIES**

The Company's principal accounting policies were outlined in the Company's annual audited consolidated financial statements for the year ended October 31, 2012 and have been applied consistently to all periods presented in these condensed consolidated interim financial statements. These statements should be read in conjunction with the annual audited consolidated financial statements for the year ended October 31, 2012.

#### **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*

Financial Instruments' is the first of three phases of the IASB's wider project to replace IAS 39, *Financial instruments: Recognition and Measurement*. IFRS 9 retains but simplifies the mixed measurement model and establishes two primary measurement categories for financial assets, amortized cost and fair value. The basis of classification depends 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, 2015. The Company intends to adopt IFRS 9 (2010) in its financial statements for the annual period beginning on November 1, 2015. 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*

The amendment establishes a single control model that applies to all entities. IFRS 10 replaces the consolidation requirements in SIC-12, *Consolidation – Special Purposes Entities*, and IAS 27, *Consolidated and Separate Financial Statements*. These changes will require management to exercise significant judgment to determine which entities are controlled, and therefore are required to be consolidated by a parent, as compared with the former requirements. The amendment becomes effective for annual periods beginning on or after January 1, 2013, and is required to be applied retroactively.

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

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. The Company intends to adopt IFRS 13 prospectively in its financial statements for annual periods beginning on November 1, 2013 and does not expect IFRS 13 to have a material impact on its financial statements.

## *Annual Improvements to IFRSs 2009-2011 Cycle*

In May 2012, the IASB published Annual Improvements to IFRS – 2009-2011 Cycle as part of its annual improvements process to make non-urgent but necessary amendments to IFRS. These amendments are effective for annual periods beginning on or after January 1, 2013 with retrospective application. The Company intends to adopt the amendments to the standards in its financial statements for the annual period beginning on November 1, 2013. The extent of the impact of the adoption of the amendments has not yet been determined.

## **FINANCIAL INSTRUMENTS AND RISK MANAGEMENT**

Fair value estimates of financial instruments are made at a specific point in time, based on relevant information about financial markets and specific financial instruments. As these estimates are subjective in nature, involving uncertainties and matters of significant judgment, they cannot be determined with precision. Changes in assumptions can significantly affect estimated fair values.

The fair value of cash and short-term investments is measured using level 1 of the fair value hierarchy.

The carrying value of accounts receivable and accounts payable and accrued liabilities approximates fair value because of the short-term nature of these instruments.

The Company has developed an approach to manage the issue of financial risks in the following manner:

## **Credit risk**

The Company's financial assets that are exposed to credit risk are cash, short-term investments and trade and other receivables. Credit risk is the risk of loss associated with a counter party's inability to fulfil its payment obligation.

Cash and short-term investments consist of deposits with a major commercial bank and are therefore subject to minimal credit risk.

The Company, in the normal course of business, is exposed to credit risk on trade and other receivables. The majority of the other receivables are amounts due from government agencies for tax recoveries and grants and are therefore subject to minimal credit risk. The credit risk associated with any remaining receivables, predominantly related to the subscription amounts due under the issuance of equity is assessed through established monitoring activities.

The Company has no current trade receivables and does not therefore need to utilize an allowance account to assess the carrying value of the trade receivables and the underlying credit risk

## **Market risk**

Market risk is the risk of loss that may arise from changes in market factors such as interest rates, foreign exchange rates and commodity and equity prices. In the current market environment, these fluctuations may continue to be significant

## **Foreign currency exchange rate risk**

The Company is exposed to foreign currency risk on fluctuations related to cash, receivables and accounts payable and accrued liabilities that are denominated in foreign currencies, which is currently only United States dollars. However, management believes the risk is not currently significant as less than 0.1% of the Company financial assets and none of the liabilities are denominated in United States dollars. There are no active operations in the US, with exception of the patent prosecution and maintenance which annual costs are estimated at approximately \$200,000 USD for both activities. A strengthening of the US dollar against the Canadian dollar by 1% would cost the Company approximately an additional \$2,000.

## **Interest rate risk**

The Company has cash and short-term investment balances but no interest-bearing debt or financial assets. The Company's current policy is to invest excess cash in investment-grade short-term deposit certificates issued by its banking institutions. The Company monitors the investments it makes and is satisfied with the credit ratings of its banks. As at January 31, 2013 the Company has approximately \$5,512,268 held in interest-bearing deposits with banks. While the deposits have a maximum three year term, the liquidity of the short-term investments is restricted in the second and third years, and the Company intends to manage such restrictions on liquidity and accordingly the deposits are classified as current assets. The investments are cashable with notice on the 15<sup>th</sup> of any month without penalty within the first year. A 1% change in the interest rates would have an effect of \$55,122 per year on interest income and the value of the asset

## **Liquidity Risk**

Liquidity risk represents the contingency that the Company is unable to gather funds required with respect to its financial obligations at the appropriate time and under reasonable conditions.

The Company's approach to managing liquidity risk is to ensure that it will have sufficient liquidity to meet current liabilities and future financial obligations when they become due under normal conditions. As at January 31 2013 the Company had cash and short-term investments of \$6,037,144 to settle current liabilities of \$143,838. All of the Company's financial liabilities are subject to normal trade terms.

## **RISKS AND UNCERTAINTIES**

### **Investment Risk**

***Volatility of Share Price, Absence of Dividends and Fluctuation of Operating Results.*** Market prices for the securities of biotechnology companies, including the Company, have historically been highly volatile. Factors such as fluctuation of the Company's operating results, announcements of technological innovations, patents or new commercial products by the Company or competitors, results of clinical testing, regulatory actions, or public concern over the safety of biopharmaceutical products and other factors could have a significant effect on the share price or trading volumes for the common shares. The Company's common shares have been subject to significant price and volume fluctuations and may continue to be subject to significant price and volume fluctuations in the future. The Company has not paid dividends to date and does not expect to pay dividends in the foreseeable future.

### **Issuer Risk**

***Early Stage Development and Scientific Uncertainty.*** The Company's products are at an early stage of development. Significant additional investment in research and development, product validation, technology transfer to manufacturing, production scale-up, manufacturing, clinical testing, and regulatory submissions of such product candidates is required prior to commercialization. There can be no assurance that any such products will actually be developed. The development and regulatory processes may require access to raw materials and inputs which may not be available to the Company in sufficient amounts or in a timely fashion to allow the Company to complete the development or receive regulatory approval of any product or process. A commitment of substantial time and resources is required to conduct research and clinical trials if the Company is to complete the development of any product. It is not known whether any of these product or process candidates will meet applicable health regulatory standards and obtain required regulatory approvals, or whether such products can be produced in commercial quantities at reasonable costs and be successfully marketed, or if the Company's investment in any such products will be recovered through sales or royalties.

***Additional Financing Requirements and Access to Capital.*** The Company will require substantial additional funds for further research and development, planned clinical testing, regulatory approvals, establishment of manufacturing capabilities and, if necessary, the marketing and sale of its products. The Company may attempt to raise additional funds for these purposes through public or private equity or debt financing, collaborations with other biopharmaceutical companies and/or from other sources. There can be no assurance that additional funding or partnership will be available on terms acceptable to the Company and which would foster successful commercialization of the Company's products.

***Patents and Proprietary Technology.*** The Company's success will depend in part on its ability to obtain, maintain, and enforce patent rights, maintain trade secret protection and operate without infringing the proprietary rights of third parties. There can be no assurance that pending patent applications will be allowed, that the Company will develop additional proprietary products that are patentable, that issued patents will provide the Issuer with any competitive advantage or will not be

challenged by any third parties, or that patents of others will not have an adverse effect on the ability of the Company to do business.

Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of the Company's products, or design around the products patented by the Company. In addition, the Company may be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any licenses required under such patents or proprietary rights will be available on terms acceptable to the Company. If the Company does not obtain such licenses it could encounter delays in introducing one or more of its products to the market, while it attempts to design around such patents, or could find that the development, manufacturing or sale of products requiring such licenses could be foreclosed. In addition, the Company could incur substantial costs in defending itself in suits brought against it on such patents or in suits where it attempts to enforce its own patents against other parties.

Until such time, if ever, that patent applications are filed, the ability of the Company to maintain the confidentiality of its technology may be crucial to its ultimate possible commercial success. While the Company has adopted procedures designed to protect the confidentiality of its technology, no assurance can be given that such arrangements will be effective, that third parties will not gain access to the Company's trade secrets or disclose the technology, or that the Company can meaningfully protect its rights to its trade secrets.

***Dependence on Collaborative Partners, Licensors and Others.*** The Company currently utilizes technology which has been licensed to it and technology which has been developed by its own researchers. In particular, the Company is dependent upon the license to use certain technology provided under a sublicense agreement with Sertoli Technologies Inc. dated August 9, 2006 for the development of its product candidates. While the company's licenses are in good standing, they may be terminated by the licensor if there is a breach of the licensing agreement.

The Company's activities will require it to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing and commercialization of its products. The Company intends to attract corporate partners and enter into additional research collaborations. There can be no assurance, however, that the Company will be able to establish such additional collaborations on favourable terms, if at all, or that its current or future collaborations will be successful. Failure to attract commercial partners for its products may result in the Company incurring substantial clinical testing, manufacturing and commercialization costs prior to realizing any revenue from product sales or result in delays or program discontinuance if funds are not available in sufficient quantities.

Should any collaborative partner fail to develop, manufacture, or commercialize successfully any product to which it has rights, or any partner's product to which the Company will have rights, the Company's business may be adversely affected. Failure of a collaborative partner to continue to participate in any particular program could delay or halt the development or commercialization of products generated from such program. In addition, there can be no assurance that the collaborative partners will not pursue other technologies or develop alternative products either alone or in collaboration with others, including the Company's competitors, as a means for developing treatments for the diseases targeted by the Company's programs.

Furthermore, the Company will hold licenses for certain technologies and there can be no assurance that these licenses will not be terminated, or that they will be renewed on conditions acceptable to the Company. The Company intends to negotiate additional licenses in respect of technologies developed by other companies and academic institutions. Terms of license agreements to be negotiated may include, inter alia, a requirement to make milestone payments, which may be substantial. The Company will also be obligated to make royalty payments on the sales, if any, of products resulting from licensed technology and, in some instances, may be responsible for the costs of filing and prosecuting patent applications.

***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.***

None of our product candidates have received regulatory approval for commercial use and sale in North America. We cannot market any product in any jurisdiction until it has completed thorough preclinical testing and clinical trials in addition to that jurisdiction's extensive regulatory approval process. Approval in one country does not assure approval in another country. In general, significant research and development and clinical trials are required to demonstrate the safety and effectiveness of our product candidates before we can submit any regulatory applications.

Clinical trials are long, expensive and uncertain processes. Clinical trials may not be commenced or completed on schedule and Health Canada or the FDA or any other regulatory body may not ultimately approve our product candidates for commercial sale.

The clinical trials of any of our product candidates could be unsuccessful, which would prevent us from advancing, commercializing or partnering the product.

Even if the results of our preclinical studies or clinical trials are initially positive, it is possible that we will obtain different results in the later stages of product development or that results seen in clinical trials will not continue with longer term treatment. Positive results in early Phase I or Phase II clinical trials may not be repeated in larger Phase II or Phase III clinical trials. We cannot assure you that our preclinical studies and clinical trials will generate positive results that allow us to move towards the commercial use and sale of our product candidates. Furthermore, negative results may cause our business, financial condition, or results of operations to be materially adversely affected.

For example, our Cell Pouch™ is in the Phase I/II stage of development but there is a long development path ahead which will take years to complete and is prone to the risks of failure inherent in the development process.

Preparing, submitting and advancing applications for regulatory approval is complex, expensive and time intensive and entails significant uncertainty. A commitment of substantial resources to conduct time-consuming research, preclinical and clinical trials will be required if we are to complete development of our products.

Clinical trials of our products require that we identify and enroll patients with the illness under investigation. We may not be able to enroll a sufficient number of appropriate patients to compete our clinical trials in a timely manner particularly in smaller indications and indications where there is significant competition for patients. If we experience difficulty in enrolling a sufficient number of patients to conduct our clinical trials, we may need to delay or terminate on-going clinical trials and will not accomplish objectives material to our success that could impact the price of our Common Shares. Delays in planned patient enrolment or lower than anticipated event rates in our clinical trials or future trials may result in increased costs, program delays, or both.

In addition, unacceptable adverse side effects may occur at any time in the course of preclinical studies or human clinical trials or, if any product candidates are successfully developed and approved for marketing, during commercial use of any approved products. The appearance of any such unacceptable adverse side effects could interrupt, limit, delay or abort the development of any of our product candidates, or if previously approved, necessitate their withdrawal from the market. Furthermore, disease resistant or other unforeseen factors may limit the effectiveness of our potential products.

Our failure to develop safe, commercially viable products would substantially impair our ability to generate revenues and sustain our operations and would materially harm our business and adversely affect our share price. We may never achieve profitability.

***Reliance on Key Personnel.*** The Company is dependent on certain members of its management and scientific staff as well as consultants and contractors, the loss of services of one or more of whom could adversely affect the Company. In addition, the Company's ability to manage growth effectively will require it to continue to implement and improve its management systems and to recruit and train

new employees. There can be no assurance that the Company will be able to successfully attract and retain skilled and experienced personnel.

***Lack of Product Revenues and History of Losses.*** To date, the Company has not recorded any revenues from the sale of cell therapy products. The Company expects to incur additional losses during the periods of research and development, clinical testing, and application for regulatory approval of its product candidates. The Company expects to incur losses unless and until such time as payments from corporate collaborations, product sales and/or royalty payments generate sufficient revenues to fund its continuing operations.

***Conflict of Interest.*** Certain of the directors and senior officers of the Company may, from time to time, be employed by or affiliated with organizations which have entered into agreements with the Issuer. As disputes may arise between these organizations and the Company, or certain of these organizations may undertake or have undertaken research with competitors of the Company, there exists the possibility for such persons to be in a position of conflict. Any decision or recommendation made by these persons involving the Company will be made in accordance with his or her duties and obligations to deal fairly and in good faith with the Company and such other organizations. In addition, as applicable, such directors and officers will refrain from voting on any matter in which they have a conflict of interest.

### **Industry Risk**

***Government Regulations.*** Biotechnology and pharmaceutical companies operate in a high-risk regulatory environment. The manufacture and sale of animal and human diagnostic and therapeutic products is governed by numerous statutes and regulations in the United States, Canada and other countries where the Company intends to market its products. The subject matter of such legislation includes approval of manufacturing facilities, controlled research and testing procedures, review and approval of manufacturing, preclinical and clinical data prior to marketing approval, as well as regulation of marketing activities, notably advertising and labeling.

The process of completing clinical testing and obtaining required approvals is likely to take several years and require the expenditure of substantial resources. Furthermore, there can be no assurance that the regulators will not require modification to any submissions which may result in delays or failure to obtain regulatory approvals. Any delay or failure to obtain regulatory approvals could adversely affect the ability of the Company to utilize its technology, thereby adversely affecting operations. Further, there can be no assurance that the Company's diagnostic product candidates will achieve levels of sensitivity and specificity sufficient for regulatory approval or market acceptance, or that its therapeutic product candidates prove to be safe and effective in clinical trials, or receive the requisite regulatory approval. There is no assurance that the Company will be able to timely and profitably produce its products while complying with all the applicable regulatory requirements. Foreign markets, other than the United States and Canada, impose similar restrictions.

***Hazardous Materials and Environmental Matters.*** Certain of the Company's research and development processes will involve the controlled use of hazardous materials. The Company is subject to federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although management of the Company believes that its procedures for handling and disposing of such materials comply with the standards prescribed, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for damages and such liability could exceed the resources of the Company. The Company is not specifically insured with respect to this liability. Although management of the Company believes that it currently complies in all material respects with applicable environmental laws and regulations, the Issuer may be required to incur significant costs to comply with environmental laws and regulations in the future. Furthermore, there can be no assurance that the operations, business or assets of the Company will not be materially adversely affected by current or future environmental laws or regulations.

**Rapid Technological Change.** The biotechnology and pharmaceutical industries are characterized by rapid and substantial technological change. There can be no assurance that developments by others will not render the Company's proposed products or technologies non-competitive, or that the Company will keep pace with technological developments. Competitors have developed or are developing technologies that could be the basis for competitive products. Some of these products have an entirely different approach or means of accomplishing the desired diagnostic or therapeutic effect as compared with products to be developed by the Company, and could be more effective and less costly than the products to be developed by the Company. In addition, alternative forms of medical treatment may be competitive with the Company's products.

**Competition.** Technological competition from pharmaceutical companies, biopharmaceutical companies and universities is intense and is expected to increase. Potential competitors of the Company have or may develop product development capabilities or financial, scientific, marketing and human resources exceeding those of the Company. Competitors may develop products before the Company develops its own products, obtain regulatory approval for such products more rapidly than the Company, or develop products which are more effective than those which the Company intends to develop. Research and development by others may render the Company's proposed technology or products obsolete or non-competitive or produce treatments or cures superior to any therapy developed or to be developed by the Company, or otherwise preferred to any therapy developed by the Company.

**Status of Healthcare Reimbursement.** The Company's ability to successfully market certain diagnostic or therapeutic products may depend in part on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Significant uncertainty exists as to whether newly approved healthcare products will qualify for reimbursement. Furthermore, challenges to the price of medical products and services are becoming more frequent. There can be no assurance that adequate third-party coverage will be available to establish price levels, which would allow the Company to realize an acceptable return on its investment in product development.

**Potential Product Liability.** Pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. Product liability insurance is costly, and availability is limited and may not be available on terms which would be acceptable to the Company, if at all. An inability to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of the Company's products. A product liability claim brought against the Company, or withdrawal of a product from the market, could have a material adverse effect upon the Company and its financial condition.

## **DIRECTORS AND OFFICERS**

Dr. George Adams, Chairman and director  
Jeffrey Bacha, director  
James Parsons, director  
Bruce Weber, director  
Dr. Philip Toleikis, President, CEO and director  
William Smethurst, Chief financial officer

### **Additional Information**

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