

**SERNOVA CORP.**  
**MANAGEMENT'S DISCUSSION AND ANALYSIS**  
**Three and Nine Months Ended July 31, 2012**

The following discussion and analysis ("MD&A") provides Management's perspective on the financial position, results of operations and cash flows of the Company on a consolidated basis for the Three and Nine Months Ended July 31, 2012 and 2011. This analysis should be read in conjunction with the Condensed Consolidated Interim Financial Statements of the Company and related notes as at and for the Three and Nine Months Ended July 31, 2012. Such Condensed Consolidated Interim Financial Statements are unaudited and have been prepared by management reflecting the adoption of International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). For all periods up to and including October 31, 2011, the Company presented its consolidated financial statements in accordance with Canadian Generally Accepted Accounting Principles ("Canadian GAAP").

Accordingly, the Company has prepared Condensed Consolidated Interim Financial Statements that comply with IFRS applicable for periods beginning on or after November 1, 2011 in accordance with the accounting policies as described in note 3 to the January 31, 2012 unaudited Condensed Consolidated Interim Financial Statements. Note 18 to the Condensed Consolidated Interim Financial Statements for the Three and Nine Months Ended July 31, 2012 and this MD&A under the heading "Transition to IFRS" explains the principal adjustments made by the Company in restating its Canadian GAAP consolidated statement of financial position and equity as at July 31, 2011, and its previously published Canadian GAAP consolidated statement of loss for the Three and Nine Months Ended July 31, 2011 to be in compliance with IFRS.

All dollar figures are in Canadian dollars unless otherwise indicated. In this report where we say "we", "us", "our", or "the Company", we mean Sernova Corp., unless otherwise indicated.

The Audit Committee and the Board of Directors have reviewed and approved the contents of the MD & A.

The information in this report is dated as of September 20, 2012

The Company's Condensed Consolidated Interim Financial Statements and MD&A for the period, and the Audited Consolidated Financial Statements and MD&A for the Year Ended October 31, 2011 are available on SEDAR.

**CAUTION REGARDING 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.

Specifically, this MD&A may contain forward-looking statements regarding:

The Company's corporate strategies and objectives  
General business and economic events

The availability of various forms of financing

The initiation and completion of clinical trials of our Cell Pouch™ with antirejection regimens and with Sertolin™ for the treatment of insulin-dependent diabetes and other potential indications;

The intention to use one or more of human donor cells, xenogeneic cells and stem cells in the treatment of chronic diseases in our Cell Pouch™;

The intention to receive regulatory approval and commercialize of our 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.

## **2012 ACTIVITIES and OVERVIEW OF TECHNOLOGY**

### **Current Financing and Development Activities 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 evaluation assessing both the safety and efficacy of the Cell Pouch™ with transplanted insulin-producing islets in patients with insulin-dependent diabetes.

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

By way of a background, 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 unawareness. These are individuals who do not receive the typical signals of hypoglycemia (low blood glucose levels) 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.

The standard current procedure for islet transplantation to treat diabetes, commonly known as the "Edmonton Protocol" involves transplanting islets directly into a blood vessel (portal vein) of the liver followed by life-long anti-rejection therapy. Here the islets lodge in the microvessels of the liver and

the surviving islets can read the sugar levels in the blood flowing past and release insulin into the bloodstream. This treatment has improved the lives of some patients with hypoglycemia unawareness.

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 patients with hypoglycemia unawareness to a much larger population of patients with diabetes.

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 microvessels grow adjacent to and into the islets, which are then nourished naturally and not bathed in blood which can result in the death, estimated to be as high as 80%, of the islets through an instant blood-mediated inflammatory response. Without the blood-mediated inflammatory response, the islets may have an improved survival potential. Use of the Cell Pouch™ would also eliminate the concern of portal vein hypertension and thrombosis associated with portal vein islet delivery and potentially reduce the cost of the procedure as the catheterization laboratory is not required for implantation of the Cell Pouch™ or islet transplantation. 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 protection of therapeutic cells rather than systemic antirejection drugs. Furthermore, the Cell Pouch™ may be an ideal environment to contain insulin-producing stem cell technologies 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 promotes cell survival and therefore could reduce the number of islets required for 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 model. This is important because it demonstrates that the Cell Pouch™ is a scalable and may be useful to treat human diabetes as well as other diseases.

For entry into clinical trials, beyond the completed preclinical safety and efficacy studies an additional series of biocompatibility studies (ISO 10993) have been conducted using product manufactured by the contract manufacturer, assessing the compatibility of the Cell Pouch™ with the body. All such testing has been completed and the Cell Pouch™ satisfied the requirements for being biocompatible in the body. These along with additional studies form the basis for which to evaluate the Cell Pouch™ in human clinical trials.

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

Using the extensive preclinical studies as a basis, the Company has 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 in part preclinical safety and efficacy results, manufacturing results and a clinical protocol were subsequently reviewed by Sernova's regulatory consultants. The appropriate regulatory documents were 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 under the renowned transplant surgeon Dr. James Shapiro is an open label, non-randomized, single arm, Phase I/II safety and efficacy study in patients with insulin-dependent diabetes undergoing allograft pancreatic islet transplantation. Patients will be implanted with the Cell Pouch™ approximately 2-12 weeks prior to transplantation of donor human islets. To prevent islet graft rejection, patients will be 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 receiving islet transplantation for the first time. This endpoint will be 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 will be measured three months post-final islet transplantation. Additional standard measures will comprise the secondary efficacy endpoint such as HbA1c, arginine-stimulated C-peptide response, and glucose response to a standard mixed meal test, etc.

In addition, the study will provide 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 will be 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 strict 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 process are relatively simple, rapid minimally invasive procedures that may be conducted on an outpatient basis under local anesthesia. 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 effective in clinical trials.

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

Beyond the clinical evaluation of the Cell Pouch™, the Company has initiated a preclinical collaboration with the University of Alberta under the direction of Dr. Shapiro. This collaboration will further seek to position the Cell Pouch™ through next generation improvements to the Edmonton Protocol to expand access to cell transplant to a much wider patient population.

### **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 currently 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 as another source of cells.

### **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 current standard of care for therapeutic cell transplantation for diabetic patients is infusing donor insulin-producing islets into the portal vein of the liver followed by the use of life-long anti-rejection therapy. The Company believes that improvement in the safety and efficacy of this procedure with its products could improve the quality of life of patients with diabetes and significantly increase the number of treatable patients. The Company is thus developing its proprietary Cell Pouch™ and Sertolin™ platform technologies using a tiered approach. The Company is first focusing on initiating human clinical trials of the Cell Pouch™ for therapeutic cell transplantation using allograft (donor human cells) with an improved antirejection protocol that has been approved by Health Canada and other regulatory jurisdictions. The Company may also initiate clinical studies in patients with chronic pancreatitis using autograft (self-cells) in those who are having their pancreas removed to alleviate intractable pain. Such patients with chronic pancreatitis would be treated with islets into the Cell Pouch™ without the need for antirejection drugs. While the company plans to advance the Sertolin™ technology, this autograft or allograft approach with currently approved antirejection therapy is expected to result in a shorter time to entry into the clinic and product approval than assessing Sertolin™ technology with porcine tissues. The Company, with input from transplantation surgeons and device engineers, has thus focused on the design, manufacture and testing of the Cell Pouch™. The Company is thus initially focused on entry of its technologies into human clinical testing and eventual marketplace with primary focus on the use of human islets using the Cell Pouch System™. The Cell Pouch™ is an implantable medical device placed under the skin in the subcutaneous space designed with chambers for therapeutic cell transplantation. Removable plugs fill the chambers while tissue and microvessels develop to the circumference of the plugs creating a natural tissue environment for cell transplantation upon removal of the plugs.

While the Cell Pouch™ is suitable for various therapeutic cell types, from a clinical perspective, the Company is focused on the use of insulin-producing islets for treatment of patients who have diabetes or who will have diabetes as a result of a medical procedure. Patients who could have diabetes as a result of a medical procedure include those with chronic pancreatitis. Patients with chronic pancreatitis may have their pancreas removed to alleviate severe chronic pain. When the pancreas is removed, the patients will become insulin-dependent diabetic because the insulin producing islets located in the pancreas are also lost. The Company proposes that the islets from the removed pancreas could be isolated and placed into the pre-implanted and vascularized Cell Pouch™. In this autograft clinical indication, no immunosuppressant drugs or Sertolin™ would be required. The Company has identified a number of clinical sites around the world where such islets are currently being infused into the portal vein of the liver. The same islets could be transplanted into the Cell Pouch™ in a clinical study to treat these patients. The Company is considering conducting a clinical study for this indication.

To further expand the clinical indications for the Company's technologies, the Cell Pouch System™ may be used in patients who are candidates for an allograft transplant as an alternative to injecting islets into the portal vein of the liver which has been hypothesized to result in a number of issues including but not limited to death of a significant number of islets due to an instant blood-mediated inflammatory reaction (IBMIR), thrombosis and portal vein hypertension among other issues. Such patients would also normally be treated for life with a cocktail of immunosuppressant drugs to prevent or reduce islet rejection. The patients with the Cell Pouch™ who have had an allograft transplant may be given either advanced antirejection therapy or could be given Sertolin™ from a human source to reduce or eliminate

the need for antirejection drugs. Due to the expectation that the Cell Pouch™ will incorporate with tissue and become vascularized, providing a more organ-like environment for the transplanted islets and avoid IBMIR associated with islets transplanted into the portal vein, it may also be possible that the device may require fewer islet cells per patient than the conventional procedure and thus may be “islet-sparing”. Furthermore, due to the proximity of the Cell Pouch™ to the skin surface, imaging of the islets and vessels may be possible providing the ability of medical personnel to monitor the health of the islets over time. Improved efficiency, safety and efficacy of islet transplantation could serve to eventually increase the number of treatable patients and thus market size for the Cell Pouch™. The Company is evaluating the Cell Pouch™ in an allograft setting with advanced antirejection therapy in a first clinical study of the Cell Pouch™ being conducted at the University of Alberta, Canada under the guidance of Dr. James Shapiro, one of the originators of the Edmonton Protocol. The Ethics Review Board at the University of Alberta has provided approval to begin the clinical study. Furthermore, Health Canada has provided clearance for the clinical evaluation of the Cell Pouch™. The Company believes this is the first assessment in humans of such a polymer device for therapeutic cell transplantation in the world.

As the Company progresses, it is also exploring the possible use of stem cells which can read glucose levels and release insulin. 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. Thus, the Company is exploring a number of options to expand its technology in the marketplace using human-derived cells, stem cells and porcine cells within the Cell Pouch System™.

In addition to the internal research and development activities, the Company is seeking collaborations with key international transplant centres that currently offer islet transplantation (known as the “**Edmonton Protocol**”) to patients suffering from insulin-dependent diabetes. The Company’s proprietary Cell Pouch™ technology, offers a potential significant technological leap forward over the Edmonton Protocol, the current standard of care where cells are injected into the portal vein of the liver followed by life-long antirejection therapy. Briefly, the Company’s technology is expected to potentially provide a safer protected environment for the islets, which could result in healthier and longer living islets, and result in a more robust and natural long-lasting insulin response, among other benefits. The use of the Cell Pouch™ may in itself provide distinct benefits to diabetic patients over the current method of injecting islets into the portal vein of the liver even using approved antirejection protocols including the potential to assess islet health through imaging. 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 Company 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 in North America with a view to establishing scientific and potential future clinical collaborations to demonstrate proof of concept and commercialize its proprietary technology. One such collaboration with the University of Illinois has been conducted and another has been announced and is under way at the University of Alberta. These collaborations may include studies to assess the various aspects of the Company’s technology as well as safety and efficacy studies, which may contribute to the data sufficient for filing an IDE or IND 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 entering the Cell Pouch™. The allogeneic transplantation of insulin producing human islets in a human clinical study will be the first human proof of the concept of cellular transplantation using the Cell Pouch™.

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 is 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 Outlook**

As outlined in the December 2011 press release, over the ensuing 12 months, the Company plans to:

- Complete contract manufacture of the Cell Pouch™ (Achieved);
- Submit regulatory documents to the University of Alberta Health Review Ethics Board (Achieved);
- Submit regulatory documents to Health Canada (Achieved);
- Gain clearance by Health Canada to initiate the Cell Pouch™ clinical study (Achieved);
- Gain University of Alberta hospital and surgical approvals, complete Investigator's Meeting and initiate screening of patients (Achieved);
- Begin enrollment of patients to assess the safety and efficacy of the Cell Pouch™ with transplanted islets in patients with diabetes (Achieved);
- Complete application for additional grants for work on local cell protector technology and for the collaboration with Dr. Shapiro to assess next generation products related to the Cell Pouch™ (ongoing)
- Seek additional collaborations with islet transplantation centres towards further clinical evaluation of the Cell Pouch™ (ongoing)
- Develop corporate collaborations to assess stem cell and other technologies in the Cell Pouch™ (ongoing); and
- Continue discussions with potential business partners towards a licensing deal (ongoing).

## **Financing and Other Activities**

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 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 biocompatibility studies, all of which were successful.

On February 16, 2012, the Company announced a non-brokered private placement of up to 19,444,444 units of the company ("Units") at a price of \$0.18 per Unit for gross proceeds of up to \$3,600,000. Each Unit will consist of one common share of the Company and one common share purchase warrant ("warrant"). Each warrant will entitle the holder to purchase one share for a period of three years, at a price of \$0.20 in the first year and at a price of \$0.35 per share for the second and third years. These funds represent a significant milestone and will enable the Company to initiate the clinical study referred to above in the second quarter of fiscal 2012.

On February 29, 2012, the Company completed the first tranche of the non-brokered private placement securing gross proceeds of \$3,491,120 and on March 30, 2012, the Company completed the second tranche of the non-brokered private placement securing gross proceeds of \$139,000.

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 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 stock option plan and are exercisable for a period of five years. Details of the options are set out in note 9 to the Condensed Consolidated Interim Financial Statements.

At the annual general meeting held April 19, 2012, Bruce Weber and 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 appointment 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 and partnerships to advance its products. The board now has the seasoned Directors with operational and transactional experience to properly govern and guide the Company.

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 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 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.

In September 2012, the Company announced that Dr. Toleikis would present at the Rodman & Renshaw Global Investment conference, providing an excellent opportunity to present 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-I diabetes.

### **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™**".

On July 26, 2007, the Company exercised its right under the Joint Venture to acquire the final one-third of the shares of Sertonex, and issued 2,315,000 common shares to Dr. David White and Mr. Justin Leushner. These common shares 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 (the "**Performance Escrow 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.

### **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 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 the 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.

Also on the Scientific Advisory Board are 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.; and 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.

### **Transition to International Financial Reporting Standards**

**IFRS and Canadian GAAP presentation in this MD & A.** The adoption of IFRS requires restatement of designated prior periods as noted in the table below. The financial information includes comparative information for quarters that have been reported using Canadian GAAP without reflecting any IFRS restatements.

### **Summary of quarterly financial results**

A summary of the quarterly net loss data for the last two complete fiscal years is as follows:

		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2010	Net loss	(448,361)	(425,609)	(478,497)	(493,904)
	Net loss per share	(\$0.01)	0.00	(\$0.01)	0.00
2011	Net loss	(569,772)	(570,284)	(423,220)	(465,670)
	Net loss per share	(\$0.01)	(\$0.01)	\$0.00	0.00
2012	Net loss	(625,833)	(677,974)	(574,489)	
	Net loss per share	(\$0.01)	(\$0.01)	0.00	

The loss for 2012 and all of 2011 has been prepared in accordance with IFRS. The loss for all of 2010 has been presented in accordance with Canadian GAAP.

## Results of Operations

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

	Three Months	Three Months	Nine Months	Nine Months
	Ended	Ended	Ended	Ended
	July 31,	July 31,	July 31,	July 31,
	2012	2011	2012	2011
	\$	\$	\$	\$
Research and development costs	388,501	317,154	1,369,301	1,208,743
General and administrative costs	200,266	105,921	533,669	359,360
Loss and comprehensive loss for the period	(574,489)	(423,220)	(1,878,296)	(1,563,276)

For the Three Months Ended July 31, 2012, the Company recorded a net loss of \$574,489 or \$0.00 per share versus a loss of \$423,220 or \$0.00 per share for the corresponding period last year, an increase of \$151,269 in the loss recorded. As a principal explanation of the increase in the loss for the Three Months Ended July 31, 2012, the non-cash stock-based compensation expense for the period was \$176,194 compared to \$36,766 in the same period in the prior year, an increase of \$139,428. In addition, the Company recorded a contribution of \$51,719 from the National Research Council in 2011 towards the costs of its product development, which amount was netted from the research and development costs, compared to nil for the same period in the current year. In addition, as explained in greater detail below the general and administrative costs (excluding stock-based compensation) increased \$17,815 for the Three Months Ended July 31, 2012 as compared to the same period in the prior year, which can be attributed to the new contract for investor relation services. Offsetting these increases, the amortization of intangible assets was \$52,849 less than the same period for the prior year.

For the Nine Months Ended July 31, 2012 the company recorded a net loss of \$1,878,296 or \$0.02 per share versus a loss of \$1,563,276 or \$0.02 per share for the corresponding period last year, an increase of \$315,020 in the loss recorded. There are a number of factors for the increase in the loss for the Nine Months Ended July 31, 2012, including a contribution of \$211,771 from the National Research Council and other parties towards the costs of its product development (which amount was netted from the research and development costs) in the prior year compared to nil for the same period in the current year. In addition, the Company incurred additional patent fees and costs of \$66,535 and investor relations fees of \$92,991 in the Nine Months Ended July 31, 2012 as compared to the same period in the prior year. While the expense related to the amortization of intangible assets was \$129,785 lower than the prior year, the non-cash share-based compensation expense was higher by \$47,901.

Further details on the research and development and the general and administrative expenses are provided below.

Research and development expenditures for the Three and Nine Months Ended July 31 were as follows:

	Three Months	Three Months	Nine Months	Nine Months	Increase
	Ended	Ended	Ended	Ended	(decrease)
	July 31,	July 31,	July 31,	July 31,	in the
	2012	2011	2012	2011	Nine Months
	\$	\$	\$	\$	\$
Salaries, supplies & contract payments	161,419	176,095	654,292	679,428	(25,136)
Amortization of property & equipment	559	541	1,677	1,690	(13)
Amortization of intangible assets	167,328	220,177	516,860	646,645	(129,785)
Share-based compensation	83,735	20,837	119,943	99,422	20,521
Patent fees and costs	31,154	24,827	132,468	65,933	66,535
Grants and tax credits	(55,694)	(125,323)	(55,939)	(284,375)	228,436
Total expense	388,501	317,154	1,369,301	1,208,743	160,558

Salaries, supplies and contract payments for the Three and Nine Months Ended July 31, 2011 included contractor payments that were partially recovered by the contribution on the completed contract with the National Research Council, while costs for the Three and Nine Months Ended July 31, 2012 are relatively stable in value, include 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.

The reduction in the amortization of the intangible assets for the Three and Nine Months Ended July 31, 2012 of \$129,785 reflects a change in the estimate of the expected life or expected pattern of consumption of future economic benefits embodied in the asset and has been accounted for by changing the amortization period and has been treated as a change in estimate effective November 1, 2011. The amortization period has been increased to 102 months from the previous estimate of 93 months.

Patent fees and costs for the Nine Months Ended July 31, 2012 were \$132,468 compared to \$65,933 for the same period in the prior year. The increase in the costs of \$66,535 reflects the costs involved in prosecution of an internally generated patent in a number of countries and the same explanation applies to the Three Months Ended July 31, 2012.

The grants and tax credits for the Three and Nine Months Ended July 31, 2012 represents the refundable provincial investment tax credits for the year ended October 31, 2011 compared to a total of \$125,333 and \$284,375 respectively for the Three and Nine Months Ended July 31, 2011. The prior year figures include \$51,719 and \$199,771 of contribution from the National Research Council for the Three and Nine Months Ended July 31, 2011 with the balance comprising refundable provincial investment and other contributions towards the costs of research and development. The program with the National Research Council was completed in September 2011.

General & administrative costs for the Three and Nine Months Ended July 31 were as follows:

	Three Months	Three Months	Nine Months	Nine Months	Increase
	Ended	Ended	Ended	Ended	(decrease)
	July 31,	July 31,	July 31,	July 31,	in the
	2012	2011	2012	2011	Nine Months
	\$	\$	\$	\$	\$
Other costs	41,106	31,449	176,014	131,631	44,383
Amortization of property & equipment	63	108	187	324	(137)
Share-based compensation	92,459	15,929	127,882	100,502	27,380
Investor relations	28,704	8,458	104,841	11,850	92,991
Consulting fees	37,934	49,977	124,745	115,053	9,692
Total expense	200,266	105,921	533,669	359,360	174,309

Consulting fees for the Nine Months Ended July 31, 2012 were \$124,745 compared to \$115,053 for the same period in the prior year, an increase of \$9,692. These fees generally relate to the provision of financial advisory services in both fiscal periods, and the increase can be attributed to additional services during the financing activities in the current fiscal year.

Other costs for the Nine Months Ended July 31, 2012 were \$176,014 compared to \$131,631 for the same period in the prior year representing an increase of \$44,383. Other operating costs for the Nine Months Ended July 31, 2012 included professional fees of \$78,857 compared to professional fees of \$45,565 for the Nine Months Ended July 31, 2011. The increased costs for the professional fees for current year of \$33,292 reflects the current research and product development activity and the requirements for advice on drafting of agreements.

The increase of \$92,991 in the investor relations charge in the Nine Months Ended July 31, 2012 is the result of retaining Russo Partners LLC in November 2011. The increase in the Three Months Ended July 31, 2012 can be attributed to the same contract.

Included in the general and administrative expenses for the Three and Nine Months Ended July 31, 2012 were \$92,459 and \$127,882 respectively of a non-cash share-based compensation expense (\$15,929 and \$100,502 for the same periods in the prior year) and the higher compensation reflects that the stock option awards for the current year that were granted in March and April of 2012.

In the Three Months Ended July 31, 2012, the other costs were \$41,106 compared to \$31,449 for the same period in the prior year, with the bulk the increase the result of higher professional fees.

No provision for an income tax recovery on either the current year or prior year losses has been recorded in the Statement of Net Loss and Comprehensive Loss due to the existence of non-capital losses of approximately \$4,079,000 in Canada and \$3,500,000 operating losses in the United States as at October 31, 2011 and it is not probable that future taxable profits will be available against which the accumulated tax losses can be utilized. In addition, the Company has significant Scientific Research and Experimental Development (SRED) pools of \$2,495,000. The ultimate realization of future tax assets is dependent upon the generation of future taxable income.

## CASH FLOWS

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

	Nine Months	Nine Months
	Ended	Ended
	July 31,	July 31,
	2012	2011
	\$	\$
Cash used by operating activities	(1,177,074)	(725,431)
Cash used by investing activities	(3,402,290)	(1,478,605)
Cash provided by financing activities	4,432,892	1,522,932

Cash flows used by operating activities for the Nine Months Ended July 31, 2012 were \$1,177,074 compared with cash flows used by operating activities of \$725,431 for the same period in the prior year, representing an additional use of cash resources of \$451,643 or 62% in the cash used by such operations. This change year over year is the result principally of increased patent fees and patent costs, a reduction on the contributions and other credits received in the respective periods, and increased investor relation costs, with a more detailed explanation provided under the operating section.

As part of the operating activities, cash used by working capital balances for the Nine Months Ended July 31, 2012 was \$38,446 compared with cash provided by working capital of \$43,987 for the prior year. The principal change in the Nine Months Ended July 31, 2012 arose principally from advances made for the clinical trial. In the prior year, the change in working capital can be attributed to the collection of the amounts receivable under the contribution from the National Research Council, the collection of the sales tax and investment tax credit receivable, and a reduction in accounts payable and accrued liabilities in the period as significant invoices from suppliers related to the National Research Council sponsored project was paid.

With respect to investing activities, the principal uses of cash included cash invested in patent licences which amounted to \$38,592 for the Nine Months Ended July 31, 2012 compared to \$77,890 for the same period in the prior year. During the Nine Months Ended July 31, 2012, net short-term investments of \$3,361,911 were made by the Company compared to an investment of \$1,398,465 in the Nine Months Ended July 31, 2011. Acquisition of property and equipment amounted to \$1,787 for the Nine Months Ended July 31, 2012 compared to \$2,250 for the same period in the prior year.

Regarding financing activities, the Company received \$4,432,892 in net proceeds from the issuance of share capital, warrants and options in the Nine Months Ended July 31, 2012 compared to \$1,522,932 for the same period in the prior year. Full details of the financing activities and changes in the warrants and options for the period are described in note 9 to the Condensed Consolidated Interim Financial Statements.

Accordingly, as a result of all these activities, cash resources decreased by \$146,472 for the Nine Months Ended July 31, 2012 compared to cash resources that were reduced by a net \$681,104 for the Nine Months Ended July 31, 2011.

## **LIQUIDITY AND CAPITAL RESOURCES**

In the Nine Months Ended July 31, 2012, the Company has experienced an increase in working capital of \$3,279,816 compared to an increase of \$719,699 for the Nine Months Ended July 31, 2011, and accordingly as at July 31, 2012 had working capital of \$4,752,856. Management will continue to explore opportunities to raise additional capital and other funds, and to find collaborative partners for the commercialization of its technologies.

In February and March 2012 the Company closed a non-brokered private placement in two tranches for net proceeds of \$3,584,835 which funds will be used to fund ongoing development of Sernova's proprietary Cell Pouch™ and, in particular, to fund the ongoing first in man clinical trial for patients with diabetes receiving an islet transplant and for general working capital.

In the Nine Months Ended July 31, 2012, the company received gross proceeds of \$848,057 from the exercise of share purchase warrants, finder's warrants and stock options.

There are no significant commitments for the acquisition of property and equipment. Management will manage the investing activities related to patent licences and in the Nine Months Ended July 31, 2012 invested \$39,542 but anticipates that the cost related to the prosecution of the patent portfolio will approximate \$140,000 US dollars over the next fiscal year as the Company files patent applications for its therapeutic cell device in various countries.

Accounts payable and accrued liabilities are all current and management does not expect any unusual trends for the balance of the year.

As at July 31, 2012, the Company had cash and short-term investments of \$4,760,430 compared to \$1,518,110 as at October 31, 2011. The Company may continue to face significant uncertainty relating to liquidity and intends to continue to search for additional sources of capital and working funds for research and administrative costs and to fund the planned projects, and/or to actively search for collaborative partners for various projects.

## **GOING CONCERN**

These condensed consolidated interim financial statements have been prepared on a going-concern basis, which assumes that the Company will be able to realize assets and discharge liabilities in the normal course of business. The Company has incurred losses since inception and the ability of the Company to continue as a going-concern depends upon its ability to develop and sustain profitable operations and to continue to raise adequate financing. The Company reported a consolidated net loss of \$1,878,296 for the Nine Months Ended July 31, 2012 and has working capital of \$4,752,856 and an accumulated deficit of \$21,354,915 as at July 31, 2012. Management is actively targeting sources of additional financing and collaborative partners which would assure continuation of the Company's operations and research and product development programs. In order for the Company to meet its liabilities as they come due and to continue its operations, the Company is solely dependent upon its ability to generate such financing. While the Company has been successful in obtaining the required financing in the past there can be no assurance that the Company will be able to continue to raise funds. These material uncertainties may cast significant doubt about the Company's ability to continue as a going-concern. These condensed consolidated interim financial statements do not include adjustments to the carrying value and classification of assets and liabilities that might be necessary should the Company be unable to continue as a going-concern and such adjustments could be material.

Selected financial data with respect to the balance sheet is as follows:

	<b>July 31,</b>	<b>October 31,</b>
	<b>2012</b>	<b>2011</b>
	<b>\$</b>	<b>\$</b>
Cash & short-term investments	4,760,430	1,518,110
Total assets	6,789,337	3,977,391
Current liabilities	128,592	119,067
Share capital & warrants	25,410,039	20,949,181
Deficit	(21,354,915)	(19,476,619)

Total assets as at July 31, 2012 were \$6,789,337 compared with \$3,977,391 at the end of the Company's last year end, representing an increase of 71% or \$2,811,946. Substantially all of the increase is accounted for by the additional cash resources provided by financing activities offset by the cash resources required to meet research and development and general and administrative expenses in the period, and the amortization of the intangible assets.

Total current assets of \$4,881,448 have increased by \$3,289,341 from the balance of \$1,592,107 as at October 31, 2011, and reflect the additional cash resources in the period. Accounts receivable balances remain relatively stable and the increase in prepaid expenses can be attributed to advances for the clinical trial which commenced in the current quarter.

The net carrying value of intangible assets as at July 31, 2012 declined to \$1,901,468 from a net carrying value of \$2,378,786 as at the end of the prior year. Additions in the Nine Months Ended July 31, 2012 amounted to \$39,542 (\$77,890 in the prior year) and amortization of \$516,860 for the same period accounted for the decrease in net carrying value. Amortization in the Nine Months Ended July 31, 2011 amounted to \$646,645.

Current liabilities were \$128,592 at the April 30, 2012 compared to \$119,067 as at October 31, 2011, an increase of \$9,525. The modest increase is the result of timing of receipt and settlement of invoices for services, 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 July 31, 2012 will be settled in the current fiscal year.

In February 2012, the Company completed the first tranche of a non-brokered private placement of 19,395,100 units of the Company at a price of \$0.18 per unit for gross proceeds of \$3,491,118. Each unit consists of one common share of the Company and one common share purchase warrant. Each whole warrant entitles the holder to purchase one additional common share for a period of three years, at a price of \$0.20 per share in the first year and at a price of \$0.35 per share in the second and third years. The warrants were ascribed a value of \$484,877 representing the difference between the issue price of the Unit and the fair market value of the shares at that time received as part of the offering.

In March 2012, the Company completed the second tranche of a non-brokered private placement of 772,222 units of the Company at a price of \$0.18 per unit for gross proceeds of \$139,000. Each unit consists of one common share of the Company and one common share purchase warrant. Each warrant

entitles the holder to purchase one additional common share for a period of three years, at a price of \$0.20 per share in the first year and at a price of \$0.35 per share in the second and third years. The warrants were ascribed a value of \$38,611 representing the difference between the issue price of the Unit and the fair market value of the shares at that time received as part of the offering.

The Company paid no finders' fees on the private placements in February and March 2012 but incurred other closing costs of \$39,283.

During the Nine Months Ended July 31, 2012, 4,005,814 warrants were exercised at an exercise price of \$0.20 per share together with 69,483 finder's warrants at an exercise price of \$0.15 per share for gross proceeds of \$811,582. A balance of 3,101,419 warrants expired in the Nine Months Ended July 31, 2012.

During the Nine Months Ended July 31, 2012, the Company granted 4,207,918 stock options with a weighted average exercise price of \$0.17 per share, with expiry dates ranging from March 2014 to April 2017. For the purposes of determining the share-based compensation the weighted average grant-date fair value of the stock options granted during the Nine Months Ended July 31, 2012 was \$0.10 (2011-N/A).

During the Nine Months Ended July 31, 2012, 273,750 stock options were exercised at a weighted average price of \$0.13 per share for gross proceeds of \$36,475. No stock options were exercised in the same period for the prior year.

Details of the warrants and stock options are detailed in Note 9 to the Condensed Consolidated Interim Financial Statements.

## **CONTRACTUAL OBLIGATIONS**

The Company has the following contractual obligations as at September 27, 2012 which are consistent with those reflected in the Company's audited Consolidated Financial Statements as at October 31, 2011.

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 allows for interim analysis at different points during the study. For each patient, while the initial primary and secondary endpoints will be reached relatively early in the study, the patients will 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 \$1,500,000 to \$2,000,000 and the commitment will be impacted by such factors as the rate of enrollment, the province in which is the patient resides and the specifics of patient insurance.

The Company has exclusive rights to use certain patents and technologies utilized in the fertilite-OV business. Under the agreement, the Company is required to pay a royalty of 2% of cumulative royalties in excess of \$1,500,000 to a maximum lifetime royalty of \$570,000. No royalties have been paid to date.

The Company has a monthly commitment of \$2,400 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 \$60,000 USD in fees to maintain its patent portfolio in good standing for the year ending October 31, 2012. It is anticipated that similar payments will be required subsequent years.

## **OFF-BALANCE SHEET ARRANGEMENTS**

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

## **TRANSITION TO IFRS**

The Condensed Consolidated Interim Financial Statements for the Three and Nine Months Ended July 31, 2012 are the third quarterly consolidated financial statements that comply with International Financial Reporting Standards (IFRS) as expected to be in effect as at October 31, 2012.

The Company's IFRS consolidated financial report for the year ending October 31, 2012 must use the standards in effect on that date, and therefore this Condensed Consolidated Interim Financial Statement has been prepared using the standards that are expected to be effective at October 31, 2012. However, the Company's IFRS accounting policies will only be finalized when the first annual IFRS financial report is prepared for the year ending October 31, 2012. Therefore, certain accounting policies that management currently expects to follow under IFRS may not be adopted and the application of such policies to certain transactions for circumstances may be modified. As a result, the Company's Condensed Consolidated Interim Financial Statements for the Three and Nine Months Ended July 31, 2012 are subject to change.

The Condensed Consolidated Interim Financial Statements for the Three and Nine Months Ended July 31, 2012 provides the following reconciliations from Canadian GAAP to IFRS for:

Consolidated statement of financial position, including equity as at July 31, 2011

Consolidated statement of net loss and comprehensive loss for the Three and Nine Months Ended July 31, 2011

The transition from Canadian GAAP to IFRS has not had a material impact on the statement of cash flows and the reconciling items between Canadian GAAP and IFRS presentation have no effect on the cash flows generated.

IFRS 1, First-time Adoption of International Financial Reporting Standards sets forth guidance for the initial adoption of IFRS. Under IFRS 1 the standards are applied retroactively at the transitional statement of financial position date with all adjustments to assets and liabilities taken to retained earnings unless certain exemptions are applied.

In preparing these Condensed Consolidated Interim Financial Statements in accordance with IFRS 1, First time adoption of International Financial Reporting Standards, the Company has applied the mandatory exemptions of IFRS to its opening statement of financial position as at November 1, 2010, as set out in the Condensed Consolidated Interim Financial Statements for the Three Months Ended January 31, 2012.

In preparing its opening IFRS statement of financial position, the company has adjusted amounts reported previously in the consolidated financial statements prepared in accordance with Canadian generally accepted accounting principles ("GAAP"). An explanation of how the transition from Canadian GAAP to IFRS has affected the Company's financial position and financial performance as at and for the Three and Nine months Ended July 31, 2011 is set out in note 18 of the Condensed Consolidated Interim Financial Statements.

The following key adjustments have been recorded:

### **Presentation of statement of loss and comprehensive loss**

Under Canadian GAAP, the statement of loss and comprehensive loss was presented using a combination of function and nature of expenses. The Company has elected to present its items in the

consolidated statement of loss and comprehensive loss by function under IFRS. Depreciation and amortization expense related to property and equipment and intangible assets, and share-based compensation has been allocated to the related function. Certain other operating expenses were also reclassified from administrative expenses to research and development to better reflect their function.

### **Share-based compensation**

Under Canadian GAAP, awards with graded vesting provisions are treated as a single award for both measurement and recognition purposes. IFRS requires such awards to be treated as a series of individual awards, with compensation measured and recognized separately for each tranche of options within a grant that has different vesting dates.

Under Canadian GAAP, compensation is recognized assuming all options will vest and adjusted as forfeitures occur. IFRS 2 requires an estimate of forfeitures to be reflected in the amount of compensation and is revised for actual forfeitures in subsequent periods. Based on the history of the Company's stock options, the forfeiture rate was estimated to be zero percent and there were no adjustments recognized related to the forfeiture rates.

As at November 1, 2010 the combined effect of these differences was \$38,330 resulting in an increase to the deficit and a corresponding increase to contributed surplus as at this date. A decrease of \$17,488 for the Three Months and an increase of \$34,350 for the Nine Months Ended July 31, 2011 were recorded to the share-based compensation expense for the combined effect of these differences with a corresponding adjustment to contributed surplus.

### **Reclassification of short-term investments**

Under IFRS certain corresponding figures under Canadian GAAP such as the disclosure of warrants, as at July 31, 2011 have been reclassified to conform to the new presentation under IFRS.

The Company has reclassified short-term investments of \$1,401,472 which are transitional or current in nature, with a maturity greater than three months from cash to short-term investments as at July 31, 2011 for the purposes of presentation under Canadian GAAP. These interest bearing deposits have certain terms and conditions that differentiate the asset from cash and accordingly these assets are disclosed separately.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

The preparation of the Condensed Consolidated Interim Financial Statements in accordance with International Financial Reporting Standards 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.

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 Condensed Consolidated Interim Financial Statements relate to the following:

### *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 when the related expenditures are incurred. 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 9 of the Condensed Consolidated Interim Financial Statements 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.

## **New Standards and Interpretations not yet effective**

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

Certain pronouncements were issued by the IASB or International Financial Reporting Interpretation Committee that are mandatory for annual periods beginning after January 1, 2011 or later periods. Many of these updates are not applicable or are inconsequential to the Company and have been excluded from the discussion below. The remaining pronouncements are being assessed to determine their impact on the Company's results and financial position.

### *IAS 12 Income Taxes*

In December 2010, the IASB amended IAS 12 for the recovery of underlying assets measured at fair value and the impact on deferred taxes. The amendments provide a solution to the problem of assessing whether recovery would be through use or through sale when the asset is measured at fair value under IAS 40 *Investment Property*, by adding the presumption that the recovery would normally be through sale. The amendment also incorporates the remaining guidance in SIC-21 *Income Taxes – Recovery of revalued Non-depreciable Assets*, as SIC-21 has been withdrawn. The effective date of the amendment is for annual periods beginning on or after January 1, 2012. The Company does not expect the amendment to have a material impact on the financial statements.

### *IFRS 7, Financial Instruments: Disclosures - Enhanced Derecognition Disclosure Requirements*

The amendment requires additional disclosure about financial assets that have been transferred but not derecognized to enable the user of the Company's financial statements to understand the relationship with those assets that have not been derecognized and their associated liabilities. In addition, the amendment requires disclosures about continuing involvement in derecognized assets to enable the user to evaluate the nature of, and risks associated with, the Company's continuing involvement in those derecognized assets. The amendment becomes effective for annual periods beginning on or after January 1, 2012. The amendment affects disclosure only and the Company does not expect the amendments to have a material impact on the financial statements because of the nature of the Company's operations and types of financial assets that it holds.

### *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.

## **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 Nine Months Ended July 31, 2012, 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.

## **FINANCIAL INSTRUMENTS**

The Company's financial instruments consist of cash, short-term investments, trade and other receivables and accounts payable and accrued liabilities. Unless otherwise noted, it is management's opinion that the Company is not exposed to significant interest or credit risks arising from these financial instruments. The fair value of these financial instruments approximates their carrying value, unless otherwise noted. The Company is not subject to significant financial risk arising from fluctuations in foreign currency exchange rates. The Company does not use any derivative instruments to reduce its exposure to fluctuations in foreign currency exchange rates.

## **FINANCIAL RISK MANAGEMENT**

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 approximately \$53,000 of these assets and \$14,000 of its 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 \$2,020.

## **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 July 31, 2012 the Company has approximately \$4,575,000 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 \$45,750 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 July 31, 2012 the Company had cash and short-term investments of \$4,760,430 to settle current liabilities of \$128,592. All of the Company's financial liabilities are subject to normal trade terms.

Financing strategies to manage this risk include resorting to the capital markets through the issuance of equity.

## **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.

The following transactions in which the directors had an interest occurred in the Three and Nine Months Ended July 31:

	Three	Three	Nine	Nine
	Months	Months	Months	Months
	Ended	Ended	Ended	Ended
	July 31,	July 31,	July 31,	July 31,
	2012	2011	2012	2011
	\$	\$	\$	\$
Consulting fees	0	0	0	0
Director fees	0	0	0	0
Share-based compensation	72,868	8,312	82,946	54,167
<b>Total expense</b>	<b>72,868</b>	<b>8,312</b>	<b>82,946</b>	<b>54,167</b>

Compensation for key management personnel of the company other than directors for the Three and Nine Months Ended July 31 is as follows:

	Three	Three	Nine	Nine
	Months	Months	Months	Months
	Ended	Ended	Ended	Ended
	July 31,	July 31,	July 31,	July 31,
	2012	2011	2012	2011
	\$	\$	\$	\$
Salaries and fees	79,125	70,625	226,625	198,125
Benefits	8,791	8,539	27,394	28,881
Share-based compensation	46,680	15,014	65,501	72,453
<b>Total expense</b>	<b>134,596</b>	<b>94,178</b>	<b>319,520</b>	<b>299,459</b>

Key management personnel control 2.4% of the issued common shares of the Company as at July 31, 2012.

During the Three and Nine Months Ended July 31, 2012 the Company paid \$19,875 and \$57,375 (2011- \$18,750 and \$55,125) in consulting fees for the services of the Chief Financial Officer, paid to a company controlled by the officer.

One of the Company's directors participated in the November 10, 2010 private placement purchasing 14,998 Units at \$0.15 per Unit.

The Company's President and CEO, and one of the directors both participated in the June 23, 2011 private placement purchasing 78,947 and 85,000 Units respectively at \$0.19 per Unit.

**PROPOSED TRANSACTIONS**

There is no proposed asset or business acquisition or disposition, or transaction that the Company's Board of Directors has decided to proceed with, or that senior management believes will be probably confirmed by the Board of Directors.

## **DISCLOSURE OF OUTSTANDING SHARE DATA**

As at date of this report, the Company has 119,623,636 common shares issued and outstanding.

The Company had a total of 8,001,376 outstanding stock options outstanding as at July 31, 2012. The details of the number of such options, the exercise price and the remaining contractual life are outlined in Note 9 to the Condensed Consolidated Interim Financial Statements. Of this total, 4,921,311 are exercisable as at July 31, 2012.

Details of the stock options outstanding are as follows:

	Number of	Exercise	Expiry
	Options	Price	Date
	130,000	\$0.30	March 13, 2013
	134,038	\$0.19	June 30, 2013
	50,000	\$0.12	October 15, 2013
	208,880	\$0.18	March 6, 2014
	700,000	\$0.10	April 28, 2014
	280,750	\$0.14	June 8, 2014
	471,875	\$0.14	June 8, 2014
	400,000	\$0.12	September 5, 2015
	250,000	\$0.20	October 28, 2015
	1,510,833	\$0.15	October 28, 2015
	670,000	\$0.14	March 6, 2017
	330,000	\$0.18	March 6, 2017
	2,865,000	\$0.18	April 2017
<b>Total</b>	<b>8,001,376</b>		

The Company has 31,099,275 common share purchase warrants outstanding as at September 20, 2012.

The details of the warrants outstanding are as follows:

	Number of	Exercise	Expiry
	Warrants	Price	Date
	1,900,000	\$0.20	October 18, 2012
	37,333	\$0.20	October 18, 2012
	1,433,334	\$0.20	November 3, 2012
	21,000	\$0.20	November 3, 2012
	700,000	\$0.20	December 5, 2012
	195,950	\$0.19	December 24, 2012
	90,410	\$0.19	March 1, 2013
	5,043,914	\$0.35	June 24, 2013
	1,510,002	\$0.35	September 1, 2013
	19,395,110	\$0.20	February 28, 2013
		then at \$0.35	February 28, 2015
	772,222	\$0.20	March 30, 2013
		then at \$0.35	March 30, 2015
	<u>31,099,275</u>		

## **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 a large number of 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 labelling.

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.