## SERNOVA CORP. MANAGEMENT'S DISCUSSION AND ANALYSIS Fiscal Year Ended October 31, 2013

#### **INTRODUCTION**

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

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

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

#### FORWARD-LOOKING STATEMENTS

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

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

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

- The Company's corporate strategies and objectives;
- General business and economic events;
- The availability of various forms of financing;
- The initiation and completion of clinical trials of our Cell Pouch<sup>TM</sup> for the treatment of insulindependent diabetes and other diseases;
- The intention to protect therapeutic cells within the Cell Pouch<sup>TM</sup> from immune attack using either systemic antirejection regimens and/or local immune protection such as Sertolin<sup>TM</sup> or a combination thereof:
- The intention to use human donor cells, xenogeneic cells and stem cells in our Cell Pouch™ for the potential treatment of chronic diseases;
- The intention to receive regulatory approval and commercialize the Cell Pouch<sup>TM</sup> 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 secure academic and industrial collaborations and to develop and implement partnering strategies; and,
- Intentions regarding the protection of Sernova's intellectual property;

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

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

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

#### **ABOUT SERNOVA**

Sernova Corp. is a Canadian-based regenerative medicine company, focused on commercializing the proprietary Cell Pouch<sup>TM</sup>, a scalable, implantable, medical device for the transplantation and survival of therapeutic cells, which then release proteins and/or hormones for the long-term treatment of a number of serious, chronic, debilitating diseases such as diabetes and haemophilia. Our patented Sertolin<sup>TM</sup> technology is being developed to create an immune privileged environment and protect the Cell Pouch<sup>TM</sup> transplant from rejection. Our initial studies have focused on the treatment of insulindependent diabetes through the transplantation of pancreatic islets, which control blood glucose levels. To date, we have successfully transplanted donor islets in our Cell Pouch<sup>TM</sup> to treat insulin-dependent diabetes in multiple animal models, and a clinical trial for the treatment of human subjects with diabetes receiving an islet transplant, protected by the standard of care antirejection drug regimen is underway in Canada at the University of Alberta with Dr. James Shapiro as principal investigator.

#### Research and Development Update for the Year Ending October 31, 2013

Sernova has been a development stage company since inception. Our research and development efforts are focused principally on the development of the Cell Pouch<sup>TM</sup>, our medical device for transplantation and treatment of chronic diseases, and on local immune protection technologies such as Sertolin<sup>TM</sup>. We have not been profitable since inception, and we expect to continue to incur substantial losses as we continue our research and development efforts. We do not expect to realize material revenues until, if and when, our medical technologies become commercially viable.

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

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

### $Cell\ Pouch^{TM}\ Clinical\ Development\ Program$

Sernova's lead program is the clinical development of the Cell Pouch<sup>TM</sup> for treatment of patients with insulin-dependent diabetes. In August 2012, the Company and the University of Alberta announced the treatment of the first patient with insulin-producing islets transplanted into the Cell Pouch<sup>TM</sup>. Dr. James Shapiro, pioneer of the Edmonton Protocol, and his team at the University of Alberta are conducting this human clinical study to assess the safety and efficacy of the Cell Pouch<sup>TM</sup> with donor islets, in up to 20 insulin-dependent diabetic subjects who are receiving islet transplantation.

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

We believe our Cell Pouch<sup>TM</sup> will offer significant benefits over the Edmonton Protocol, the current standard-of care, to restore the body's insulin production and glucose control in insulin-dependent diabetic patients. The Cell Pouch<sup>TM</sup> was designed to take into consideration the biological requirements of therapeutic cells. A tissue matrix rich in microvessels forms within the Cell Pouch<sup>TM</sup> when implanted

subcutaneously prior to islet transplantation, providing an ideal environment for placement of therapeutic cells, including insulin-producing islets. We have demonstrated in a series of ISO10993 biocompatibility studies and multiple animal studies that the Cell Pouch<sup>TM</sup> is biocompatible and safe. Long-term studies in multiple animal models have demonstrated that the islets become well-supported with microvessels and even infiltrated with microvessels as in their natural pancreatic environment following islet transplantation into the Cell Pouch<sup>TM</sup>.

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

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

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

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

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

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

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

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

The results showed device-tissue biocompatibility, tissue and microvessel development within the Cell Pouch<sup>TM</sup>, proof of islet cell survival with microvessels at and within islets, and the presence of islet insulin, glucagon, and somatostatin. There was also no evidence of immune attack of the islets within the Cell Pouch<sup>TM</sup>. Based on these encouraging initial results, which confirm the positive results of our multiple preclinical models, we believe the Cell Pouch<sup>TM</sup> provides a safe and suitable environment for therapeutic cells, and the clinical study is ongoing.

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

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

#### Haemophilia

As part of our strategy to develop the Cell Pouch<sup>TM</sup> for different therapeutic indications, in September, 2013 we announced a material transfer agreement with Medicyte GmbH to jointly evaluate the use of Medicyte's upcyte® cell technology in Sernova's Cell Pouch<sup>TM</sup> for the treatment of patients with haemophilia A. Both parties have also entered into a non-binding term sheet describing the general terms of a collaboration, outlining the pre-clinical and clinical development of the novel Cell Pouch<sup>TM</sup>/upcyte® product for the treatment of haemophilia A. The parties intend to complete negotiations of a definitive agreement while initial proof of concept research is being carried out under the terms of the material transfer agreement. Positive results in the proof of concept studies are anticipated to lead to initiation of a formal development program towards entry into clinical trials.

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

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

On March 25, 2013, we announced our award of a third non-repayable financial contribution of up to \$254,300 from the National Research Council of Canada for the optimization of our Sertolin<sup>TM</sup> technology within our Cell Pouch<sup>TM</sup> to treat chronic diseases. This financial contribution is being used for a series of studies to optimize the safety and efficacy of Sertolin<sup>TM</sup> with insulin-producing islets in the Cell Pouch<sup>TM</sup>. Data derived from this research is anticipated to be used in a regulatory submission for potential future testing in human clinical trials.

#### **Alternative Sources of Cells**

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

#### **Manufacturing**

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

#### **Intellectual Property**

At October 31, 2013 our patent portfolio consisted of over 22 issued and pending patents in five families covering our enabling platforms. We strive to receive broad claims in our patents, to have exclusivity using our Cell Pouch<sup>TM</sup> and Sertolin<sup>TM</sup> in combination with a wide range of therapeutic cell types and to treat a number of chronic diseases. We intend to continue to expand our patent portfolio through proprietary internal inventions as well as strategic in-licensing, to maximize the commercial potential for our platform technology.

The following patents issued during the year:

In June 2013, the Australian Patent Office issued a Notice of Patent Allowance for a patent entitled "Adult sertoli cells and uses thereof".

In July 2013, the Japan Patent Office issued a Notice of Patent Allowance for a patent entitled "The production of a biological factor and creation of an immunologically privileged environment using genetically altered Sertoli cells."

In December 2013, the Canadian Intellectual Property Office issued a Notice of Allowance for a patent entitled "Compositions containing sertoli cells and myoid cells and use thereof in cellular transplants."

#### **Financing Activity**

On February 19, 2013 we completed a non-brokered private placement for gross proceeds of \$2,000,000. The offering consisted of 10,000,000 units sold at a price of \$0.20 per unit. Each unit consisted of one common share and one common share purchase warrant, with each warrant entitling the holder to purchase one common share of the Company for a period of 36 months from closing of the offering at a price of \$0.35 per share for the first 24 months and at a price of \$0.40 per share for the last 12 months. The warrants were ascribed a value of \$250,000 representing the difference between the issue price of the unit and the fair market value of the shares at that time received as part of the offering.

#### Research and Development Outlook for 2014

Our planned development activities will continue to focus on the principal activities described under "Research and Development Activities for the year ended October 31, 2013." Our product development program for 2014 includes the following:

- Anticipated interim results from a patient cohort in the Cell Pouch<sup>TM</sup> diabetes clinical trial with donor islets in patients with diabetes receiving an islet transplant;
- Anticipated preclinical results from our studies of local immune protection within the Cell Pouch<sup>TM</sup>, based on the NRC-IRAP contribution agreement;

- Anticipated preclinical proof of concept results from the collaborative agreement with Medicyte GMBH evaluating feasibility of the use of Medicyte's upcyte® cells in Sernova's Cell Pouch<sup>TM</sup> for the treatment of patients with haemophilia A;
- Anticipated regulatory submission to initiate a clinical trial to assess the safety and efficacy of the Cell Pouch<sup>TM</sup> in another clinical indication; and,
- Ongoing assessment of complementary immune protection technologies and alternative sources of cells, which may result in additional academic and /or corporate relationships to further develop and expand Sernova's technologies towards commercialization.

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

#### **RESULTS OF OPERATIONS**

#### **Selected Annual Information**

Selected financial information from the statement of net loss and comprehensive loss for the years ended October 31, 2013, 2012 and 2011 follows:

(all amounts in Cdn\$)	Three Months Ended October 31, 2013	Three Months Ended October 31, 2012	Year Ended October 31, 2013	Year Ended October 31, 2012	Year Ended October 31, 2011
Research and development costs	433,743	550,110	1,574,614	1,919,411	1,551,207
General and administrative costs	121,079	150,305	490,522	683,974	492,161
Loss and comprehensive loss for the period	537,443	689,732	2,002,921	2,568,028	2,028,278

For the year ended October 31, 2013, the Company recorded a net loss of \$2,002,921 or \$0.02 per share versus a loss of \$2,568,028 or \$0.02 per share for the corresponding period last year, a decrease of \$565,107. Changes in research and development expenditures and general and administrative costs during the year are reviewed in detail below.

For the three months ended October 31, 2013, the Company recorded a loss of \$537,443 compared to \$689,732 for the same period in the prior year. The decrease in the current year loss of \$152,289 was attributable in large part to an increase in contributions and tax credits partially offset by research and development costs, as described more fully below.

#### **Research and Development Expenses**

Research and development expenditures for the years ended October 31, 2013 and 2012 were as follows and reflected an overall decrease of \$344,797 or 18% year over year:

	Three Months	Three Months	Year Ended	Year Ended
	Ended	Ended	October 31,	October 31,
(all amounts in Cdn\$)	October 31,	October 31,	2013	2012
	2013	2012		
Salaries, supplies and contract payments	296,075	296,412	943,249	950,704
Patent fees and costs	16,363	24,588	141,590	157,056
Amortization of equipment	1,147	784	2,484	2,461
Amortization of intangible assets	184,280	179,371	710,503	696,231
Share-based compensation	8,728	48,955	74,401	168,898
Contributions and tax credits	(72,850)	-	(297,613)	(55,939)
Total research and development expense	433,743	550,110	1,574,614	1,919,411

The reduction in overall research and development expenses year over year was attributable mainly to an increase of \$241,674 in contributions and tax credits for the year ended October 31, 2013. We were awarded our third non-repayable financial contribution from the National Research Council of Canada Industrial Research Assistance Program ("NRC/IRAP"), this one to optimize our Sertolin<sup>TM</sup> technology within the Cell Pouch<sup>TM</sup> to treat chronic disease. We received \$211,500 of the grant during the fiscal year, and the balance of \$42,800 remains to be claimed in the year ending October 31, 2014. The remaining contributions and tax credits during the year are comparable with the prior year.

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

Share-based compensation expense decreased by \$94,497 in the year ended October 31, 2013 to \$74,401 due to the award of fewer stock options during the year.

Research and development expenditures for the three months ended October 31, 2013 decreased by \$116,367 compared to the same period in the prior year, due in large part to the receipt of the NRC/IRAP award.

#### **General and administrative expenses**

General and administrative costs for the years ended October 31, 2013 and 2012 were as follows and reflected a decrease of \$193,452 or 28% year over year:

(all amounts in Cdu\$)	Three Months Ended	Three Months Ended	Year Ended October 31,	Year Ended October 31,
(all amounts in Cdn\$)	October 31,	October 31,	2013	2012
	2013	2012		
Other costs	34,589	53,016	200,845	229,030
Investor relations	41,879	23,653	127,314	128,494

Consulting fees	39,463	24,829	117,890	149,574	
Depreciation of equipment and furniture	127	86	276	273	
Share-based compensation	5,021	48,721	44,197	176,603	
Total general and administrative expense	121.079	150,305	490,522	683,974	

The reduction in general and administrative expenses for the year ended October 31, 2013 was due, in part, to a decrease in consulting fees of \$31,684 or 21%. These fees generally relate to the provision of financial advisory services, and we carried out one financing this year compared to two in the prior year.

The decrease in other general and administrative expenses for the year ended October 31, 2013 of \$28,185 or 12% was attributable to reduced professional fees in connection with the one financing carried out during the year compared to two in the prior year. The decrease in share-based compensation of \$132,406 or 75% from October 31, 2012 to October 31, 2013 is a result of the grant of fewer options during the year.

General and administrative expenses for the three months ended October 31, 2013 declined by \$29,226 or 19% from the prior year's fourth quarter. This decrease was driven by reduced professional fees and share-based compensation, partially offset by increases in investor relations and consulting fees as described above. We believe that investor relations are critical for the Company to continue to be able to access capital and we outsource this work to specialized firms.

#### **Finance Income**

Finance income, representing mainly interest income earned on the Company's term deposits, was \$63,795 during the current year, compared to \$39,311 for the prior year. This increase of \$24,484 or 62% was due to the larger average holdings of cash and short-term investments resulting from the additional capital secured in the current year through completion of a financing and the exercise of warrants.

#### **Income Taxes**

No provision for an income tax recovery on either the current year or prior year losses has been recorded due to the existence of non-capital losses of approximately \$9,878,000 as at October 31, 2013 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 \$3,632,000. The ultimate realization of future tax assets is dependent upon the generation of future taxable income.

The basic and diluted loss per common share remained at \$0.02 per share.

#### **SUMMARY OF QUARTERLY RESULTS**

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

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

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

#### LIQUIDITY AND CAPITAL RESOURCES

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

#### **Liquidity**

Statement of Financial Position

As at October 31, 2013 and 2012 our cash and short-term investments and working capital positions were as follows:

	October 31,	October 31,	October 31,
	2013	2012	2011
Cash and short-term investments	\$4,975,906	\$4,359,721	\$1,518,110
Total assets	6,243,771	6,202,639	3,977,391
Current liabilities	225,148	133,950	119,067
Share capital and warrants	27,244,296	25,410,039	20,949,181
Deficit	(24,047,568)	(22,044,647)	(19,476,619)

As at October 31, 2013, the Company had cash and short term investments of \$4,975,906 compared to \$4,359,721 at the prior year end date. Management believes working capital is sufficient to meet the cost of our research and development programs for at least the next twelve months. We may face significant uncertainty related to long-term liquidity and we intend to continue to search for additional sources of capital to fund our programs and to actively search for collaboration partners.

Total current assets at October 31, 2013 were \$5,158,345, an increase of \$701,836 from the balance of \$4,456,509 at October 31, 2012, reflecting net proceeds from the issue of common shares, net of resources used mainly to finance operations and investments in intangible assets.

We invested \$44,284 in the acquisition of patent rights during the year ended October 31, 2013, compared to \$51,117 for the previous year. During the year ended October 31, 2013 we invested \$141,590 in internally generated patent development, inclusive of amounts capitalized compared to \$157,056 in the prior year. We will continue to manage the patent portfolio and anticipate continuing expenditures on such assets.

There are no significant commitments for equipment, although we expect some modest capital expenditures in the year ending October 31, 2014 related to additional personnel and the expansion of research and clinical development activities.

Total assets as at October 31, 2013 were \$6,243,771 compared with \$6,202,639 at the end of the Company's last year end. The year over year increase in cash and short term investments of \$616,185 was due to net proceeds from the issue of common shares, partly offset by use in operations.

During the year ended October 31, 2013, the Company received net proceeds of \$1,831,857 from the issue of common shares, warrants and stock options after deducting cash share issue costs of \$168,143. During the prior year, the Company raised net proceeds of \$4,434,392 after deducting share issue costs of \$43,783. Details of these transactions are described below.

The Company does not have any debt or credit facilities.

There were no financing activities in the three months ended October 31, 2013 and October 31, 2012.

#### **Common Shares**

Changes in the number of issued common shares from October 31, 2011 to the date of this report are highlighted in the table below.

	Number of Common Shares
Balance as at October 31, 2011	95,147,277
Shares issued under warrant exercise	4,075,277
Shares issued under offering memorandum	20,167,332
Shares returned to treasury	(40,000)
Shares issued under stock option exercise	273,750
Balance as at October 31, 2012	119,623,636
Shares issued under private placement	10,000,000
Shares issued under stock option exercise	20,000
Balance as at October 31, 2013 and	
February 26, 2014	129,643,636

Common shares issued – year ended October 31, 2013

On February 19, 2013 the Company completed a non-brokered private placement for gross proceeds of \$2,000,000. The offering consisted of 10,000,000 units sold at a price of \$0.20 per unit. Each unit consisted of one common share and one common share purchase warrant, with each warrant entitling the holder to purchase one common share of the Company for a period of 36 months from closing of the offering at a price of \$0.35 per share for the first 24 months and at a price of \$0.40 per share for the last 12 months. The warrants were ascribed a value of \$250,000 representing the difference between the issue price of the unit and the fair market value of the shares at that time received as part of the offering.

Costs associated with the private placement totaled \$228,383 including cash fees of \$168,143 and the issue of 985,931 finder's warrants valued at \$60,240, which have been deducted from the gross proceeds.

Common shares issued – year ended October 31, 2012

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.

There were no finders' fees due or payable on the private placements in February and March 2012 but other closing costs of \$43,783 were incurred.

#### Performance Escrow Shares

Included in the number of issued common shares as at October 31, 2013 are 3,472,500 (2012 – 3,472,500) performance escrow shares related to the licensing of the Sertolin technology. These common shares will not be released, transferred or assigned without the consent of the regulatory authorities, and are subject to performance-based release terms as follows:

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

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

#### Warrants

The following table reflects the activity of the warrants for the year ended October 31, 2013 and to the date of this report, as well as the previous year:

		Weighted Average
	Number of Warrants	Exercise Price
Balance outstanding October 31, 2011	18,148,639	\$0.20
Issued	20,167,332	\$0.20
Exercised	(4,075,277)	\$0.20
Warrants – re-pricing	(6,553,916)	\$0.20
Warrants – re-pricing	6,553,916	\$0.35
Expired	(5,078,752)	\$0.20
Balance outstanding October 31, 2012	29,161,942	\$0.23
Issued	10,985,931	\$0.34
Warrants – re-pricing	(20,167,332)	\$0.20
Warrants – re-pricing	20,167,332	\$0.35
Expired	(8,994,610)	\$0.31
Balance outstanding October 31, 2013 and		
February 26, 2014	31,153,263	\$0.35

The warrants outstanding as at October 31, 2013 are detailed in note 8 to the annual consolidated financial statements.

#### **Incentive Stock Options**

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

The following table reflects the activity to the date of this Management Discussion and Analysis:

	Number of Options	Weighted Average
		Exercise Price
Balance outstanding October 31, 2011	4,597,208	\$0.20
Granted	4,207,918	\$0.17
Expired	(530,000)	\$0.64
Cancelled	-	-
Exercised	(273,750)	\$0.13
<b>Balance outstanding October 31, 2012</b>	8,001,376	\$0.16
Granted	160,000	\$0.15
Expired	(180,000)	\$0.25
Cancelled	(285,931)	\$0.18
Exercised	(20,000)	\$0.12
Balance outstanding October 31, 2013	7,675,445	\$0.16
Granted	3,360,000	\$0.15
Cancelled	(294,250)	\$0.15
Balance outstanding February 26, 2014	10,741,195	\$0.16

#### **COMMITMENTS AND CONTINGENCIES**

The Company is committed to the payment of certain costs under the clinical trial which commenced in the third quarter of the previous fiscal year. The study is a Phase I/II study with a primary endpoint of safety and a secondary endpoint of efficacy. The study is designed to allow for interim analyses at various points as sufficient data are collected. In this study patients will also be followed for a minimum of three years to assess longer-term safety and efficacy of the Cell Pouch™ with transplanted islets. The commitment under the agreement includes the cost of clinical staff and overhead thereon, trial insurance, and may include travel and a portion of drug-or procedure −related expenses or transplantation expenses not covered by insurance. The total commitment over the duration of the trial is expected to be approximately \$2,000,000 but will be impacted by such factors as the rate of enrollment, the province in which the patient resides and the specifics of patient insurance.

The Company is committed to an estimated payment of approximately \$66,000 USD in fees to maintain the patents in good standing for the year ending October 31, 2014. Similar payments will be required for subsequent years.

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

#### TRANSACTIONS WITH RELATED PARTIES

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

Amounts due to related parties, including amounts due to key management personnel, at the 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 years ended October 31:

(In \$Cdn)	2013	2012
Consulting fees	-	-
Director fees	-	-
Share-based compensation	28,638	121,251
Total expenses	28,638	121,251

Compensation for key management personnel of the company other than directors for the years ended October 31 is as follows:

(In \$Cdn)	2013	2012
Salaries and consulting fees	322,500	390,000
Benefits	29,724	29,477
Share-based compensation	51,858	94,968
Total expenses	404,082	514,445

Executive officers and directors participate in the stock option plan and officers participate in the Company's health plan. Key management personnel control 2.0% of the issued common shares of the Company as at October 31, 2013.

During the year ended October 31, 2013 the Company paid \$82,500 (2012- \$77,500) in consulting fees for the services of the then chief financial officer, to a company controlled by the officer.

#### **OFF-BALANCE SHEET ARRANGEMENTS**

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

### 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 year ended October 31, 2013, the Company made no material changes to its system of internal controls over financial reporting.

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

#### CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The Company makes estimates and assumptions about the future that affect the reported amounts of assets and liabilities. Estimates and judgments are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions.

The effect of a change in an accounting estimate is recognized prospectively by including it in comprehensive loss in the period of the change, if the change affects that period only, or in the period of the change and future periods, if the change affects both.

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

#### i. Intangible assets – impairment

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

#### ii. Intangible assets – useful lives

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

#### iii. Share-based compensation

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

#### **CHANGES IN ACCOUNTING POLICIES**

#### New standards and interpretations not yet effective

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

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

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

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

#### IFRS 10, Consolidated Financial Statements

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

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

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

1, 2013. The Company is currently assessing the impact of the standard on the consolidated financial statements.

#### IFRS 13, Fair Value Measurement

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

#### **Financial Instruments and Risk Management**

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

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

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

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

#### Credit risk

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

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

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

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

#### Market risk

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

#### Foreign currency 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 a foreign currency, which is currently only United States dollars. However, management believes the risk is not currently significant as less than 0.1% of the Company's financial assets and none of its liabilities as at October 31, 2013 are denominated in United States dollars. There are no active operations in the US, with the exception of patent prosecution and maintenance costs, which are estimated at approximately US\$200,000 (2012 – US\$200,000) annually in aggregate. A strengthening of the US dollar against the Canadian dollar by 1% would cost the Company approximately an additional \$2,000.

#### Interest rate risk

The Company has cash and short-term investment balances and no interest-bearing debt. The Company's current policy is to invest excess cash in investment-grade short-term deposit certificates issued by its banking institutions. The Company periodically monitors the investments it makes and is satisfied with the credit ratings of its banks. The principal amount of the short-term investments as at October 31, 2013 of \$4,702,301 (2012 – \$4,104,164) is held in interest-bearing guaranteed investment certificates with its bank. While the deposits have a maximum three year term, the liquidity of the short-term investments is restricted in the second and third years. 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 their anniversary date in any month without penalty within the first year. A 1% change in interest rates would have an effect of \$47,023 on interest income.

#### **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 October 31, 2013 the Company had cash and short-term investments of \$4,975,906 (2012 - \$4,359,721) to settle current liabilities of \$225,148 (2012 - \$133,950). All of the Company's financial liabilities are subject to normal trade terms.

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

#### 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<sup>™</sup> is in the Phase I/II stage of development but there is a long development path ahead which will take years to complete and is prone to the risks of failure inherent in the development process.

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

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

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

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

**Reliance on Key Personnel.** The Company is dependent on certain members of its management and scientific staff as well as consultants and contractors, the loss of services of one or more of whom could adversely affect the Company. In addition, the Company's ability to manage growth effectively will require it to continue to implement and improve its management systems and to recruit and train new employees. There can be no assurance that the Company will be able to successfully attract and retain skilled and experienced personnel.

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

corporate collaborations, product sales and/or royalty payments generate sufficient revenues to fund its continuing operations.

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

#### **Industry Risk**

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

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

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

**Rapid Technological Change.** The biotechnology and pharmaceutical industries are characterized by rapid and substantial technological change. There can be no assurance that developments by others will not render the Company's proposed products or technologies non-competitive, or that the Company will keep pace with technological developments. Competitors have developed or are developing

technologies that could be the basis for competitive products. Some of these products have an entirely different approach or means of accomplishing the desired diagnostic or therapeutic effect as compared with products to be developed by the Company, and could be more effective and less costly than the products to be developed by the Company. In addition, alternative forms of medical treatment may be competitive with the Company's products.

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

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

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

#### **DIRECTORS AND OFFICERS**

Dr. George Adams, Chairman of the Board of Directors
Jeffrey Bacha, Director
James Parsons, Director
Bruce Weber, Director
Dr. Philip Toleikis, President, Chief Executive Officer and Director
Cathy Steiner, Chief Financial Officer

#### **ADDITIONAL INFORMATION**

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