

# SERNOVA CORP.

MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE YEARS ENDED OCTOBER 31, 2015 AND 2014

Dated January 14, 2016

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The following management's discussion and analysis ("MD&A") explains the variations in the consolidated operating results, financial position and cash flows of Sernova Corp. ("Sernova", the "Company", "We", "Us" or "Our") for the three months ended October 31, 2015 and 2014 and the years ended October 31, 2015 and 2014. This MD&A should be read in conjunction with the Company's audited consolidated financial statements for the years ended October 31, 2015 and 2014, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The Company's accounting policies under IFRS are set out in Note 3 of the audited consolidated financial statements for the years ended October 31, 2015 and 2014.

The information in this report is dated as of January 14, 2016.

# 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 words such as "will", "intend", "believe", "estimate", "consider", "expect", "anticipate", and "objective" or similar expressions and 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 contains 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 such as private equity, government funding and other programs;
- The initiation and completion of pre-clinical studies and clinical trials of our Cell Pouch<sup>™</sup> for the treatment of insulin-dependent diabetes and other diseases;
- The expected benefit of the Cell Pouch<sup>TM</sup> with therapeutic cells;
- The expected benefit of the European Commission's Horizon 2020 grant for our hemophilia program;
- The intention to protect therapeutic cells within the Cell Pouch<sup>™</sup> from immune attack using local immune protection such as microencapsulation or Sertolin<sup>™</sup>, or through the use of systemic antirejection regimens or a combination thereof;
- The intention to use human autograft cells, or human donor cells for treatment, or human stem cell derived cells or xenogeneic cells as virtually unlimited cell sources for our Cell Pouch<sup>™</sup> for the potential treatment of chronic diseases;
- The intention to receive regulatory approval and commercialize the Cell Pouch<sup>™</sup> for the treatment of insulin-dependent diabetes and other potential indications such as hemophilia and thyroid disease;

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

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

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

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

# ABOUT SERNOVA

Sernova Corp. is a Canadian-based regenerative medicine company, focused on commercializing its proprietary Cell Pouch<sup>TM</sup> and associated technologies including therapeutic cells. The Cell Pouch<sup>TM</sup> is a scalable, implantable, medical device, designed to create an ideal microvessel rich, tissue environment for the transplantation and engraftment of therapeutic cells, which then release proteins and/or hormones for the long-term treatment of a number of serious, chronic diseases such as diabetes, hemophilia and thyroid disease. Depending on the clinical indication, the therapeutic cells may be obtained directly from human donors autograft (self-cells) or allograft cells (other's donor cells), or derived from sources known to provide a virtually unlimited supply of cells such as from a stem cell derived or xenogeneic (non-human) source. Depending on the need, the therapeutic cells may be protected, within the Cell Pouch<sup>TM</sup> using systemic or local immune protection technologies such as our patented Sertolin<sup>TM</sup> or microencapsulation being developed to create an immune privileged environment and protect the Cell Pouch<sup>TM</sup> transplant from rejection.

Our initial studies have focused on the treatment of insulin-dependent diabetes through the transplantation of pancreatic islets, which control blood glucose levels. To date, we have successfully transplanted donor islets in our Cell Pouch<sup>TM</sup> to treat insulin-dependent diabetes in multiple animal models, and initiated a proof of principle clinical trial for the treatment of human subjects with diabetes receiving an islet transplant, protected by the standard of care antirejection drug regimen. In this study, interim results in a small cohort of patients have shown the Cell Pouch<sup>TM</sup> to be safe alone and with donor islets. With these encouraging results, the Company is securing unlimited sources of cells which are not limited by donor availability, through license agreements and/or partnerships, which can then be immune-protected within the Cell Pouch<sup>TM</sup> as a product to enable potential treatment of millions of people with diabetes. The Company is also investigating other diseases amenable to treatment with therapeutic cells such as hemophilia and thyroid disease.

## **Research and Development**

Sernova has been a development stage company since inception. Our research and development efforts are focused principally on the development of the Cell Pouch<sup>TM</sup> with therapeutic cells for the treatment of chronic diseases, and on local immune protection technologies (e.g. microencapsulation) that may protect the therapeutic cells within the Cell Pouch<sup>TM</sup> from immune system attack. We have not been profitable since inception, and we expect to continue to incur substantial losses as we continue our research and development efforts. We do not expect to realize material revenues until, if and when, our medical technologies become commercially viable.

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

- Conducting clinical trials required to gain marketing approval for the Cell Pouch<sup>™</sup> device in countries that have a significant market opportunity. Our first product is being developed for the treatment of insulin-dependent diabetes. Our first clinical trial, designed to demonstrate the proof of concept of the Cell Pouch<sup>™</sup> and therapeutic cells, was initiated in Canada. That clinical trial is evaluating the Cell Pouch<sup>™</sup> transplanted with human donor islets, protected using the standard of care antirejection drug regimen, in subjects with insulin-dependent diabetes with hypoglycemia unawareness. Our goal is the treatment of diabetes using the Cell Pouch<sup>™</sup> transplanted with locally immune protected cells from an unlimited source of cells such as glucose-responsive stem cell derived cells or xenogeneic cells. These programs may involve third party collaborations and corporate partnerships in addition to our internal clinical development efforts;
- 2. Conducting pre-clinical research programs to examine a range of therapeutic indications for our platform Cell Pouch<sup>TM</sup> technology which may include: diabetes, hemophilia, thyroid disease, and other chronic diseases that require a hormone or protein which is missing or in short supply in the body. These programs may involve third party collaborations in addition to our internal research and development efforts;
- 3. Identification and development of complementary technologies which may improve the safety and efficacy of cells within the Cell Pouch<sup>TM</sup>, including local immune protection technologies such as microencapsulation. These programs may involve third party collaborations in addition to our internal research and development efforts;
- 4. Development of various sources of therapeutic cells for transplantation within our Cell Pouch<sup>TM</sup>, including, depending on the clinical application, autologous cells, allogeneic cells such as donor cells or glucose responsive stem cell derived cells that could be used to treat large numbers of patients as well as xenogeneic cells. These programs may involve third party collaborations in addition to our internal research and development efforts;
- 5. Manufacturing and supply of the Cell Pouch<sup>TM</sup> and the processing and supply of therapeutic cells; and,
- 6. Generation and/or licensing of intellectual property.

#### Corporate Update for the year ended October 31, 2015 and to the date of this MD&A

In November 2014, we announced an update of the clinical assessment of the Cell Pouch<sup>TM</sup> in diabetic patients with hypoglycemia unawareness who have received an islet transplant. In the first small cohort of patients in interim analysis, the Cell Pouch<sup>TM</sup> was biocompatible and safe following implant and transplant with safety being the primary endpoint of the study. Initial data from the study have also shown that islets within the Cell Pouch<sup>TM</sup>, as shown by histological analysis, are well-vascularized, living within a natural

tissue matrix and are able to make insulin, glucagon and somatostatin, key hormones in the control of blood glucose levels. We believe such revascularization of islets and islet metabolic function within an implantable medical device for therapeutic cells in humans in this patient population is a first in the regenerative medicine field. These findings also suggest that the Cell Pouch<sup>™</sup> may form a suitable environment for the survival and function of multiple types of therapeutic cells including human stem cells which can represent a virtually unlimited supply of cells for treating disease.

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

In March 2015, we announced that Frank Holler was appointed Chairman of the Board and that Dr. George Adams was retiring as a director of Sernova at the end of his term and has stepped down as Chairman of the Board. Mr. Holler brings a wide-range of experience to his role as Sernova's Chairman of the Board as an active investor and successful entrepreneur.

In April 2015, we announced that the U.S. Patent and Trademark Office issued Sernova a patent that helps protect Sernova's entire Cell Pouch System<sup>TM</sup>. This patent entitled "Methods and Devices for Cellular Transplantation" includes claims covering implantable polymer devices such as the Cell Pouch<sup>™</sup> itself, as well as methods using the same combined with therapeutic cells such as self-cells, donor cells, stem cell derived technologies and genetically modified cells as well as surgical tools for cell transplantation. This new patent provides Sernova with patent protection through 2030.

In May 2015, we appointed Mr. Ralph Deiterding, CPA, CA, CMA, CPA (Illinois) as CFO to replace Interim CFO, Mr. David Garland. Mr. Deiterding has extensive public company experience including Controller positions at MKS Inc. and Workbrain Corporation, both of which were Toronto Stock Exchange listed software vendors.

In July 2015, we announced a research collaboration with Massachusetts General Hospital, supported by funding from JDRF to develop a novel treatment for diabetes. Sernova and Dr. Mark Poznansky, M.D., Ph.D., Associate Professor of Medicine at Harvard Medical School and Director of the Vaccine and Immunotherapy Center at Massachusetts General Hospital will collaborate on the project, with JDRF providing \$150,000 USD in funding support. The collaboration will incorporate a proprietary local immune protectant technology within Sernova's novel Cell Pouch<sup>™</sup> as a potential new treatment for patients with insulin-dependent diabetes.

In September 2015, we announced the signing of a license agreement with the University Health Network (UHN) of Toronto, Canada to gain exclusive worldwide rights to certain patent-pending technologies developed by UHN researchers. These technologies relate to the development of stem cells into insulin producing glucose-responsive therapeutic cells for the treatment of patients with insulin-dependent diabetes.

In December 2015, we announced that the European Commission's Horizon 2020 program has awarded a €5.6 million (approximately \$8.5 million) non-repayable grant to a consortium consisting of Sernova Corp and five European academic and private partners to advance development of a GMP clinical grade Factor VIII releasing therapeutic cell product in combination with Sernova's Cell Pouch<sup>TM</sup> for the treatment of severe hemophilia A, a serious genetic bleeding disorder caused by missing or defective factor VIII in the blood

stream. The therapeutic goal of the product is to use the patient's own cells corrected for the factor VIII gene. These cells placed in the implanted Cell Pouch<sup>TM</sup> are expected to release factor VIII on a continual basis at a rate that would be expected to significantly reduce disease-associated hemorrhaging and joint damage. The constant delivery of factor VIII is also expected to reduce or eliminate the need for multiple weekly infusions which is the current standard of care using plasma-derived or recombinant, genetically engineered factor VIII for the prophylactic treatment of hemophilia A.

# Research and Development Outlook for the 2016 Calendar Year

Our product development program for 2016 includes the following:

- Further clinical evaluation of the Cell Pouch<sup>™</sup> in patients with insulin-dependent diabetes receiving an islet transplant;
- Follow up of the HemAcure consortium product development work relating to a treatment for hemophilia A consisting of Factor VIII releasing therapeutic cells transplanted within Sernova's Cell Pouch<sup>™</sup>;
- Initiation of product development work of another disease indication such as thyroid disease in preparation for human evaluation in a clinical trial to assess the safety and efficacy of the Cell Pouch<sup>™</sup>;
- Human stem cell differentiation, characterization and production of progenitor cells for diabetes and in vivo proof of principle assessment of these cells for their safety and efficacy within Sernova's Cell Pouch<sup>™</sup> for the treatment of insulin-dependent diabetes; and,
- Development and assessment of complementary local immune protection technologies, under academic and /or corporate collaborations to further develop and expand Sernova's therapeutic vision for diabetes of a product consisting of locally immune protected therapeutic cells within the Cell Pouch<sup>TM</sup> using an unlimited source of cells for the future treatment of people with insulin-dependent diabetes.

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

Sernova's lead program is the clinical development of the Cell Pouch<sup>TM</sup> for treatment of patients with insulindependent diabetes. Dr. James Shapiro, pioneer of the Edmonton Protocol, and his team at the University of Alberta initiated a proof of concept human clinical study to evaluate the Cell Pouch<sup>TM</sup> with donor islets, in insulin-dependent diabetic subjects with hypoglycemia unawareness who are receiving islet transplantation.

The Edmonton Protocol is the current standard of care cell-based treatment for insulin-dependent diabetic patients with hypoglycemia unawareness that involves infusing donor pancreatic islets, often from multiple donors, into a patient's liver portal vein, followed by life-long administration of immunosuppressive drugs to prevent rejection of the transplant. Overall, benefits of islet transplantation may include a reduction in the incidence of hypoglycemia unawareness, a reduced requirement for exogenous insulin and reduced diabetes-induced microvascular damage and potential insulin independence. It is believed, however, following islet infusion that with portal vein delivery of islets, 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. A further limitation is that infusion of cells into the portal vein is limited to donor islets and is not amenable to advanced technologies such as glucose-responsive insulin producing stem cell derived cells or xenogeneic cells being developed to overcome the limited supply of donor islet cells.

There is thus a need for an improved environment in which to place therapeutic cells that more closely mimics the natural environment of cells which are surrounded by tissue matrix and in close proximity to microvessels but not actually bathed in blood. Furthermore, and of critical importance is the fact that the portal vein is not a suitable location for alternative but virtually unlimited sources of cells such as glucose responsive insulin producing stem cell derived cells or xenogeneic cells that are locally immune protected that could be used to treat the large numbers of patients with insulin-dependent diabetes.

We believe our Cell Pouch<sup>TM</sup> may offer significant benefits over portal vein delivery, the current standard-of care, to restore the body's insulin production and glucose control in insulin-dependent diabetic patients. The Cell Pouch<sup>TM</sup> was designed to take into consideration the biological requirements of therapeutic cells. A tissue matrix rich in microvessels forms within the Cell Pouch<sup>TM</sup> when implanted subcutaneously prior to islet transplantation, providing an ideal environment for placement of therapeutic cells, including insulin-producing islets. We believe these conditions are key for maintaining long term survival and function of therapeutic cells. We have demonstrated in a series of ISO10993 biocompatibility studies and multiple animal studies that the Cell Pouch<sup>TM</sup> is biocompatible and safe. Long-term studies in multiple animal models have demonstrated that the islets become well-supported with microvessels 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 mitigated, as the therapeutic cells are surrounded by microvessels similar to the islets' natural microenvironment in the pancreas rather than being bathed in a constant flow of blood. This reduced inflammatory response should enable improved islet survival and potentially lead to the need to implant fewer islets or other sources of insulin producing cells. In the case of donor islets, this could potentially enable patients with diabetes to be treated with fewer donor pancreata than are currently being used. It can take up to three pancreata to treat a single patient and achieve a reduction in insulin injections using the Edmonton Protocol.

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

While the Cell Pouch<sup>TM</sup> cells can function with systemic immune protection it may accommodate local immunoprotection technologies reducing or eliminating the need for lifelong systemic antirejection drug treatment. Local immune protection of islets such as microencapsulation could result in a significant reduction or elimination of 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 glucose responsive insulin producing cells derived from stem cells or xenogeneic cells, addressing the limited availability of donors and allowing the widespread treatment of insulin-dependent diabetes. Thus, we believe our approach offers

substantial benefit over the currently-used Edmonton Protocol, and its ease of use may provide an opportunity for the Cell Pouch<sup>TM</sup> to become the standard of care in therapeutic cell transplantation, if it proves to be safe and effective in clinical trials. In fact, Sernova believes it has the only such device technology of its kind in which therapeutic cells have been definitely proven to survive in a tissue matrix integrated with microvessels in close association with the therapeutic cells.

In our human clinical trial, subjects have been implanted with the Cell Pouch<sup>™</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 have been 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.

To date, interim analysis of a small cohort of patients has been presented at a number of international transplantation conferences where the Cell Pouch<sup>™</sup> was shown to demonstrate biocompatibility and safety following implant and transplant. Safety is the primary endpoint of the study. These results have shown the following these important findings:

- First, biocompatibility and a positive safety profile of the Cell Pouch<sup>™</sup> have been shown in the first cohort of patients;
- Second, the islets within the Cell Pouch<sup>TM</sup>, as shown by histological analysis, are well-vascularized, living within a natural tissue matrix and are able to make insulin, glucagon and somatostatin, key hormones in the control of blood glucose levels. We believe such revascularization of islets and islet metabolic function within an implantable medical device for therapeutic cells in humans in this patient population is a first in the regenerative medicine field; and,
- Based on these encouraging results from the study, we believe that Sernova's Cell Pouch<sup>TM</sup> may form a suitable environment for the survival and function of multiple types of therapeutic cells, including glucose responsive cells derived from human stem cells or xenogeneic islets which can represent an unlimited supply of cells for treating disease.

In the collaboration with Dr. Shapiro of the University of Alberta, a pre-clinical study of the Cell Pouch<sup>TM</sup> with islets demonstrated that the Cell Pouch<sup>TM</sup> provided insulin independence for the length of the study (100 days), in a small animal model of diabetes using a marginal (minimal) transplanted islet mass. This study supports the concept that the Cell Pouch<sup>TM</sup> may require a smaller than anticipated number of cells to achieve efficacy, one of the parameters being considered for human clinical evaluation to achieve glucose control in patients with diabetes.

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

#### Hemophilia

As part of our strategy to develop the Cell Pouch<sup>TM</sup> for various therapeutic indications, we have been evaluating Sernova's Cell Pouch<sup>TM</sup> for the treatment of patients with hemophilia A.

This approach involves taking a small blood sample from the patient, correcting the genetic defect in isolated cells and then expanding the cell numbers for placement into Sernova's Cell Pouch<sup>™</sup> for release of Factor VIII. Initial proof of concept studies have been conducted by Sernova and a European team of experts forming a consortium called HemAcure. The HemAcure consortium was successful in obtaining €5.6 million (approximately \$8.5 million), funded by a European Commission's Horizon 2020 grant, to develop a GMP human cell product suitable for human clinical testing for the completion of safety and efficacy studies in the Cell Pouch<sup>™</sup> as part of a regulatory package in preparation for human clinical testing.

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

As the Company continues its work on the diabetes and hemophilia indications, we are exploring new indications to further expand the application of our cell therapy platform technologies including for the treatment of thyroid disease.

# Local Immune Protection & Other Complementary Technologies

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

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

# **Alternative Sources of Cells**

Our transplantation technologies may incorporate autologous cells, donor cells or other sources of cells including glucose-responsive insulin producing cells derived from human-stem cells or islets derived from xenogeneic sources, depending on the clinical indication under evaluation and the need for expanded numbers of cells for treatment of larger populations. As such, we will continue to work with academic collaborators and industry partners to identify and secure the required cells for our therapeutic indications. In this regard, Sernova has signed a license agreement with the University Health Network of Toronto (UHN) to gain access to worldwide, exclusive rights to certain patent-pending technologies developed by UHN researchers, for the advancement of glucose-responsive insulin-producing stem cells for the treatment of patients with insulin-dependent diabetes. A tech-transfer, and cell-production plan has been developed for production and evaluation of these cells in Sernova's Cell Pouch<sup>TM</sup>.

Sernova is also committed to working with corporate and academic partners to evaluate various glucose responsive, insulin-producing cell technologies that use different approaches, with a goal of combining Sernova and partner technologies to create best in class products. In this regard, Sernova has signed an agreement to test and evaluate a partner's advanced stem cell derived glucose responsive, insulin-producing technology in our Cell Pouch<sup>TM</sup>.

# Manufacturing

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

# **Intellectual Property**

Our patent portfolio currently consists of 54 issued and pending patents in eight families covering our enabling platforms. We strive to obtain broad claims in our patents, including exclusivity of our Cell Pouch<sup>™</sup> device and related technologies in combination with a wide range of therapeutic cell technologies including glucose-responsive insulin producing stem cell derived cells and to treat a number of chronic diseases. Importantly, our Cell Pouch<sup>™</sup> patents extend to 2030. We intend to continue to expand our patent and licensing portfolio through proprietary internal inventions as well as strategic in-licensing, to maximize the commercial potential for our platform technologies.

#### **Business Development**

Sernova is committed to business development activities to in-license complementary technologies to expand Sernova's product development portfolio, and intellectual property base that is of key importance for partnering activities. This work is also expected to result in corporate partnerships which we are actively pursuing to develop products with other companies. Furthermore, Sernova is actively pursuing potential pharmaceutical and medical device corporate partners to develop and market its products.

# **RESULTS OF OPERATIONS**

#### **Selected Financial Information**

Selected financial information from the statements of loss and comprehensive loss for the three months ended October 31, 2015 and 2014 and the years ended October 31, 2015, 2014 and 2013, were as follows:

Three months ended October 31,		Years ended October 31,			
(all amounts in Canadian Dollars)	2015	2014	2015	2014	2013
Research and development expenses	\$ 497,047	\$ 558,747	\$ 1,793,218	\$ 2,026,189	\$ 1,574,614
General and administrative expenses	394,866	128,449	1,092,470	767,346	490,522
Loss and comprehensive loss for the period	\$ 886,116	\$ 678,180	\$ 2,859,477	\$ 2,746,059	\$ 2,002,921

For the year ended October 31, 2015, the Company recorded a loss of \$2.9 million or \$0.02 per share, compared to \$2.7 million or \$0.02 per share in the prior year, an increase of \$113,418 or 4.1%. The higher loss in fiscal 2015 over fiscal 2014 was a result of an increase in general and administrative expenses that was partially offset by a decrease in research and development expenses.

For the three months ended October 31, 2015, the Company recorded a loss of \$886,116, compared to \$678,180, for the same period in the prior year, an increase of \$207,936 or 30.7%. The higher loss in the three months ended October 31, 2015 over the comparable period in fiscal 2014, was a result of an increase in general and administrative expenses that was partially offset by a decrease in research and development expenses.

The period to period changes in expenses are explained in greater detail in the following sections on research and development expenses and general and administrative expenses.

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

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

	Three months ended October 31,		Years ended October 31,	
(all amounts in Canadian Dollars)	2015	2014	2015	2014
Salaries, supplies and contract payments	\$ 322,512	\$ 170,364	\$ 1,062,739	\$ 1,077,187
Patent fees and costs	144,468	38,009	295,536	168,186
Depreciation of property and equipment	1,189	1,189	4,756	4,756
Amortization of intangible assets	-	284,205	492,075	774,108
Share-based compensation	48,511	64,293	102,745	150,970
Contributions and tax credits	(19,633)	687	(164,633)	(149,018)
Total	\$ 497,047	\$ 558,747	\$ 1,793,218	\$ 2,026,189

Total research and development expenses, for the year ended October 31, 2015, decreased by \$232,971 or 11.5% from the prior fiscal year. Salaries, supplies and contract payments, for the year ended October 31, 2015,

decreased by \$14,448 or 1.3%, compared to the prior fiscal year due to reduced contract payments in the year ended October 31, 2015, which were partially offset by an increase in salaries. Patent fees and costs, for the year ended October 31, 2015, increased by \$127,350 or 75.7%, compared to the prior fiscal year, due to increased patent prosecution and maintenance payments in the year ended October 31, 2015. The increase in patent related costs was, in part, due to costs incurred as a result of a license agreement executed with the University Health Network in the year ended October 31, 2015. Amortization of intangible assets, for the year ended October 31, 2015, decreased by \$282,033 or 36.4%, compared to the prior fiscal year, due to the intangible assets coming to the end of their expected useful life as at April 30, 2015. Share-based compensation, for the year ended October 31, 2015, decreased by \$48,225 or 31.9%, compared to the prior fiscal year, due to fewer options being granted during fiscal 2015 and later in the fiscal year, as compared to the grant in the previous fiscal year. Contributions and tax credits, for the year ended October 31, 2015, increased by \$15,615 or 10.5%, compared to the prior fiscal year, due to more tax credits being earned during fiscal 2015, as compared to the previous fiscal year.

Total research and development expenses, for the three months ended October 31, 2015, decreased by \$61,700 or 11.0% compared to the equivalent period of the prior fiscal year. Salaries, supplies and contract payments, for the three months ended October 31, 2015, increased by \$152,148 or 89.3%, compared to the equivalent period of the prior fiscal year. The increase was due to increased salaries and contract payments in the three months ended October 31, 2015, compared to the same period in the previous fiscal year. Patent fees and costs, for the three months ended October 31, 2015, increased by \$106,459, compared to the equivalent period of the prior fiscal year due to increased patent prosecution and maintenance payments in the three months ended October 31, 2015. The increase in patent related costs was primarily due to costs incurred as a result of a license agreement executed with the University Health Network in the three months ended October 31, 2015. Amortization of intangible assets, for the three months ended October 31, 2015, decreased by \$284,205 or 100.0%, compared to the equivalent period of the prior fiscal year, due to the intangible assets coming to the end of their expected useful life at April 30, 2015. Share-based compensation, for the three months ended October 31, 2015, decreased by \$15,782 or 24.5%, compared to the equivalent period of the prior fiscal year due to fewer options being granted during fiscal 2015 and later in the fiscal year, as compared to the grant in the previous fiscal year. Contributions and tax credits, for the three months ended October 31, 2015, increased by \$20,320, compared to the equivalent period of the prior fiscal year, due to more tax credits being earned during the three months ended October 31, 2015, as compared to the same period in the previous fiscal year.

The Company expects to pay certain future costs related to its pre-clinical and clinical trials. Such payments are expected to include 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 payments over the duration of the trial will be impacted by such factors as the rate of enrollment, the province in which the patient resides and the specifics of patient insurance.

#### General and administrative expenses

General and administrative costs for the three months ended October 31, 2015 and 2014 and the years ended October 31, 2015 and 2014, were as follows:

	Three months ende	ed October 31,	Years ended October 31,	
(all amounts in Canadian Dollars)	2015	2014	2015	2014
Salaries, benefits and consulting fees	\$ 123,126	\$ 57,324	\$ 320,236	\$ 186,751
Professional fees	21,856	16,823	116,058	103,579
Director fees and benefits	31,225	29,861	115,895	99,119
Investor relations	100,312	20,378	212,869	139,718
Travel and other costs	27,569	63,790	148,612	123,384
Depreciation of property and equipment	138	31	231	124
DSU's issued for director compensation	27,517	_	38,284	_
Share-based compensation	63,123	(59,758)	140,285	114,671
Total	\$ 394,866	\$ 128,449	\$ 1,092,470	\$ 767,346

General and administrative expenses consist mainly of professional fees, personnel costs related to corporate activities, costs for shareholder-related activities including investor relations, director's fees, stock exchange fees and share-based compensation.

Total general and administrative expenses, for the year ended October 31, 2015, increased by \$325,124 or 42.4%, as compared to the prior year. Salaries, benefits and consulting fees, for the year ended October 31, 2015, increased by \$133,485 or 71.5% compared to the prior year, due to increased consulting fees in the year ended October 31, 2015. Professional fees, for the year ended October 31, 2015, increased by \$12,479 or 12.0% compared to the prior year, due to increased fees incurred in the year ended October 31, 2015. Director's fees and benefits, for the year ended October 31, 2015, increased fees incurred in the year ended October 31, 2015. Director's fees and benefits, for the year ended October 31, 2015, increased fees incurred in the year ended October 31, 2015. Investor relations expenses, for the year ended October 31, 2015, increased fees incurred in the year ended October 31, 2015. Investor relations expenses, for the year ended October 31, 2015, increased by \$73,151 or 52.4%, compared to the prior year, primarily due to one-time costs incurred related to the listing of the Company's shares on the OTCQB market during the year ended October 31, 2015. Travel and other costs, for the year ended October 31, 2015, increased by \$25,228 or 20.4%, as compared to the prior year, due to an increased level of travel in the year ended October 31, 2015. Deferred share units (DSU's) issued for director's compensation were first granted during the year ended October 31, 2015, increased by \$25,614 due to greater stock-based compensation, for the year ended to the stock options granted in fiscal 2015, as compared to the grant in the prior fiscal year.

Total general and administrative expenses, for the three months ended October 31, 2015, increased by \$266,417, as compared to the same period in the prior year. Salaries, benefits and consulting fees, for the three months ended October 31, 2015, increased by \$65,802 compared to the same period in the prior year, due to increased consulting fees in the three months ended October 31, 2015. Professional fees, for the year ended October 31, 2015, increased by \$5,033 or 29.9% compared to the prior year, due to increased fees incurred in the three months ended October 31, 2015. Investor relations expenses, for the three months ended October 31, 2015, increased by \$79,934, compared to the same period in the prior year, primarily due to one-time costs incurred related to the listing of the Company's shares on the OTCQB market during the three months ended October 31, 2015. Travel and other costs, for the three months ended October 31, 2015, decreased by \$36,221 or 56.8%, as compared to the same period in the prior year, due to a decreased level of travel in the three months ended October 31, 2015 compared to the same period in the prior fiscal year. Deferred share units

(DSU's) issued for director's compensation were first granted during the year ended October, 31 2015, resulting in an expense of \$27,517 for the three months ended October 31, 2015. Share-based compensation, for the three months ended October 31, 2015, increased by \$122,881 due to greater stock-based compensation attached to the stock options granted in fiscal 2015, as compared to the grant in the prior fiscal year as well as a forfeiture reflected in the three months ended October 31, 2015 that resulted in negative stock-based compensation during that period.

#### **Finance income**

Finance income, represented primarily by interest income earned on the Company's term deposits, was \$31,995, during the year ended October 31, 2015, compared to \$51,128, for the prior fiscal year. The decrease was primarily due to a decrease in the average balances of cash and short-term investments during the most recent fiscal year. In addition, a general decrease in the prevailing interest rates paid on short-term investments in the most recent fiscal year also contributed to the decrease.

Finance income was \$7,674, during the three months ended October 31, 2015, compared to \$10,171, for the same period in the prior fiscal year. The decrease was primarily due to a decrease in the average balances of cash and short-term investments in the three months ended October 31, 2015. In addition, a general decrease in the prevailing interest rates paid on short-term investments in the three months ended October 31, 2015 also contributed to the decrease.

# Income taxes

Income taxes have not been recognized in profit and loss to date, as the Company 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. Accordingly, the Company has substantial deferred tax assets that have not been recognized in the financial statements that would be available to shelter potential future taxable income from income taxes. See Note 12 to the Company's audited consolidated financial statements for the years ended October 31, 2015 and 2014, for further details related to the Company's income tax position.

# LIQUIDITY AND CAPITAL RESOURCES

As At October 31,	2015	2014	2013
Cash and marketable securities	\$ 2,880,963	\$ 3,416,710	\$ 4,975,906
Total assets	3,153,299	4,021,072	6,243,771
Current liabilities	199,850	240,087	225,148
Share capital, warrants and contributed			
Surplus	32,606,553	30,574,612	30,066,191
Deficit	\$(29,653,104)	\$(26,793,627)	\$(24,047,568)

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

As at October 31, 2015, the Company had cash and marketable securities of \$2.9 million compared to \$3.4 million as at October 31, 2014. Management believes the Company has sufficient working capital to maintain its operations for at least the next twelve months.

The Company does not have any debt or credit facilities.

# **Financing Activities**

In May 2015, the Company completed a non-brokered private placement for gross proceeds of \$1.6 million. The offering consisted of 8,888,889 units sold at a price of \$0.18 per unit. Each unit consists 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 24 months at a price of \$0.30 per share, subject to abridgement of the exercise period (after the expiry of the 4 month hold period) with 30 days' notice to holders in the event that the twenty-day volume weighted price of the Company's common share shares exceeds \$0.50. The warrants were ascribed a value of \$nil, representing the difference between the issue price of the units and the fair market value of the shares received as part of the offering.

Costs associated with the private placement totaled \$87,167, including cash fees of \$75,873 and the issue of 137,151 finder's warrants valued at \$11,294, which have been deducted from the gross proceeds. Each finder's warrant entitles the holder to purchase one common share of the Company for a period of 24 months at a price of \$0.30 per share, subject to the same hold and abridgement conditions as the warrants included in each unit of the offering.

For the year ended October 31, 2015, 1,455,000 stock options were exercised for gross proceeds of \$226,500.

For the year ended October 31, 2014, 1,734,195 stock options were exercised for gross proceeds of \$222,780 and 100,000 warrants were exercised for gross proceeds of \$20,000.

Subsequent to October 31, 2015, the Company has issued an aggregate of 1,208,750 common shares pursuant to the exercise of stock options for gross proceeds of \$187,813.

In December 2015, the Company announced that the European Commission's Horizon 2020 program awarded an overall  $\notin$ 5.6 million (approximately \$8.5 million) non-repayable grant to a consortium called HemAcure, where the Company is a member. The Company expects to receive total funding in the amount of  $\notin$ 944,178 (approximately \$1.4 million), which represents its portion of the overall grant, based upon the terms of the grant agreement.

Historically, funding requirements have been met through the issuance of common shares from treasury and common share purchase warrants that are converted into 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 capital, such as grants and contributions, as well as collaborative partners which would assist in progressing our operations and research and clinical development programs.

We anticipate the cash requirements to fund our planned activities for 2016 will increase over the previous year. Our actual cash requirements for 2016 will depend on the clinical, pre-clinical, and collaborative activities that we ultimately undertake and the ability to secure partners, and non-dilutive funding in the form of government grants.

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

#### **Common Shares**

The following table reflects the changes in the number of issued common shares for the years ended October 31, 2015 and 2014, as well as to the date of this MD&A:

	Number of
	Common Shares
Balance as at October 31, 2013	129,643,636
Shares issued on the exercise of warrants	100,000
Shares issued on the exercise of stock options	1,734,195
Balance as at October 31, 2014	131,477,831
Shares issued related to private placement	8,888,889
Shares issued on the exercise of stock options	1,455,000
Balance as at October 31, 2015	141,821,720
Shares issued on the exercise of stock options	1,208,750
Balance as at January 14, 2016	143,030,470

#### **Performance Escrow Shares**

Included in issued common shares and representing escrow shares as at October 31, 2015 are 3,472,500 (2014 -3,472,500) common shares which will not be released, transferred or assigned without the consent of the regulatory authorities, and which shares 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 years ended October 31, 2015 and 2014, as well as to the date of this MD&A:

	Number of Warrants	Weighted Average Exercise Price
Balance as at October 31, 2013	31,153,263	\$ 0.35
Warrants exercised	(100,000)	0.20
Balance as at October 31, 2014	31,053,263	0.35
Warrants – scheduled exercise price increase	(10,000,000)	0.35
Warrants – scheduled exercise price increase	10,000,000	0.40
Warrants expired	(21,053,263)	0.34
Warrants issued related to private placement	8,888,889	0.30
Finder's warrants issued related to private placement	137,151	0.30
Balances as at October 31, 2015 and January 14, 2015	19,026,040	\$ 0.35

The warrants outstanding as at October 31, 2015 are described in Note 8 to the audited consolidated financial statements for the years ended October 31, 2015 and 2014.

#### 2015 Incentive Plan

The Company has a 2015 Incentive Plan (the "Plan"), the terms of which were approved by shareholders of the Company on April 28, 2015. The Plan includes both stock options and deferred share units ("DSU's"). Further details on the Company's 2015 Incentive Plan are provided in Note 8 to the audited consolidated financial statements for the years ended October 31, 2015 and 2014.

The following table reflects the activity for stock options for the years ended October 31, 2015 and 2014, as well as to the date of this MD&A:

	Number of Options	Weighted Average
		<b>Exercise</b> Price
Balance as at October 31, 2013	7,675,445	\$ 0.16
Granted	3,360,000	0.15
Expired	(143,250)	0.14
Cancelled/Forfeited	(1,169,250)	0.15
Exercised	(1,734,195)	0.13
Balance as at October 31, 2014	7,988,750	0.16
Granted	2,460,000	0.26
Expired	(120,000)	0.15
Exercised	(1,455,000)	0.16
Balance as at October 31, 2015	8,873,750	0.19
Exercised	(1,208,750)	0.16
Balance as at January 14, 2016	7,665,000	\$ 0.20

The following table reflects the activity for deferred share units (DSU's) for the years ended October 31, 2015 and 2014, as well as to the date of this MD&A:

	Number of DSU's
Balance as at October 31, 2013 and 2014	_
Granted	625,000
Balances as at October 31, 2015 and January 14, 2016	625,000

# COMMITMENTS AND CONTINGENCIES

The Company expects to pay certain future costs related to its pre-clinical and clinical trials. Such payments are expected to include 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 payments over the duration of the trial will be impacted by such factors as the rate of enrollment, the location in which the patient resides and the specifics of patient insurance.

The Company expects to make future payments of approximately \$300,000 for the year ending October 31, 2016 in order to maintain and expand its patent portfolio in good standing. For the years ended October 31, 2015 and 2014, such payments amounted to \$354,571 and \$309,579, respectively.

The Company entered into a lease commitment beginning on August 1, 2015, with remaining gross payments required under the lease of approximately \$115,000 related to the rental of laboratory space over a period of two years. The lease also includes options for the Company to extend the lease for two additional one year periods.

# **RELATED PARTY TRANSACTIONS**

The key management personnel of the company are the Directors, the President and Chief Executive Officer 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 generally occurs in cash. There have been no guarantees provided or received for any related party receivables or payables. Included in accounts payable and accrued liabilities at October 31, 2015 was 2,121 due to key management personnel (2014 - 74,477).

Compensation to key management personnel for the three months ended October 31, 2015 and 2014 and for the years ended October 31, 2015 and 2014, was as follows:

	Three months ende	ed October 31,	Years ended October 31,		
(all amounts in Canadian Dollars)	2015	2014	2015	2014	
Salaries, benefits and consulting fees	\$ 127,223	\$ 67,611	\$ 391,637	\$ 372,826	
Director fees and benefits	31,225	22,776	115,895	85,314	
DSU's issued for director compensation	27,517	_	38,284	_	
Share-based compensation	43,979	(13,177)	81,750	161,251	
Total	\$ 229,944	\$ 77,210	\$ 627,566	\$ 619,391	

Key management personnel controlled approximately 2% of the issued common shares of the Company as at October 31, 2015. (2014 - 3%)

Executive officers and directors participate in the Company's 2015 Incentive Plan, so they are eligible to receive stock options and deferred share units. Executive officers also participate in the Company's health benefits plan.

# SUMMARY OF QUARTERLY RESULTS

Fiscal Year		1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter
2015	Net loss	\$630,294	\$676,212	\$666,855	\$886,116
	Net loss per share	\$ 0.00	\$ 0.01	\$ 0.00	\$ 0.01
2014	Net loss	\$594,105	\$747,935	\$725,839	\$678,180
	Net loss per share	\$ 0.00	\$ 0.01	\$ 0.01	\$  0.01

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

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

# **OFF-BALANCE SHEET ARRANGEMENTS**

We do not have any off-balance sheet arrangements.

# QUANTITATIVE & QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### Fair value

IFRS 13 *Fair Value Measurement* provides a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs are those which reflect market data obtained from independent sources, while unobservable inputs reflect the Company's assumptions with respect to how market participants would price an asset or liability. These two inputs used to measure fair value fall into the following three different levels of the fair value hierarchy:

- Level 1 Quoted prices in active markets for identical instruments that are observable.
- Level 2 Quoted prices in active markets for similar instruments; inputs other than quoted prices that are observable and derived from or corroborated by observable market data.
- Level 3 Valuations derived from valuation techniques in which one or more significant inputs are unobservable.

The hierarchy requires the use of observable market data when available.

The Company has classified its cash and marketable securities as Level 1.

Cash, marketable securities, amounts receivable, accounts payable and accrued liabilities, due within one year, are all short-term in nature and, as such, their carrying values approximate fair values.

#### Risks

We are exposed to credit risk, liquidity risk, interest rate risk and foreign currency risk. Our Board of Directors has overall responsibility for the establishment and oversight of our risk management framework. The Audit Committee is responsible for reviewing our risk management policies.

#### Credit risk

Credit risk is the risk of loss to the Company if a counterparty to a financial instrument fails to meet its contractual obligations. The Company's credit risk is primarily attributable to cash and marketable securities and there is additional risk since those financial instruments are primarily held by a single counterparty. Management believes the risk of the counterparty, a Canadian Schedule A bank, failing to meet its obligations related to the cash and marketable securities held by the Company is remote. Amounts receivable are primarily composed of amounts due from the Canadian federal government.

#### Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company is a development stage company and is reliant on external fundraising to support its operations. Once funds have been raised, the Company manages its liquidity risk by investing in cash and marketable securities to provide regular cash flow for its operations and monitoring actual and projected cash flows. As at October 31, 2015 and 2014, the Company had cash and marketable securities of \$2,880,963 and \$3,416,710, respectively which are available to settle current liabilities of \$199,850 and \$240,087, respectively. The majority of the Company's accounts payable and accrued liabilities are due within three months or less.

#### Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company holds its cash in bank accounts or guaranteed investment certificates with a fixed rate of interest and multiple maturity dates. The Company manages its interest rate risk by holding highly liquid short-term instruments and by holding its investments to a maturity date. For the years ended October 31, 2015 and 2014, the Company earned interest income of \$31,995 and \$51,128, respectively. A 1% change in the average interest rate earned for the years ended October 31, 2015 and 2014, would have a net impact on finance income of \$26,690 and \$29,529, respectively.

#### Foreign currency risk

The Company is exposed to foreign currency risk on fluctuations in foreign exchange rates for any cash, marketable securities, amounts receivable or accounts payable and accrued liabilities that are denominated in foreign currencies. The Company's foreign currency risk is primarily related to amounts denominated in United States dollars. Management believes the Company's foreign currency risk is not currently significant, since less than 0.3% (2014 - 0.1%) of the Company's assets and less than 10% (2014 - 17%) of its liabilities as at October 31, 2015 were denominated in United States dollars. There are no active operations in the United States, with the exception of patent prosecution, maintenance costs and consulting fees, which, for the years ended October 31, 2015 and 2014, were estimated to be approximately US\$415,000 and US\$400,000, respectively. Accordingly, a strengthening of the US dollar against the Canadian dollar by 1% for the years ended October 31, 2015 and 2014, would have increased the Company's net loss by approximately \$4,150 and \$4,000, respectively, assuming that all other variables remained constant.

# CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of financial statements in conformity with IFRS requires the Company to make judgements, estimates and assumptions that affect the application of accounting policies, the reported amounts of assets, liabilities and expenses, as well as the Company's ability to continue as a going concern. The estimates and assumptions made are continually evaluated and have been based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Such estimates and assumptions are inherently uncertain. Actual results could differ materially from these estimates and assumptions. Revisions to estimates are recognized in the period in which the estimate is revised and may impact future periods. A summary of the Company's significant accounting policies and estimates under IFRS is found in Note 3 of the Company's audited consolidated financial statements for the years ended October 31, 2015 and 2014.

Management has applied significant estimates and assumptions to the following:

#### Valuation of 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: option life, volatility, risk-free interest rate, forfeiture rates, stock option exercise behaviours, dividend yield and corporate performance. Changes in these assumptions affect the fair value estimate for share-based compensation. The assumptions and models used for estimating fair value for share-based payment transactions are discussed in Note 8 of the audited consolidated financial statements for the years ended October 31, 2015 and 2014.

# INTERNAL CONTROLS OVER FINANCIAL REPORTING

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

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

# CHANGES IN ACCOUNTING POLICIES

# New standards and interpretations not yet effective

Standards issued, but not yet effective up to the date of issuance of the Company's consolidated financial statements are listed below. This listing is of standards and interpretations issued, which the Company

reasonably expects may 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, 2016 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

In October 2010, the IASB published amendments to IFRS 9 *Financial Instruments* ("IFRS 9") which provides added guidance on the classification and measurement of financial liabilities. In July 2014, the IASB issued its final version of IFRS 9, which completes the classification and measurement, impairment and hedge accounting phases of the IASB's project to replace IAS 39 *Financial Instruments: Recognition and Measurement*. The final standard is mandatorily effective for annual periods beginning on or after January 1, 2018, with earlier application permitted. The Company is currently monitoring the developments of this standard and assessing the impact that the adoption of this standard may have on the consolidated financial statements.

#### IFRS 15 Revenue from Contracts with Customers

In May 2014, the IASB issued IFRS 15 *Revenue from Contracts with Customers* ("IFRS 15"), which covers principles for reporting about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. In September 2015, the IASB issued an amendment to IFRS 15 reflecting a one-year deferral of the effective date of the standard to January 1, 2018. The Company is currently monitoring the developments of this standard and assessing the impact that the adoption of this standard may have on the consolidated financial statements.

## **RISKS AND UNCERTAINTIES**

An investment in our common shares involves a high degree of risk and should be considered speculative. An investment in our common shares should only be undertaken by those persons who can afford the total loss of their investment. You should carefully consider the risks and uncertainties described below, as well as other information contained in this MD&A. The risks and uncertainties below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition and results of operations could be seriously harmed and you could lose all or part of your investment. Further, if we fail to meet the expectations of the public market in any given period, the market price of our common shares could decline. We operate in a highly competitive environment that involves significant risks and uncertainties, some of which are outside of our control.

#### **Investment Risk**

*Volatility of Share Price, Absence of Dividends and Fluctuation of Operating Results.* Market prices for the securities of biotechnology companies, including ours, have historically been highly volatile. In the year ended October 31, 2015, our common shares traded on the TSX Venture Exchange, at a high of \$0.40 and a low of \$0.13 per share (2014 – a high of \$0.34 and a low of \$0.10 per share). Factors such as fluctuation of our operating results, announcements of technological innovations, patents or new commercial products by us or our 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 our common shares. Our common shares have been subject to significant price and volume fluctuations in the future. We have not paid dividends to date and we do not expect to pay dividends in the foreseeable future.

#### **Issuer Risk**

*Early Stage Development and Scientific Uncertainty.* Our 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 will be 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 us in sufficient amounts or in a timely fashion to allow us 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 we are 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 our investment in any such products will be recovered through sales or royalties.

Additional Financing Requirements and Access to Capital. We 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 our products. We expect our current cash and marketable securities of \$2.9 million to enable us to fund our currently planned operating requirements at least into early calendar 2017. We may attempt to raise additional funds 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 us and which would foster the successful commercialization of our products.

*Dilution.* We may sell additional equity securities in future offerings, including through the sale of securities convertible into equity securities, to finance our operations, acquisitions or projects, and issue additional common shares if outstanding warrants or stock options are exercised, which may result in dilution. As of the date of this MD&A, we had 7.7 million outstanding stock options convertible into common shares with an average exercise price of \$0.20 per share, 625,000 outstanding DSU's convertible into common shares and 19.0 million outstanding warrants convertible into common shares with an average exercise price of \$0.35 per share.

Our board of directors has the authority to authorize certain offers and sales of additional securities without the vote of, or prior notice to, shareholders. Based on the need for additional capital to fund expected expenditures and growth, it is likely that we will issue additional securities to provide such capital. Such additional issuances may involve the issuance of a significant number of common shares at prices less than the current market price for our common shares.

Sales of substantial amounts of our securities, or the availability of such securities for sale, as well as the issuance of substantial amounts of our common shares upon the exercise of outstanding warrants, DSU's or stock options, could adversely affect the prevailing market prices for our securities and dilute our investors' earnings per share. A decline in the market prices of our securities could impair our ability to raise additional capital through the sale of securities should we desire to do so.

*Patents and Proprietary Technology.* Our success will depend in part on our 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 we will develop additional proprietary products that are patentable, that issued patents will provide us 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 our ability to conduct our business.

Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of our products, or design around the products patented by us. In addition, we 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 us, if at all. If we do not obtain such licenses, we could encounter delays in introducing one or more of our products to the market, while we attempt to design around such patents, or we could find that our development, manufacturing or sale of products requiring such licenses could be foreclosed. In addition, we could incur substantial costs in defending ourselves in suits brought against us on such patents or in suits where we attempt to enforce our patents against other parties.

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

*We depend heavily on the success of our Cell Pouch*<sup>TM</sup> *platform.* All of our current product candidates involve the use of our Cell Pouch<sup>TM</sup> platform and are still in preclinical or clinical development. If we are unable to commercialize our product or experience significant delays in doing so, the business may be materially harmed.

We have committed significant resources to the development of our Cell Pouch<sup>TM</sup> platform. Our ability to generate product revenues, which is not expected to occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of our Cell Pouch<sup>TM</sup> platform and related therapeutic cells.

We may expend our limited resources to pursue particular research and development opportunities and fail to capitalize on others that may be more profitable or for which there is a greater likelihood of success. Because we have limited resources, we focus our research and development programs on therapeutic cell candidates for specific indications. As a result, we may forego or delay the pursuit of opportunities for other therapeutic cell candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and therapeutic cell candidates may not yield any commercially viable products.

We have based our research and development efforts on assessing various therapeutic cells within our Cell Pouch<sup>™</sup> platform. As a result of pursuing the development of certain therapeutic cells within the Cell Pouch<sup>™</sup> platform, the Company may fail to develop other therapeutic cells or address alternate scientific approaches that could offer greater commercial potential or for which there is a greater likelihood of success.

*Dependence on Collaborative Partners, Licensors and Others.* We currently utilize technology which we have licensed and technology which has been developed by our own researchers. In particular, we are dependent upon our license to use certain technology provided under a sublicense agreement with University Health Network, dated September 9, 2015, for the development of our 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 license agreement.

Our activities will require us 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 our products. We intend to attract corporate partners and enter into additional research collaborations. There can be no assurance, however, that we will be able to establish such additional collaborations on favourable terms, if at all, or that our current or future collaborations will be successful. Failure to attract 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 we will have rights, our 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 our competitors, as a means for developing treatments for the diseases targeted by our programs.

Furthermore, we 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 us. We intend 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. We 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.

We rely and will continue to rely on third parties to conduct some portions of our preclinical and clinical development activities. Preclinical activities include proof of concept and safety studies. Clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in our relationship with third parties, or if they are unable to provide quality services in a timely manner and at a reasonable cost, our active development programs will face delays. Further, if any of these third parties fails to perform as we expect or if their work fails to meet regulatory requirements, our testing could be delayed, cancelled or rendered ineffective.

We rely on a third party contract manufacturer to manufacture our products. Health Canada and the FDA ensure the quality of products by carefully monitoring manufacturers' compliance with Good Manufacturing Practices regulations ("GMP"). Any manufacturing failures or delays or compliance issues could cause delays in the completion of our preclinical and clinical activities. There can be no assurances that our contract manufacturer will be able to meet our timetable and requirements. We have currently not contracted with alternate suppliers, in the event our contract manufacturer is unable to scale up production, or if they otherwise experience any other significant problems. If we are unable to arrange for alternative third-party manufacture of our product. Further, contract manufacturers must operate in compliance with GMP and failure to do so could result in, among other things, the disruption of our product supplies. Our dependence upon third parties for the manufacture of our products may adversely affect our profit margins and our ability to develop and deliver products on a timely and competitive basis.

*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 or any other jurisdiction. 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>TM</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 resistance 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.** We are dependent on certain members of our management and scientific staff as well as consultants and contractors, the loss of services of one or more of whom could adversely affect us. In addition, our ability to manage growth effectively will require us to continue to implement and improve our management systems and to recruit and train new employees. There can be no assurance that we will be able to successfully attract and retain skilled and experienced personnel.

*Employee misconduct or other improper activities.* We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with Health Canada or FDA regulations, provide accurate information to those agencies, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a substantial impact on our business and results of operations, including the imposition of substantial fines or other sanctions.

*Lack of Product Revenues and History of Losses.* To date, we have not recorded any revenues from the sale of cell therapy products. We expect to incur additional losses during the periods of research and development, clinical testing, and application for regulatory approval of our product candidates. For the years ended October 31, 2015 and 2014, we incurred losses of \$2.9 million and \$2.7 million, respectively and had an

accumulated deficit to October 31, 2015 of \$29.7 million. We expect to incur further losses unless and until such time as payments from corporate collaborations, product sales and/or royalty payments generate sufficient revenues to fund our continuing operations.

*Conflict of Interest.* Certain of our directors and senior officers may, from time to time, be employed by or affiliated with organizations which have entered into agreements with us. As disputes may arise between these organizations and us, or certain of these organizations may undertake or have undertaken research with our competitors, there exists the possibility for such persons to be in a position of conflict. Any decision or recommendation made by these persons involving us will be made in accordance with his or her duties and obligations to deal fairly and in good faith with us 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 we intend to market our 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 our ability to utilize our technology, thereby adversely affecting our operations. Further, there can be no assurance that our diagnostic product candidates will achieve levels of sensitivity and specificity sufficient for regulatory approval or market acceptance, or that our therapeutic product candidates prove to be safe and effective in clinical trials, or receive the requisite regulatory approval. There is no assurance that we 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 our research and development processes will involve the controlled use of hazardous materials. We are 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 our management 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, we could be held liable for damages and such liability could exceed our resources. We are not specifically insured with respect to this liability. Although our management believes that it currently complies in all material respects with applicable environmental laws and regulations, we may be required to incur significant costs to comply with environmental laws and regulations in the future. Furthermore, there can be no assurance that our operations, business or assets 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 our proposed products or technologies non-competitive, or that we 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 us, and could be more effective and less costly than the products to be developed by us. In addition, alternative forms of medical treatment may be competitive with our products.

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

*Status of Healthcare Reimbursement.* Our 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 us to realize an acceptable return on our 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 us, 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 our products. A product liability claim brought against us, or withdrawal of a product from the market, could have a material adverse effect upon us and our financial condition.

# **DIRECTORS AND OFFICERS**

Frank Holler, Chairman of the Board of Directors Jeffrey Bacha, Director James Parsons, Director Bruce Weber, Director Dr. Philip Toleikis, President, Chief Executive Officer and Director Ralph Deiterding, Chief Financial Officer

# **ADDITIONAL INFORMATION**

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