

# SERNOVA CORP.

# MANAGEMENT'S DISCUSSION AND ANALYSIS

# FOR THE THREE AND SIX MONTHS ENDED APRIL 30, 2017 AND 2016

Dated June 9, 2017

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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 and six months ended April 30, 2017 and 2016. This MD&A should be read in conjunction with the Company's unaudited interim condensed consolidated financial statements for the three and six months ended April 30, 2016 and its audited consolidated financial statements and related notes for the years ended October 31, 2016 and 2015, 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, 2016 and 2015.

All amounts are in Canadian dollars.

# 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 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;
- The initiation and completion of pre-clinical studies and clinical trials of our Cell Pouch<sup>TM</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>TM</sup> from immune attack using local immune protection such as microencapsulation or other local immune protection technologies, 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 and the intention to use human stem cell derived cells or xenogeneic cells which are considered unlimited cell sources for our Cell Pouch<sup>™</sup> for the potential treatment of chronic diseases;
- The intention to obtain 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 pharmaceutical 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 this 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 this 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.

This 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 independent Directors who are financially knowledgeable.

# ABOUT SERNOVA

Sernova Corp. is a regenerative medicine company, focused on commercializing its proprietary Cell Pouch<sup>TM</sup> and associated technologies including therapeutic cells and local immune protection. The Cell Pouch<sup>TM</sup> is a scalable, implantable, medical device, designed to create a 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 autograft (self-cells) or allograft cells (non-self, 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 microencapsulation or other local immune protection technologies being developed to create an immune privileged environment for protection of 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 into our Cell Pouch<sup>TM</sup> to treat insulin-dependent diabetes in multiple animal models, and conducted a proof of principle clinical study for the treatment of human subjects with diabetes receiving an islet transplant, protected by the standard of care antirejection drug regimen. In this study, results in a small cohort of patients have shown the Cell Pouch<sup>TM</sup> to be safe alone and when transplanted with human donor islets. The Company plans to continue clinical investigation of the Cell Pouch<sup>TM</sup> with donor islets. The Company has also secured a potential source of unlimited cells, through 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 that are related to the differentiation of stem cells into insulin producing glucose-responsive therapeutic cells developed by UHN researchers. We continue to identify additional potential sources of cells

which are not limited by donor availability through license agreements and/or partnerships. 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> in conjunction with various therapeutic cells for the treatment of chronic diseases and 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; however, we continue to seek partnerships with pharmaceutical companies to partially offset the development costs related to our products.

Our objective is to advance our medical technologies through the various stages of preclinical and clinical development required to develop a commercial product. The programs we undertake may involve third party collaborations and corporate partnerships in addition to our internal preclinical and clinical development efforts. To achieve our goals, our primary activities include the following:

 Conducting clinical trials required to gain marketing approval for the Cell Pouch<sup>™</sup> System 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 and is ongoing. The treatment consists of our proprietary Cell Pouch<sup>™</sup> transplanted with human donor islets, protected using the standard of care antirejection drug regimen, for subjects with insulin-dependent diabetes with hypoglycemia unawareness.

The Company also has a long-term goal of the treatment of diabetes using the Cell Pouch<sup>TM</sup> transplanted with locally immune protected cells from an unlimited source of cells such as glucose-responsive stem cell derived cells or xenogeneic cells and has work ongoing in these areas;

- Conducting pre-clinical research programs in other therapeutic indications for our platform Cell Pouch<sup>TM</sup> technology including: hemophilia, thyroid disease, and other chronic diseases that require a hormone, protein or other factor which is missing or in short supply in the body;
- 3. Development of various sources of therapeutic cells for transplantation within our Cell Pouch<sup>™</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;
- Identification and development of complementary technologies which may improve the safety and efficacy of cells within the Cell Pouch<sup>™</sup>, including local immune protection technologies such as microencapsulation;
- 5. Manufacturing and supply of the Cell Pouch<sup>TM</sup> and the processing and supply of therapeutic cells;
- 6. Generation and/or licensing of intellectual property; and,
- 7. Developing partnerships with pharmaceutical companies for the development of our products.

# Corporate Update for the three and six months ended April 30, 2017 and to the date of this MD&A

In October 2016, the Company entered into a collaboration with an international pharmaceutical company to study Sernova's Cell Pouch<sup>TM</sup> in a large animal diabetes model. The collaboration involves the study of safety, survival and efficacy of locally immune protected therapeutic cells in our Cell Pouch<sup>TM</sup> in proof of concept studies with the goal to establish a future development and commercial partnership. The preclinical safety and efficacy studies are ongoing. This agreement included 50% cost sharing for the agreed studies. The first payment in the amount of US\$185,778 (\$249,611) was received in December 2016.

We made significant progress toward initiating clinical development with our Cell Pouch<sup>™</sup> in the United States in collaboration with JDRF. In November 2016, we retained the services of CTI Clinical Trial and Consulting Services ("CTI"), on regulatory matters respecting Sernova's Cell Pouch System<sup>™</sup>. CTI is an expert in cell therapy, and immunology. CTI is supporting Sernova's clinical trial regulatory processes including submission of Sernova's regulatory package with the FDA. Pending clearance by FDA and the Institutional Review Board, the clinical trial will be initiated with enrolment and treatment of patients.

In November 2016, we announced that we have retained Mackie Research Capital Corporation ("Mackie") to provide market making services to the company in compliance with the guidelines of the TSX Venture Exchange (the "TSXV").

In May 2017, we announced that we received TSX Venture Exchange acceptance, to extend the expiry date of 5,745,633 share purchase warrants that are exercisable to purchase up to 5,745,633 common shares of Sernova at an exercise price of \$0.30 per share, from May 8, 2017 to November 8, 2017. The Company also obtained approval from the TSV Venture Exchange to extend the expiry date of 3,043,256 share purchase warrants that are exercisable to purchase up to 3,043,256 common shares of Sernova at an exercise price of \$0.30 per share, from May 14, 2017 to November 14, 2017. All other terms of the Warrants will remain unchanged, including the exercise period, as extended, being subject to abridgement on 30 days notice to holders in the event that the twenty-day volume weighted price of the Company's shares exceeds \$0.50.

Our advanced diabetes glucose responsive insulin producing stem cell derived program with our inlicensed technology from UHN is advancing with completion of technical transfer of the manufacturing process to a commercial manufacturing facility in preparation for next step preclinical studies.

#### Research and Development Outlook for the 2017 Calendar Year

Our product development program for 2017 includes the following:

- Initiate clinical trials of our Cell Pouch<sup>TM</sup> in the United States in collaboration with JDRF for patients with hypoglycemia unawareness using human donor islets and a standard of care antirejection drug regimen to further study the safety and efficacy of the device and islets.
- Continued clinical evaluation of the Cell Pouch<sup>TM</sup> in patients with insulin-dependent diabetes who have received an islet transplant;
- Conduct IND-enabling cell production and preclinical studies for treatment of hemophilia A consisting of factor VIII releasing therapeutic cells transplanted within Sernova's Cell Pouch<sup>™</sup>;
- Conduct IND-enabling preclinical studies for treatment of hypo-thyroid disease consisting of thyroid hormone releasing tissue transplanted within Sernova's Cell Pouch<sup>™</sup>;

- Production of human stem cell derived cells for diabetes and *in vivo* proof of principle assessment of these differentiated human stem cells for their safety and efficacy within Sernova's Cell Pouch<sup>TM</sup> for the treatment of insulin-dependent diabetes;
- Assessment of novel microencapsulation technologies within the Cell Pouch<sup>TM</sup> cells, to further develop and advance Sernova's therapeutic vision for diabetes of a product consisting of locally immune protected therapeutic cells within the Cell Pouch<sup>TM</sup>; and,
- Continue to collaborate with pharmaceutical companies to assess safety and efficacy of our combined technologies in preclinical studies for potential negotiation of a licensing arrangement and commercial development partnership for our hemophilia and diabetes programs.

# Sernova's Cell Pouch System<sup>TM</sup>

The Cell Pouch<sup>TM</sup> was uniquely designed and patented to take into consideration the biological requirements of therapeutic cells. Our research demonstrated that a tissue matrix rich in microvessels develops within the Cell Pouch<sup>TM</sup> environment when implanted subcutaneously or in other locations prior to transplantation of therapeutic cells. We believe the Cell Pouch<sup>TM</sup> provides a unique and ideal environment consisting of vascularized tissue chambers for the placement of therapeutic cells for the potential treatment of diabetes, hemophilia and other diseases. In long-term pre-clinical evaluation, the Cell Pouch<sup>TM</sup> has been shown to maintain a stable, vascularized tissue environment prior to placement of these transplanted therapeutic cells. 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>.

An independent pre-clinical study published in the journal Transplantation (Transplantation 2015 Nov: 99 (11):2294-300) demonstrated that the Cell Pouch<sup>TM</sup> with islets provided insulin independence for the length of the study (100 days) in a small animal model of diabetes using a marginal transplanted islet mass where over 95% of the animals achieved insulin independence. 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 under consideration for further human clinical evaluation to achieve glucose control in patients with diabetes.

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. We believe the Cell Pouch<sup>TM</sup> technologies achieve this ideal islet/microvessel connection through alteration of the subcutaneous environment and should allow for improved glucose control. Our studies have shown that islets transplanted into the Cell Pouch<sup>TM</sup> can control glucose levels in small and large animal models of diabetes over extended periods.

# Clinical Development of the Cell Pouch<sup>™</sup> in Diabetes

Sernova's lead program is the clinical development of the Cell Pouch<sup>TM</sup> for treatment of patients with insulindependent diabetes. A proof of concept, first in human clinical study to evaluate the Cell Pouch<sup>TM</sup> with human donor islets, in insulin-dependent diabetic subjects with hypoglycemia unawareness who are receiving islet transplantation, has demonstrated initial safety data for the Cell Pouch<sup>TM</sup> alone and with transplanted islets and survival of the well-vascularized islets within the Cell Pouch<sup>TM</sup>. Furthermore, histological analysis demonstrated that islets transplanted into Sernova's Cell Pouch<sup>TM</sup> are be able to make insulin, glucagon and

somatostatin, key hormones in the control of blood glucose levels. With these encouraging results, the Company was awarded a US\$2.45 million (approximately \$3.2 million) grant under an agreement with JDRF. The grant will support expansion of our Cell Pouch<sup>TM</sup> diabetes clinical trials program in the United States.

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 inhibit 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 diabetesinduced 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 ("IBMIR"), which may damage and destroy a significant proportion of the islets infused into the portal vein. Due to IBMIR and other factors, up to three pancreata are required to treat a single patient and achieve a reduction in insulin injections using the Edmonton Protocol. 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 glucoseresponsive insulin producing stem cell derived cells or xenogeneic cells being developed to overcome the limited supply of donor islet cells, as these cell technologies must be transplanted into an implantable and retrievable medical device for safety reasons.

We believe IBMIR may also be mitigated, using the Cell Pouch<sup>TM</sup>. The therapeutic cells live within a tissue matrix surrounded by microvessels similar to the islets' natural microenvironment in the pancreas rather than being bathed in a constant flow of blood with immune reactive cells. 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. This could potentially enable patients with diabetes to be treated with fewer donor pancreata than are currently being used in the Edmonton Protocol.

The Cell Pouch<sup>™</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 from infusion of cells into the portal vein such as portal vein hypertension, thrombosis, and liver steatosis (fatty liver), along with the costs of treating them, will be eliminated as cells will not be placed in this location.

Our current Cell Pouch<sup>™</sup> clinical trials employ standard systemic immune protection regimens; however, the Cell Pouch<sup>™</sup> may also accommodate local immune protection of therapeutic cells.. Local immune protection of islets within the cell pouch using technologies 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 immune protection may provide a safer environment for the transplanted islets. The Cell Pouch<sup>™</sup> is believed to be an ideal environment to support microencapsulated cells as the encapsulated cells are housed within the vascularized tissue matrix allowing vessels to be in very close contact with the islets. This has been demonstrated in our preclinical studies of encapsulated 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 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. Sernova believes it has the only such

device technology of its kind in which therapeutic cells have been 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>TM</sup>, which is allowed to incorporate with tissue and microvessels prior to transplantation of donor human islets. In this first-in-human study, to prevent islet graft rejection, patients have been treated with the state of the art standard of care Alemtuzumab-induction protocol and provided maintenance immunosuppression.

Our results have shown the following important findings:

- First, biocompatibility and a positive safety profile of the Cell Pouch<sup>™</sup> have been shown in the patients. Safety is the primary endpoint of the clinical study;
- Second, the islets within the Cell Pouch<sup>™</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 for a range of diseases.

Based on these initial findings, we have established a collaboration through a grant from JDRF to continue human clinical evaluation of the Cell Pouch<sup>TM</sup> with human donor islets in the United States. In this regard, the company is actively working with CTI as its clinical research organization.

# 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 are evaluating Sernova's Cell Pouch<sup>TM</sup> for the treatment of patients with hemophilia A.

One such 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 constant release of factor VIII. Initial proof of concept studies have been conducted by Sernova and a European team of experts formed the HemAcure consortium ("The Consortium"). The 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 hypo-thyroid disease.

# Local Immune Protection & Other Complementary Technologies

To broaden Sernova's local immune protection technologies, we continue to evaluate additional advanced technologies such as microencapsulation to reduce or eliminate the need for antirejection medications. 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. We believe this will enable 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 therapeutic cells derived from human stem cells or derived from xenogeneic sources, depending on the clinical indication under evaluation. 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 UHN to gain access to worldwide, exclusive rights to certain patent-pending technologies for the advancement of glucose-responsive insulin-producing stem cells for treatment of patients with insulin-dependent diabetes. Process development and robust cell-production processes will provide a high standard of production of cells which consistently meets strict release criteria for evaluation of these cells in Sernova's Cell Pouch<sup>TM</sup>.

Sernova is also committed to working with pharmaceutical and academic partners to evaluate various insulinproducing cell technologies using different approaches, with the goal of combining Sernova and partner technologies to create best in class products. In this regard, Sernova has signed a number of agreements to test and evaluate several insulin-producing cell technologies in our Cell Pouch<sup>TM</sup>. The Company entered into a collaboration with an international pharmaceutical company to study Sernova's Cell Pouch<sup>TM</sup> in a large animal diabetes model. The collaboration involves the study of safety, survival and efficacy of locally immune protected therapeutic cells in our Cell Pouch<sup>TM</sup> in proof of concept studies with the goal to establish a future development and commercial partnership. Sernova plans to continue to develop multiple collaborations with pharmaceutical companies for its diabetes and hemophilia indications for establishment of potential long-term licensing and co-development relationships.

# Manufacturing

Our contract manufacturing process has enabled manufacture of both our Cell Pouch<sup>™</sup> and mini-Cell Pouch<sup>™</sup> technologies for preclinical and clinical evaluation in a number of clinical indications. Device specifications have been set, a semi-automated manufacturing process developed and the product manufactured, packaged and sterilized under strict regulatory guidelines (ISO 13485) 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 demonstrating stability of the product and packaging over this time-period.

#### **Intellectual Property**

Our patent portfolio currently consists of 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.

#### **RESULTS OF OPERATIONS**

# **Selected Financial Information**

Selected financial information from the statements of loss and comprehensive loss for the three and six months ended April 30, 2017 and 2016, were as follows:

	Three months ended April 30,		Six months ended April 30.	
	2017	2016	2017	2016
Research and development expenses	\$ 389,425	\$ 386,865	\$ 452,947	\$ 775,348
General and administrative expenses	285,577	266,461	541,799	546,964
Loss and comprehensive loss for the period	\$ 638,432	\$ 691,917	\$ 955,955	\$ 1,368,367

For the three months ended April 30, 2017, the Company recorded a loss of \$638,432, compared to \$691,917 in the prior year. The reduced loss was attributable to an increase in research and development contributions, and foreign exchange gains for the period.

For the six months ended April 30, 2017, the Company recorded a loss of \$955,955, compared to \$1,368,367 in the prior year. The reduced loss was primarily due to increased research and development contributions. In December 2016, the Company received \$249,611 from a collaboration with an international pharmaceutical company. The Company also recognized \$225,816 of funding from the European Commission's Horizon 2020 program due to expenditures incurred during the period which were covered by the grant.

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

Research and development expenditures for the three and six months ended April 30, 2017 and 2016, were as follows:

	Three months ended April 30,		Six months ended April 30	
	2017	2016	2017	2016
Employee costs, supplies and contract payments	\$ 441,191	\$ 313,214	\$ 735,203	\$ 694,838
Manufacturing costs	29,028	-	29,028	-
Patent fees and costs	51,827	31,922	83,612	83,711
Depreciation of property and equipment	6,460	1,775	12,920	3,552
Share-based compensation	50,020	79,403	119,509	122,892
Contributions and tax credits	(189,101)	(39,449)	(527,325)	(129,645)
Total	\$ 389,425	\$ 386,865	\$ 452,947	\$ 775,348

Total research and development expenses, for the three months ended April 30, 2017, increased by \$2,560 compared to the equivalent period of the prior fiscal year. Excluding the impact of funding received, research and development expenses amounted to \$578,526 during the three months ended April 30, 2017, an increase of \$152,212. Employee costs, supplies and contract payments, for the three months ended April 30, 2017 increased by \$127,977 compared to the equivalent period of the prior fiscal year. The increase is primarily a combination of higher research and development laboratory supplies and accruals for employee costs. During the three

months ended April 30, 2017 the Company incurred \$29,028 in consulting fees regarding Sernova's Cell Pouch<sup>™</sup> manufacturing processes related to Sernova's preclinical and clinical programs. Patent fees and costs increased by \$19,905 due to increased patent development costs and maintenance fees. Depreciation of property and equipment increased due to the purchase of laboratory equipment in the first quarter of fiscal 2017. Share-based compensation for the three months ended April 30, 2017, decreased by \$29,383, due to the higher costs associated with the initial vesting of the DSU's in the same period of the prior year. Contributions and tax credits increased by \$149,652 mostly attributable to funding from the European Commission's Horizon 2020 program which has been recognized during the period.

Total research and development expenses, for the six months ended April 30, 2017, decreased by \$322,401 compared to the equivalent period of the prior fiscal year however, excluding the impact of funding received, research and development expenses increased by \$75,279. Employee costs, supplies and contract payments, for the six months ended April 30, 2017, increased by \$40,365, compared to the equivalent period of the prior fiscal year. The increase is primarily a combination of higher research and development laboratory supplies and accruals for employee costs. The Company incurred \$29,028 in the six months ended April 30, 2017 in consulting fees regarding Sernova's Cell Pouch<sup>™</sup> manufacturing processes related to Sernova's preclinical and clinical programs. Depreciation of property and equipment increased due to the purchase of laboratory equipment in the six months ended April 30, 2017. Contributions and tax credits increased by \$397,680, primarily due to the payment received in December 2016 of \$249,611 from a collaboration with an international pharmaceutical company. The Company also recognized \$225,816 of funding from the European Commission's Horizon 2020 program during the six month period ending April 30, 2017, an increase of \$148,294 over the same period in the prior year.

#### General and administrative expenses

	Three months ended April 30,		Six months ended April 3	
	2017	2016	2017	2016
Employee costs and consulting fees	\$ 85,662	\$ 47,874	\$ 145,421	\$ 102,798
Professional fees	25,136	17,910	41,048	44,965
Director fees and benefits	26,494	24,984	51,479	50,796
Investor relations	59,726	40,802	111,355	109,132
Travel and other costs	42,118	53,513	87,559	97,933
Depreciation of property and equipment	79	115	158	230
DSU's issued for director compensation	21,680	33,626	48,719	61,143
Share-based compensation	24,682	47,637	56,060	79,967
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Total	\$ 285,577	\$ 266,461	\$ 541,799	\$ 546,964

General and administrative costs for the three and six months ended April 30, 2017 and 2016, were as follows:

Total general and administrative expenses, for the three months ended April 30, 2017 increased by \$19,116, as compared to the same period in the prior year. Employee costs and consulting fees increased by \$37,788 due to financial advisory fees incurred. Professional fees increased by \$7,226 which relates to increased legal fees. Investor relations increased by \$18,924 due to increased activity in the current quarter. Travel and other costs decreased by \$11,395. DSU's issued for director compensation and share-based compensation for the three months ended April 30, 2017, decreased due to the higher costs associated with the initial vesting of the DSU's in the same period of the prior year.

Total general and administrative expenses, for the six months ended April 30, 2017, decreased by \$5,165, as compared to the same period in the prior year. Employee costs and consulting fees increased by \$42,623 due to financial advisory fees incurred. Travel and other costs decreased by \$10,374 mostly attributable to lower air travel costs. DSU's issued for director compensation and share-based compensation for the three months ended April 30, 2017, decreased due to the higher costs associated with the initial vesting of the DSU's in the same period of the prior year.

## Other items

	Three months ended April 30,		Six months ended April 30,	
	2017	2016	2017	2016
Finance income	\$ (12,278)	\$ (5,127)	\$ (31,282)	\$ (11,657)
Finance costs	4,077	2,731	8,042	4,081
Foreign exchange (gain) loss	(28,370)	40,987	(15,551)	53,631
Net Finance (Income) Costs	\$ (36,571)	\$ 38,591	\$ (38,791)	\$ 46,055

# **Finance income**

Finance income, represented primarily by interest income earned on the Company's cash and marketable securities, was \$12,278 and \$31,282 for the three and six months ended April 30, 2017, compared to \$5,127 and \$11,357 for the same periods in the prior year. The increase is related to higher interest income from increased average balances of cash and marketable securities due to the Company's June 2016 private placement, consortium payments and grants received.

## **Finance costs**

Finance costs, represented primarily by bank charges were \$4,077 and \$8,042 for the three and six months ended April 30, 2017, compared to \$2,731 and \$4,081 for the same periods in the prior year. The increase is due to a change in the Company's investment accounts to highly liquid short term instruments.

#### Foreign exchange gains and losses

Foreign exchange gains were \$28,370 and \$15,551 for the three and six months ended April 30, 2017. The gain for the three months ended April 30, 2017 was attributable to earnings on US bank accounts due to the strengthening US dollar in the period. For the six months ended April 30, 2017, the gain was offset by the loss on the payment received in December 2016 of US \$185,778 from a collaboration with an international pharmaceutical company. The prior year loss was incurred from a €566,507 payment related to the European Commission's Horizon 2020 grant, as well as the depreciation of the US dollar compared to the Canadian dollar up to 30 April 2016.

#### **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, 2016 and 2015, for further details related to the Company's income tax position.

# LIQUIDITY AND CAPITAL RESOURCES

Selected financial information from the statements of financial position as at April 30, 2017 and October 31, 2016, were as follows:

As At	April 30,	October 31,
	2017	2016
Cash and marketable securities	\$ 5,517,147	\$ 5,899,451
Total assets	5,822,693	6,225,244
Current liabilities	704,891	846,274
Share capital, warrants and contributed surplus	38,226,483	37,531,696
Deficit	\$(33,108,681)	\$(32,152,726)

As at April 30, 2017, the Company had cash and marketable securities of \$5.5 million compared to \$5.9 million as at October 31, 2016. 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**

For the six months ended April 30, 2017, 2,695,000 stock options were exercised for gross cash proceeds of \$470,500. During the same period 330,000 stock options expired.

For the six months ended April 30, 2016, 1,208,750 stock options were exercised for gross cash proceeds of \$187,812.

In December 2015, the Company was awarded a  $\notin$ 5.6 million (approximately \$8.5 million) non-dilutive grant by the European Commission's Horizon 2020 program, as part of a consortium. The Company expects to receive total funding in the amount of  $\notin$ 944,178 (approximately \$1.4 million), representing its portion of the grant, based upon the terms of the grant agreement. In January 2016, the Company received an initial funding payment related to the grant in the amount of  $\notin$ 566,507 (\$873,213).

In July 2016, the Company was awarded a US\$2.45 million (approximately \$3.2 million) grant under an agreement with JDRF. The grant supports a human clinical trial of Sernova's Cell Pouch<sup>™</sup> technologies for treatment of hypoglycemia unawareness patients with severe type 1 diabetes at a major transplantation center in the United States. Pursuant to the agreement with JDRF, the Company has committed to perform certain clinical trial activities and to use commercially reasonable efforts to introduce a diabetes product into a major market. Further, the agreement creates a commitment for repayment by the Company following successful commercialization of a diabetes product. In August 2016, the Company received an initial funding payment from JDRF in the amount of US\$367,768 (\$480,783) as per the terms under the agreement.

In October 2016, the Company entered into a collaboration with an international pharmaceutical company regarding a material transfer agreement to study Sernova's Cell Pouch safety, survival and efficacy of locally immune protected therapeutic cells in a large animal diabetes model. This agreement included 50% cost sharing for the agreed studies. The first payment in the amount of US\$185,778 (\$249,611) was received by the Company in December 2016.

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 fiscal 2017 will increase over the previous year. Our actual cash requirements for fiscal 2017 will depend on the clinical, pre-clinical, and collaboration activities that we ultimately undertake and the ability to secure partners, and non-dilutive funding in the form of government grants.

The interim condensed consolidated financial statements have been prepared using IFRS that are applicable to a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business for the foreseeable future. The Company has experienced operating losses and cash outflows from operations since 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 from the most recent year ended October 31, 2016 to the date of this MD&A:

	Number of
Balance as at October 31, 2016	Common Shares 156,679,498
Shares issued on the exercise of stock options	2,695,000
Balance as at April 30, 2017 and the date of this MD&A	159,374,498

#### Warrants

The following table reflects the changes in the number of issued warrants from the most recent year ended October 31, 2016 to the date of this MD&A:

Balance as at October 31, 2016 and April 30, 2017	Number of Warrants 26,216,362	Weighted Average Exercise Price \$ 0.33	
Expired	(105,623)	0.33	
Balance as at the date of this MD&A	26,110,739	\$ 0.33	

The warrants outstanding as at April 30, 2017 are described in Note 7 to the unaudited interim condensed consolidated financial statements for the three and six months ended April 30, 2017 and 2016.

# 2015 Incentive Plan

The Company has a 2015 Incentive Plan (the "Plan"), the terms of which were most recently approved by shareholders of the Company on April 26, 2017. 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 7 to the unaudited interim condensed consolidated financial statements for the three and six months ended April 30, 2017 and 2016.

The following table reflects the changes in the number of issued stock options from the most recent year ended October 31, 2016 to the date of this MD&A:

	Number of Options	Weighted Average Exercise Price
Balance as at October 31, 2016	10,436,100	\$ 0.19
Granted	250,000	0.26
Cancelled/forfeited	(1,177,500)	0.22
Exercised	(2,695,000)	0.17
Balance as at April 30, 2017 and the date of this MD&A	6,813,600	\$ 0.22

The following table reflects the changes in the number of issued deferred share units (DSU's) from the most recent year ended October 31, 2016 to the date of this MD&A:

	Number of DSU's
Balance as at October 31, 2016 and at April 30, 2017 and the date of this MD&A	1,075,000

# 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.

By participating in the HemAcure consortium and accepting grant funding, the Company has committed to perform certain product development activities, as outlined in the grant agreement with the European Commission's Horizon 2020 program. While it is anticipated that the funding that has been received and further funding expected to be received by the Company will cover most of the costs expected to be incurred related to the planned product development activities, the actual amount of effort and the related costs may differ from what was expected and may be more than the maximum amounts the European Commission has agreed to cover. Accordingly, any excess costs required to complete the activities would become the

Company's responsibility. Under the grant agreement, consortium members may also shift the funding allocated under the grant between members in order to cover excess costs, so the Company may ultimately receive a different amount of funding than currently expected. The project is subject to a number of risks and uncertainties, and in particular the risks outlined under the risk factor titled '*Dependence on collaborative partners, licensors, contract manufacturer and others*', please refer to the risk factors discussed elsewhere in this MD&A and included in the annual MD&A for the years ended October 31, 2016 and 2015.

In July 2016, the Company was awarded a US\$2.45 million (approximately \$3.2 million) grant under an agreement with JDRF. The grant supports a human clinical trial of Sernova's Cell Pouch<sup>TM</sup> for treatment of patients with type 1 diabetes at a major transplantation center in the United States. In August 2016, the Company received an initial funding payment from JDRF in the amount of US\$367,768 (\$480,783) as per the terms under the agreement. Pursuant to the agreement with JDRF, the Company has committed to perform certain clinical trial activities and to use commercially reasonable efforts to introduce a diabetes product into a major market. Further, the agreement creates an obligation for the Company to pay royalties to JDRF on any future net sales received by the Company from a diabetes product or in certain future license or disposition transactions limited to a certain percentage of funds received over time up to a prescribed limit related to the amount of the grant funding.

In October 2016, the Company entered into a collaboration with an international pharmaceutical company regarding a material transfer agreement to study Sernova's Cell Pouch safety, survival and efficacy of locally immune protected therapeutic cells in a large animal diabetes model. Pursuant to the collaboration agreement, the Company has committed to perform certain pre-clinical activities. This agreement included 50% cost sharing for the agreed studies. The first reimbursement payment in the amount of US\$185,778 (\$249,611) was received by the Company in December 2016.

The Company entered into a two year lease commitment on August 1, 2015. Remaining gross payments required under this lease is approximately \$17,000 related to the rental of laboratory space payable in the 2017 fiscal year. The lease also included options for the Company to extend the lease for two additional one year periods. In April 2017, the Company exercised the option to extend the lease for one year. Gross payments required under the extended period amount to approximately \$70,000. An option to extend the lease for one further year still remains.

# **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 April 30, 2017 was \$4,782 due to key management personnel (October 31, 2016 – \$3,564).

Compensation to key management personnel for the three and six months ended April 30, 2017 and 2016, was as follows:

	Three months ended April 30,		Six months ended April 3	
	2017	2016	2017	2016
Salaries, benefits and consulting fees	\$ 115,178	\$ 113,528	\$ 211,513	\$ 270,561
Director fees and benefits	24,984	24,984	49,969	50,796
DSU's issued for director compensation	21,680	33,626	48,719	61,143
Share-based compensation	17,174	58,554	41,215	100,499
Total	\$ 179,016	\$ 230,692	\$ 351,416	\$ 482,999

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

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

Fiscal Year		1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter
2017	Net loss	\$ 317,524	\$ 638,432		
	Net loss per share	\$ 0.00	\$ 0.00		
2016	Net loss	\$ 676,450	\$ 691,917	\$ 964,947	\$ 166,308
	Net loss per share	\$ 0.00	\$ 0.01	\$ 0.01	\$ 0.00
2015	Net loss	\$ 630,294	\$ 676,212	\$ 666,855	\$ 886,116
	Net loss per share	\$ 0.00	\$ 0.01	\$ 0.00	\$ 0.01

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.

# 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, 2016 and 2015.

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, 2016 and 2015.

# INTERNAL CONTROLS OVER FINANCIAL REPORTING

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

As a venture issuer, the Company is not required to certify the design and evaluation of the Company's disclosure controls and procedure ("DC&P") and internal controls over financial reporting ("ICFR"), and as such has not completed such an evaluation. Investors should be aware that inherent limitations on the ability of 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 has not yet assessed the impact of this standard on the interim condensed 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 has not yet assessed the impact of this standard on the interim condensed consolidated financial statements.

#### IFRS 16 Leases

In January 2016, the IASB issued IFRS 16 *Leases* ("IFRS 16"), its new lease standard that requires lessees to recognize assets and liabilities for most leases on the statement of financial position. Lessees applying IFRS 16 will have a single accounting model for all leases, with certain exemptions. Lessor accounting is substantially unchanged. The new standard will be effective from January 1, 2019 with limited early application permitted. The Company has not yet assessed the impact of this standard on the interim condensed 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.

The following is a summary list of risks and uncertainties for the Company. For a detailed description of each risk and uncertainty, please refer to the annual Management's Discussion and Analysis for the years ended October 31, 2016 and 2015 as filed on SEDAR.

# **Investment Risk**

• Volatility of share price, absence of dividends and fluctuation of operating results.

# **Issuer Risk**

- Early stage development and scientific uncertainty.
- Additional financing requirements and access to capital.
- Dilution.
- Patents and proprietary technology.
- We depend heavily on the success of our Cell Pouch<sup>TM</sup> platform.
- 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.
- Dependence on collaborative partners, licensors, contract manufacturer and others.
- Clinical trials are long, expensive and uncertain processes and Health Canada or the FDA may ultimately not approve any of our products. We may never develop any commercial applications or products that generate revenues.
- *Reliance on key personnel.*
- Employee misconduct or other improper activities.
- Lack of product revenues and history of losses.
- Conflict of interest.

#### **Industry Risk**

- *Government regulations.*
- Hazardous materials and environmental matters.
- *Rapid technological change.*
- Competition.
- Status of healthcare reimbursement.
- *Potential product liability.*

#### HemAcure consortium: forward looking statements

*The HemAcure Consortium* is the name of the consortium developing a product for hemophilia A. This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 667421. The consortium members include the University Hospital Wurzburg (Coordinating Institute), Integrierte Management Systeme IMS e.K., Universita del Piemonte Orientale "Amedeo Avogadro," Loughborough University, GABO:mi Gesellschaft für Ablauforganisation: milliarium mbH & Co. and Sernova Corp. The main objective of the HemAcure project is to develop and refine the tools and technologies for a novel ex vivo prepared cell based therapy within Sernova's prevascularized Cell Pouch to treat this bleeding disorder that should ultimately lead to improved quality of life of the patients.

The European Commission's Horizon 2020 program had awarded a Euro 5.6M (\$8.5M CAD) grant to the HemAcure Consortium 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. In February 2016, the Company also posted a link on Twitter.com to an article by Richard Mills entitled "Regenerative Medicine's Fountain of Youth" that appears on the website Aheadoftheherd.com. The Company has paid an annual fee to Richard Mills to advertise the Company on the Aheadoftheherd.com website and to link articles and news releases about the Company on the Aheadoftheherd.com website.

In the news releases and the article, it is stated that a potential product from the HemAcure Consortium would be disruptive to the current standard of care, which involves regular infusions (approximately 3 times per week) of factor VIII and that the current market is estimated at approximately \$5 billion per year. In addition, the news releases and the article included the following forward looking statements (the "HemAcure FLI") with respect to the product being developed by the HemAcure Consortium that the Company is a part of:

- With successful safety and efficacy leading to regulatory approval to sell, a GMP clinical grade Factor VIII releasing therapeutic cell product in combination with Sernova's Cell Pouch<sup>™</sup> could take over the current market and significantly improve patient quality of life, likely commanding a premium price; and
- Future revenues from this product stand to be significant, providing product diversification and more than a single billion dollar market.

Readers are cautioned that actual results may vary from the HemAcure FLI and should not to place undue reliance on those forward looking statements, which speak only as of the date initially disclosed and the date of this MD&A.

The following are the material factors or assumptions used to develop the HemAcure FLI:

• The global hemophilia market was valued at USD 9.3 billion in 2015 and is expected to grow at a CAGR of 5.6% over the forecast period. Hemophilia is a rare genetic bleeding disorder estimated to have affected about 400,000 people globally as of 2013. According to the World Federation of Hemophilia (WFH), the disease is more prevalent in males and about 1 in 5,000 neonates suffer from type A.\*

\*Hemophilia Market Analysis by Type (Hemophilia A, Hemophilia B, Hemophilia C), By Treatment (On-demand, Prophylaxis), By Therapy (Replacement Therapy, Immune Tolerance Induction [ITI] Therapy, Gene Therapy), And Segment Forecasts to 2024. August, 2016 Grandview Research Report. Report ID: 978-1-68038-989-0.

The following are the material risk factors that could cause actual results to differ materially from the HemAcure FLI.

- The HemAcure consortium may not be able to develop a GMP source of Factor VIII cells
- The preclinical safety and efficacy of Factor VIII producing cells in the Cell Pouch<sup>™</sup> may not be sufficient to warrant clinical evaluation
- Clinical studies may not prove the combination of the Cell Pouch<sup>TM</sup> and Factor VIII producing cells to be safe and efficacious and thus may not result in a commercial product.

#### **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 Scott Langille, Chief Financial Officer

#### **ADDITIONAL INFORMATION**

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