

## MANAGEMENT'S DISCUSSION AND ANALYSIS

# FOR THE THREE MONTHS ENDED JANUARY 31, 2016 AND 2015

Dated March 10, 2016

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## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2016 AND 2015

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 January 31, 2016 and 2015. This MD&A should be read in conjunction with the Company's unaudited interim condensed consolidated financial statements for the three months ended January 31, 2016 and 2015 and its audited consolidated financial statements and related notes 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 March 10, 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>TM</sup> from immune attack using local immune protection such as microencapsulation or Sertolin<sup>TM</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™ for the potential treatment of chronic diseases;
- The intention to receive regulatory approval and commercialize the Cell Pouch™ for the treatment of insulin-dependent diabetes and other potential indications such as hemophilia and thyroid disease;

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- 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 has 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 development 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, which can then be immune-protected within the Cell Pouch<sup>TM</sup> as a product to enable potential treatment of

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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. The programs we undertake may involve third party collaborations and corporate partnerships in addition to our internal clinical development efforts. To achieve our goals, our primary activities include the following:

- 1. Conducting clinical trials required to gain marketing approval for the Cell Pouch<sup>TM</sup> device in countries that have a significant market opportunity. Our first 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>TM</sup> and therapeutic cells, was initiated in Canada. That clinical trial is evaluating the Cell Pouch<sup>TM</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>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;
- 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:
- 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;
- 4. 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;
- 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 three months ended January 31, 2016 and to the date of this MD&A

In December 2015, the European Commission's Horizon 2020 program awarded a €5.6 million (approximately \$8.5 million) non-dilutive grant to the HemAcure consortium, which consists of Sernova Corp and five European academic and private partners. The purpose is to advance the development of a GMP clinical grade factor VIII releasing therapeutic cell product in combination with Sernova's Cell Pouch™ 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

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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. In January 2016, the Company received an initial funding payment related to the grant in the amount of €566,607 (approximately \$873,000).

In January 2016, we entered into a service agreement with the Centre for Commercialization of Regenerative Medicine (CCRM) to establish, optimize and validate Sernova's licensed technology for creating stem cell derived therapeutic cells that produce insulin and are glucose responsive. Partnership with CCRM's expertise in developing production processes for cellular therapies is an important step in our plan to commercialize an unlimited supply of glucose responsive, insulin producing cells for the Cell Pouch System<sup>TM</sup> in order to be able to address the broader population of patients with insulin dependent diabetes.

In February 2016, we were selected as a member of the "2016 TSX Venture 50" and ranked fourth in the Life Sciences and Clean Technologies category based on a number of key measures of market performance, including market capitalization growth, share price appreciation and trading volume. The TSX ranked companies from among the 1,791 companies listed on the TSX Venture Exchange as of December 31, 2015.

## 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>TM</sup> in patients with insulin-dependent diabetes receiving an islet transplant;
- 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>TM</sup>;
- Initiation of product development for thyroid disease using Sernova's Cell Pouch™ technologies in preparation for human evaluation in a clinical trial;
- 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>TM</sup> for the treatment of insulin-dependent diabetes; and,
- Development and assessment of complementary local immune protection technologies, 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.

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

Sernova's lead program is the clinical development of the Cell Pouch<sup>TM</sup> for treatment of patients with insulindependent diabetes. 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 has demonstrated safety of 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, the islets were shown in histological analysis to be able to make insulin, glucagon and somatostatin, key hormones in the control of blood glucose levels.

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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.

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. The Cell Pouch<sup>TM</sup> is believed to provide an ideal environment for 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. We believe 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 therapeutic cells within the Cell Pouch<sup>TM</sup> may function with systemic immune protection, it may also 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.

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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. 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>TM</sup>, which is allowed to incorporate with tissue and microvessels prior to transplantation of donor human islets. In this "first-inhuman" 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, our results have shown the following important findings:

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

Recently, an independent pre-clinical study conducted in a collaboration with Dr. James Shapiro, 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.<sup>1</sup>

## **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.

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™ for constant 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

<sup>&</sup>lt;sup>1</sup> Transplantation. 2015 Nov;99 (11):2294-300. This study shows the efficiency of Sernova's Cell Pouch™ technologies and 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.

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(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>TM</sup> as part of a regulatory package in preparation for human clinical testing.

New Cell Pouch<sup>TM</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**

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>TM</sup> may provide a means to contain therapeutic cells within the Cell Pouch<sup>TM</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 insulindependent diabetes. A tech-transfer, and cell-production plan has been initiated 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 have been 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.

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## **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>TM</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>TM</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 expand Sernova's product development portfolio, and intellectual property. Sernova is actively pursuing corporate partnerships 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 January 31, 2016 and 2015, were as follows:

	Three months end	Three months ended January 31,	
(all amounts in Canadian Dollars)	2016	2015	
Research and development expenses	\$ 388,483	\$ 496,481	
General and administrative expenses	280,503	142,163	
Loss and comprehensive loss for the period	\$ 676,450	\$ 630,294	

For the three months ended January 31, 2016, the Company recorded a loss of \$676,450 or \$0.00 per share, compared to \$630,294 or \$0.00 per share in the prior year, an increase of \$46,156 or 7.3%. The higher loss in the three months ended January 31, 2016 over the comparable period in the prior fiscal year, was a result of an increase in general and administrative expenses that was partially offset by a decrease in research and development expenses.

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

Research and development expenditures for the three months ended January 31, 2016 and 2015, were as follows:

	Three months end	ed January 31,
(all amounts in Canadian Dollars)	2016	
Salaries, supplies and contract payments	\$ 381,624	\$ 230,277
Patent fees and costs	51,789	23,619
Depreciation of property and equipment	1,777	1,189
Amortization of intangible assets	_	224,425
Share-based compensation	43,489	16,971
Contributions and tax credits	(90,196)	_
Total	\$ 388,483	\$ 496,481

Total research and development expenses, for the three months ended January 31, 2016, decreased by \$107,998 compared to the equivalent period of the prior fiscal year, primarily due to an increase in contributions and tax credits during the three months ended January 31, 2016. Excluding the impact of depreciation of property and equipment, amortization of intangible assets and share-based compensation, all non-cash items, research and development expenses increased by \$89,321 during the three months ended January 31, 2016 compared to the equivalent period in the prior fiscal year. Salaries, supplies and contract payments, for the three months ended January 31, 2016, increased by \$151,347, 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 January 31, 2016, compared to the same period in the previous fiscal year. Patent fees and costs, for the three months ended January 31, 2016, increased by \$28,170, compared to the equivalent period of the prior fiscal year due to increased patent prosecution and maintenance payments in the three months ended January 31, 2016. Amortization of intangible assets, for the three months ended January 31, 2015, decreased by \$224,425, 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 January 31, 2016, increased by \$26,518, 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. Contributions and tax credits, for the three months ended January 31, 2016, increased by \$90,196, compared to the equivalent period of the prior fiscal year, due to tax credits and support from the European Commission's Horizon 2020 grant recognized during the three months ended January 31, 2016, where no tax credits or grant amounts were recognized in the same period of 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 January 31, 2016 and 2015, were as follows:

	Three months ende	Three months ended January 31,		
(all amounts in Canadian Dollars)	2016	2015		
Salaries, benefits and consulting fees	\$ 54,924	\$ 17,967		
Professional fees	27,055	23,481		
Director fees and benefits	25,812	28,438		
Investor relations	68,330	41,985		
Travel and other costs	44,420	22,522		
Depreciation of property and equipment	115	31		
DSU's issued for director compensation	27,517	_		
Share-based compensation	32,330	7,739		
Total	\$ 280,503	\$ 142,163		

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 three months ended January 31, 2016, increased by \$138,340, as compared to the same period in the prior year. Salaries, benefits and consulting fees, for the three months ended January 31, 2016, increased by \$36,957 compared to the same period in the prior year, due to increased salaries and benefits, which were partially offset by a decrease in consulting fees in the three months ended January 31, 2016. Investor relations expenses, for the three months ended January 31, 2016, increased by \$26,345, compared to the same period in the prior year, primarily due to increased costs related to additional investor relations activities in the United States during the three months ended January 31, 2016. Travel and other costs, for the three months ended January 31, 2016, increased by \$21,898, as compared to the same period in the prior year, due to an increased level of travel in the three months ended January 31, 2016 compared to the same period in the prior fiscal year. Deferred share units (DSU's) issued for director's compensation were first granted after January 31, 2015, resulting in an expense of \$27,517 for the three months ended January 31, 2016. Share-based compensation for the three months ended January 31, 2016, increased by \$24,591, 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.

#### Finance income

Finance income, represented primarily by interest income earned on the Company's marketable securities, was \$6,530, during the three months ended January 31, 2016, compared to \$8,986, for the same period in the prior fiscal year. The decrease was primarily due to a decrease in the average balances of cash and marketable securities in the three months ended January 31, 2016. In addition, a general decrease in the prevailing interest rates paid on marketable securities in the three months ended January 31, 2016 also contributed to the decrease.

#### Finance costs

Finance costs, represented primarily by bank charges and foreign exchange losses, were \$13,994, during the three months ended January 31, 2016, compared to \$636, for the same period in the prior fiscal year. The increase was primarily due to a foreign exchange loss incurred from a €566,507 payment the Company

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received related to the European Commission's Horizon 2020 grant late in the three months ended January 31, 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, 2015 and 2014, 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 January 31, 2016 and October 31, 2015, were as follows:

As At	January 31,	October 31,
	2016	2015
Cash and marketable securities	\$ 3,575,783	\$ 2,880,963
Total assets	3,751,663	3,153,299
Current liabilities	1,183,516	199,850
Share capital, warrants and contributed		
surplus	32,897,701	32,606,553
Deficit	\$(30,329,554)	\$(29,653,104)

As at January 31, 2016, the Company had cash and marketable securities of \$3.6 million compared to \$2.9 million as at October 31, 2015. 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 three months ended January 31, 2016, 1,208,750 stock options were exercised for gross cash proceeds of \$187,812.

For the three months ended January 31, 2015, there were no share capital transactions.

In December 2015, the Company was awarded a  $\in$ 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  $\in$ 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  $\in$ 566,507 (approximately \$873,000).

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

## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2016 AND 2015

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 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, 2015 to the date of this MD&A:

	Number of
	Common Shares
Balance as at October 31, 2015	141,821,720
Shares issued on the exercise of stock options	1,208,750
Balance as at January 31, 2016 and March 10, 2016	143,030,470

#### **Performance Escrow Shares**

Included in issued common shares and representing escrow shares as at January 31, 2016 are 3,472,500 (October 31, 2015 - 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.

## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2016 AND 2015

#### Warrants

The following table reflects the changes in the number of issued warrants from the most recent year ended October 31, 2015 to the date of this MD&A:

	Number of Warrants	Weighted Average Exercise Price
Balance as at October 31, 2015 and January 31, 2016	19,026,040	\$ 0.35
Expired	(10,000,000)	0.40
Balance as at March 10, 2015	9,026,040	\$ 0.30

The warrants outstanding as at January 31, 2016 are described in Note 8 to the unaudited interim condensed consolidated financial statements for the three months ended January 31, 2016 and 2015.

#### 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 unaudited interim condensed consolidated financial statements for the three months ended January 31, 2016 and 2015.

The following table reflects the changes in the number of issued stock options from the most recent year ended October 31, 2015 to the date of this MD&A:

	Number of Options	Weighted Average
		Exercise Price
Balance as at October 31, 2015	8,873,750	\$ 0.19
Exercised	(1,208,750)	0.16
Balance as at January 31, 2016 and March 10, 2016	7,665,000	\$ 0.20

There were no changes in the number of issued deferred share units (DSU's) from the most recent year ended October 31, 2015 to the date of this MD&A:

	Number of DSU's
Balance as at October 31, 2015, January 31, 2016 and March 10, 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.

## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2016 AND 2015

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 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, 2015 and 2014.

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 three months ended January 31, 2016 and 2015, such payments amounted to \$51,789 and \$39,344, respectively.

The Company entered into a lease commitment beginning on August 1, 2015, with remaining gross payments required under the lease of approximately \$100,000 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 January 31, 2016 was \$45,975 due to key management personnel (October 31, 2015 – \$2,121).

Compensation to key management personnel for the three months ended January 31, 2016 and 2015, was as follows:

Three months ended January 31,	
2016	2015
\$ 157,033	\$ 86,625
25,812	28,438
27,517	_
41,945	7,739
\$ 252 307	\$ 122,802
	2016 \$ 157,033 25,812 27,517

## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2016 AND 2015

Key management personnel controlled approximately 2% of the issued common shares of the Company as at January 31, 2016 (October 31, 2015 – 2%).

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		1 <sup>st</sup> Quarter	2 <sup>nd</sup> Quarter	3 <sup>rd</sup> Quarter	4 <sup>th</sup> Quarter
Year					
2016	Net loss	\$676,450			
	Net loss per share	\$ 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
2014	Net loss	\$594,105	\$747,935	\$725,839	\$678,180
	Net loss per share	\$ 0.00	\$ 0.01	\$ 0.01	\$ 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, 2015 and 2014.

## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 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, 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

## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2016 AND 2015

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.

#### 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 begun the process of evaluating the impact of this standard 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.

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, 2015 and 2014 as filed on SEDAR.

## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE MONTHS ENDED JANUARY 31, 2016 AND 2015

#### **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 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.

#### **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.