



## **SERNOVA CORP.**

### **MANAGEMENT'S DISCUSSION AND ANALYSIS**

**FOR THE THREE MONTHS ENDED  
JANUARY 31, 2018 AND 2017**

Dated March 29, 2018

700 Collip Circle  
The Stiller Centre, Suite 114  
London, ON N6G 4X8  
[www.sernova.com](http://www.sernova.com)

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The following management's discussion and analysis ("MD&A") explains the variations in the consolidated operating results, financial position and cash flows of Sernova Corp. ("Sernova", the "Company", "We", "Us" or "Our") for the three months ended January 31, 2018 and 2017. 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, 2018 and 2017 and its audited consolidated financial statements and related notes for the years ended October 31, 2017 and 2016, 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, 2017 and 2016. All amounts are in Canadian dollars.

The information in this report is dated as of March 29, 2018.

### **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;
- The availability of various forms of financing;
- The initiation and completion of pre-clinical studies and clinical trials of our Cell Pouch™ for the treatment of insulin-dependent diabetes and other diseases;
- The expected benefit of the Cell Pouch™ with therapeutic cells;
- The intention to protect therapeutic cells within the Cell Pouch™ 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™ for the potential treatment of chronic diseases;
- Sernova's intentions to secure academic and pharmaceutical collaborations and to develop and implement partnering strategies;
- The intention to obtain regulatory approval and commercialize the Cell Pouch™ for the treatment of insulin-dependent diabetes and other potential indications such as hemophilia and thyroid disease;
- The expected benefit of the European Commission's Horizon 2020 grant for our hemophilia program;

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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;
- Intentions regarding the development and protection of Sernova's intellectual property; and
- General business and economic events.

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 developing and commercializing its proprietary Cell Pouch™ and associated technologies including therapeutic cells and local immune protection. The Cell Pouch™ 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. Based 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™ 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™ 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™ 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™ to be safe alone and when transplanted with human donor islets. The Company plans to continue clinical investigation of the Cell Pouch™ with donor islets. Related to our strategy of obtaining unlimited supplies of cells for our therapeutic applications, the Company 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

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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 Product Development**

Our research and development efforts are focused principally on the development of the Cell Pouch™ 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™ from immune system attack.

Our research and product development strategy 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:

1. Conducting clinical trials required to gain marketing approval for the Cell Pouch™ 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™ and therapeutic cells, was initiated in Canada and is ongoing. The treatment consists of our proprietary Cell Pouch™ 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™ 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;
2. Conducting pre-clinical research programs in other therapeutic indications for our platform Cell Pouch™ 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™, 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;
4. Identification and development of complementary technologies which may improve the safety and efficacy of cells within the Cell Pouch™, including local immune protection technologies such as microencapsulation;
5. Manufacturing and supply of the Cell Pouch™ and the processing and supply of therapeutic cells;
6. Generation and/or licensing of intellectual property; and,
7. Establishing partnerships with medical device and/or pharmaceutical companies for the development of our products.

#### **Corporate Update**

In February 2018, Sernova announced that continuous glucose monitoring systems (CGM) (Medtronic Minimed, Northridge, CA) will be provided to patients in Sernova's US regenerative medicine clinical trial of its Cell Pouch™. It is believed that continuous glucose monitoring of patients may be an important and sensitive method to closely track the function of the transplanted therapeutic cells within the Cell Pouch™.

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CGM will be used to track the function of the transplanted cells at multiple time points following transplantation into the Cell Pouch.

In December 2017, Sernova announced it received US Food and Drug Administration (FDA) notice of allowance for its IND (Investigational New Drug) for a new human clinical trial with the Cell Pouch System™ (CPS) in the United States. Sernova plans to initiate the new clinical trial under this US IND to further investigate the Cell Pouch for treatment of type 1 diabetes (T1D) in individuals with hypoglycemia unawareness. The trial is a Phase I/II prospective single arm study of islets transplanted into patients having previously received the implanted Cell Pouch™. The primary objective of the study is to demonstrate safety and tolerability of islet transplantation into the Cell Pouch and the secondary objective is to assess efficacy through a series of defined measures. Patient enrolment is set to begin following institutional review board clearance.

In November 2017, Sernova received a second payment of non-dilutive funds from the European Commission in the amount of €226,602.60 (\$331,770 CDN). The payment is to continue funding activities related to the European Union Horizon 2020 HemAcure Consortium's development of a Factor VIII releasing therapeutic cell product combined with Sernova's Cell Pouch™ to treat severe hemophilia A, a serious genetic bleeding disorder caused by missing or defective Factor VIII in the blood stream.

#### **Research and Development Outlook for the 2018 Calendar Year**

Our research and development program for 2018 includes the following:

- Initiate a clinical trial of our Cell Pouch™ in collaboration with JDRF under our recently cleared US IND 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;
- Clinical evaluation of the Cell Pouch™ for insulin-dependent diabetes who have received an islet transplant;
- In coordination with the EU Horizon 2020 HemAcure Consortium. conduct cell production and preclinical studies for treatment of hemophilia A consisting of factor VIII releasing therapeutic cells transplanted within Sernova's Cell Pouch™;
- Conduct preclinical studies for treatment of hypo-thyroid disease consisting of thyroid hormone releasing tissue transplanted within Sernova's Cell Pouch™;
- 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™ for the treatment of insulin-dependent diabetes;
- Assessment of novel microencapsulation technologies within the Cell Pouch™ 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™; 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.

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#### **Sernova's Cell Pouch System™**

The Cell Pouch™ has been uniquely designed and patented to take into consideration the biological requirements of therapeutic cells. Our research demonstrates that a tissue matrix rich in microvessels develops within the Cell Pouch™ environment when implanted subcutaneously or in other locations prior to transplantation of therapeutic cells. We believe the Cell Pouch™ 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™ has been shown to maintain a stable, vascularized tissue environment prior to placement of these transplanted therapeutic cells. We believe these conditions are important 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™ is biocompatible and safe. Long-term studies in multiple animal models have demonstrated that the islets become well-supported with microvessels following islet transplantation into the Cell Pouch™.

Benefits of the Cell Pouch™ are anticipated to be enhanced long-term therapeutic cell survival and function. It is important for therapeutic cells to have close contact with microvessels. For diabetes, as an example, this enables islets 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™ technologies achieve this ideal therapeutic/microvessel connection through alteration of the subcutaneous environment and may allow for improved efficacy. For example, our studies have shown that islets transplanted into the Cell Pouch™ can control glucose levels in small and large animal models of diabetes over extended periods and we believe this may also be applicable to other therapeutic cellular applications.

#### **Clinical Development of the Cell Pouch™ in Diabetes**

Sernova's lead program is the clinical development of the Cell Pouch™ for treatment of patients with insulin-dependent diabetes. A proof of concept, first in human clinical study to evaluate the Cell Pouch™ 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™ alone and with transplanted islets and survival of the well-vascularized islets within the Cell Pouch™.

In summary our human clinical results have shown the following important findings:

- First, biocompatibility and a positive safety profile of the Cell Pouch™ have been shown in these patients. Safety is the primary endpoint of the clinical study; and
- Second, the islets within the Cell Pouch™, as shown by independent 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 an important step forward in the regenerative medicine field.

Based on these encouraging results, the Company was awarded up to US\$2.45 million (approximately \$3.2 million) grant under an agreement with JDRF. With the recent clearance of Sernova's IND by FDA, the grant will support our Cell Pouch™ diabetes clinical trial in the United States.

The Edmonton Protocol (Portal Vein Transplant) 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

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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 ("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 glucose-responsive 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™. The therapeutic cells live within a tissue matrix surrounded by microvessels similar to the islets' natural microenvironment in the pancreas rather than being subjected to 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™ 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.

An independent pre-clinical study published in the journal *Transplantation* (*Transplantation* 2015 Nov; 99 (11):2294-300) demonstrated that the Cell Pouch™ 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™ may require a smaller than anticipated number of cells to achieve efficacy, one of the parameters being investigated for further human clinical evaluation to achieve glucose control in patients with diabetes.

Our current Cell Pouch™ clinical trials employ standard systemic immune protection regimens; however, the Cell Pouch™ 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™ 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 as demonstrated in our preclinical studies of encapsulated islets.

Finally, the Cell Pouch™ 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™ 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.

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Table I. Potential Benefits of the Cell Pouch™ Islet Transplant over the Portal Vein Islet Transplant

Characteristics	Cell Pouch™	Portal Vein Transplant
Reduced Islet Mass	yes	no
Tissue matrix to house islets	yes	no
Vascularized Islets	yes	no
Retrievable site	yes	no
Future stem cell technologies	yes	no
Minimally invasive site	yes	no
Elimination of liver associated toxicities	yes	no
Elimination of IBMIR	yes	no

In our human clinical trial, subjects have been implanted with the Cell Pouch™, which is allowed to incorporate with tissue and microvessels prior to transplantation of donor human islets. In this first-in-human study in a small group of patients, 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.

Based on the encouraging results from this study and our other preclinical studies, we believe Sernova's Cell Pouch™ may form a suitable environment for the survival and function of multiple types of therapeutic cells for a range of diseases.

With these initial findings, we have established a collaboration through a grant from JDRF to continue human clinical evaluation of the Cell Pouch™ with human donor islets in the United States. Furthermore, we have filed documents to initiate a human clinical study in the United States and have received FDA clearance to begin this study. The study will be initiated following institutional review board clearance, and patients are planned to be enrolled in the study during 2018.

#### **Developing the Cell Pouch™ for Hemophilia A**

We believe the Cell Pouch™ has multiple potential therapeutic applications. As part of this strategy to expand Cell Pouch™ clinical applications, we are evaluating Sernova's Cell Pouch™ 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™ 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 (Good Manufacturing Practice) human cell product suitable for human clinical testing for the completion of safety and efficacy studies in the Cell Pouch™ as part of a regulatory package in preparation for human clinical testing. To date, significant progress has been made in the development of this product. Blood outgrowth endothelial cells have been successfully isolated from patients with hemophilia A. The cells have been successfully transduced with the gene for Factor VIII. The cells have been scaled up to produce a significant number of cells for preclinical testing. In addition, the cells have been shown to produce Factor VIII on a constant basis and have been demonstrated to survive and engraft in the Cell Pouch™ when placed in a mouse model of hemophilia.



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#### **Developing the Cell Pouch™ for Additional 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**

We continue to evaluate microencapsulation to reduce or eliminate the need for antirejection medications. We believe that microencapsulation of therapeutic cells within the Cell Pouch™ may provide a means to contain therapeutic cells within the Cell Pouch™ 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 are expected to provide a high standard of production of cells which consistently meets strict release criteria for evaluation of these cells in Sernova's Cell Pouch™.

Sernova is also committed to working with pharmaceutical and academic partners to evaluate various insulin-producing 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™. The Company entered into a collaboration with an international pharmaceutical company to study Sernova's Cell Pouch™ 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™ 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 manufacturer has successfully cGMP manufactured both our Cell Pouch™ and mini-Cell Pouch™ technologies for preclinical and clinical evaluation. In order to complete the manufacturing, device specifications have been set, a semi-automated manufacturing process developed and the product manufactured, packaged and sterilized under strict regulatory guidelines suitable for testing in clinical trials in North America and Europe. Sterilization verification studies were completed and the product previously released for testing in our human clinical trial in Canada with Sernova's ITA (Investigational Testing Authorization) under the jurisdiction of Health Canada. A two-year packaging and product stability study has also been successfully completed demonstrating stability of the product and packaging over this time-period.

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**Intellectual Property**

Our patent portfolio currently consists of issued and pending patents in eight families covering our enabling platforms in important markets in North America, Europe and Asia. We strive to obtain broad claims in our patents, including exclusivity of our Cell Pouch™ device and related technologies in combination with a wide range of therapeutic cell technologies including glucose-responsive insulin producing stem cell derived cells and for the treatment of a number of chronic diseases, and therefore, we intend to continue to expand our patent and licensing portfolio, through inventions developed internally as well as through strategic in-licensing, to maximize the commercial potential for our platform technologies.

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**RESULTS OF OPERATIONS****Selected Financial Information**

Selected financial information from the statements of loss and comprehensive loss for the three months ended January 31, 2018 and 2017, were as follows:

	Three months ended January 31,	
	2018	2017
Research and development expenses	\$ 497,006	\$ 63,522
General and administrative expenses	\$ 272,187	\$ 256,221
Net loss and comprehensive loss for the period	\$ 769,193	\$ 317,524

For the three months ended January 31, 2018, the Company recorded a loss of \$769,193. The increased loss was due to increased research and development costs relating primarily to manufacturing expenses and European patent related fees.

**Research and Development Expenses**

Research and development expenditures for the three months ended January 31, 2018 and 2017, were as follows:

	Three months ended January 31,	
	2018	2017
Salaries, supplies and contract payments	\$ 340,335	\$ 294,012
Manufacturing costs	211,074	-
Patent fees and costs	135,325	31,785
Depreciation of property and equipment	15,315	6,460
Share-based compensation	84,188	69,488
	786,237	401,745
Contributions and tax credits	(289,231)	(338,223)
Total	\$ 497,006	\$ 63,522

For the three months ended January 31, 2018, the Company incurred total research and development expenses of \$497,006, an increase of \$433,484 compared to the same period in the prior year. Excluding the impact of funding received, research and development expenses amounted to \$786,237 for the three months ended January 31, 2018, an increase of \$384,492 compared to the same period in the prior year.

Salaries, supplies and contract payments increased by \$46,323 due to the increased purchase of research supplies. During the three months ended January 31, 2018 the Company incurred \$211,074 for materials and consulting fees regarding Sernova's Cell Pouch™ manufacturing processes related to Sernova's preclinical and clinical programs. Patent fees and costs increased by \$103,540 due to higher European patent related expenses. Depreciation of property and equipment increased due to the purchase of laboratory and manufacturing equipment. Contributions and tax credits decreased by \$48,992. Prior year contributions included the recognition of the HemAcure

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consortium funds for the period, as well as a \$249,611 collaboration payment with an international pharmaceutical company. Current year contributions were comprised only of the HemAcure consortium funds.

**General and administrative expenses**

General and administrative costs for the three months ended January 31, 2018 and 2017, were as follows:

	Three months ended January 31,	
	2018	2017
Salaries, benefits and consulting fees	\$ 62,438	\$ 59,759
Professional fees	24,270	15,912
Director fees and benefits	25,496	24,984
Investor relations	46,459	51,629
Travel and other costs	57,154	45,441
Depreciation of property and equipment	538	79
DSUs issued for director compensation	14,660	27,039
Share-based compensation	41,142	31,378
Total	\$ 272,187	\$ 256,221

Total general and administrative expenses, for the three months ended January 31, 2018, increased by \$15,966, as compared to the same period in the prior year.

**Other items**

	Three months ended January 31,	
	2018	2017
Finance income	\$ (9,375)	\$ (19,004)
Finance costs	3,359	3,966
Foreign exchange loss	3,178	12,819
Total	(\$ 2,838)	(\$ 2,219)

**Finance income**

Finance income, represented primarily by interest income earned on the Company's cash and marketable securities, was \$9,375 during the three ended January 31, 2018, compared to \$19,004 for the same period in the prior fiscal year. The decrease resulted from lower average balances of cash and marketable securities compared to the prior period.

**Foreign exchange losses**

Foreign exchange losses were \$3,178, for the three months ended January 31, 2018 compared to \$12,819 for the same period in the prior fiscal year. The prior year loss related to a US\$185,778 (\$249,611) collaboration payment from an international pharmaceutical company in respect of a 50% cost sharing study.

**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

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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 11 to the Company's audited consolidated financial statements for the years ended October 31, 2017 and 2016, for further details related to the Company's income tax position.

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**LIQUIDITY AND CAPITAL RESOURCES**

Selected financial information from the statements of financial position as at January 31, 2018 and October 31, 2017, were as follows:

As at	January 31, 2018	October 31, 2017
Cash and marketable securities	\$ 3,289,270	\$ 3,631,887
Total assets	3,764,612	4,551,518
Current liabilities	567,457	901,066
Share capital, warrants and contributed surplus	38,755,715	38,442,657
Deficit	\$(35,558,560)	\$(34,792,205)

As at January 31, 2018, the Company had cash and marketable securities of \$3.3 million compared to \$3.6 million as at October 31, 2017. 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, 2018, 53,125 stock options were exercised for gross cash proceeds of \$10,078 and 465,600 warrants were exercised for gross cash proceeds of \$162,960. During the same period 676,875 stock options expired and 8,788,889 warrants expired. For the three months ended January 31, 2017, there were no share capital transactions.

Historically, funding requirements have been met through the issuance of common shares from treasury and common share purchase warrants and stock options 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 2018 will increase over the previous year. Our actual cash requirements for fiscal 2018 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.

**SERNOVA CORP.**

## MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE MONTHS ENDED JANUARY 31, 2018 AND 2017

**Common Shares**

The following table reflects the changes in the number of issued common shares from the most recent year ended October 31, 2017 to the date of this MD&A:

	Number of Common Shares
Balance as at October 31, 2017	159,374,498
Shares issued on the exercise of stock options	53,125
Shares issued on the exercise of warrants	465,600
Balance as at January 31, 2018 and the date of this MD&A	159,893,223

**Warrants**

The following table reflects the changes in the number of issued warrants from the most recent year ended October 31, 2017 to the date of this MD&A:

	Number of Warrants	Weighted Average Exercise Price
Balance as at October 31, 2017	26,110,739	\$ 0.33
Expired	(8,788,889)	0.30
Exercised	(465,600)	0.35
Balance as at January 31, 2018 and the date of this MD&A	16,856,250	\$ 0.35

The warrants outstanding as at January 31, 2018 are described in Note 7 to the unaudited interim condensed consolidated financial statements for the three months ended January 31, 2018 and 2017.

**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 ("DSUs"). 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 months ended January 31, 2018 and 2017.

The following table reflects the changes in the number of issued stock options from the most recent year ended October 31, 2017 to the date of this MD&A:

	Number of Options	Weighted Average Exercise Price
Balance as at October 31, 2017	10,548,600	\$ 0.23
Cancelled/forfeited	(676,875)	0.24
Exercised	(53,125)	0.19
Balance as at January 31, 2018 and the date of this MD&A	9,818,600	\$ 0.23

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The following table reflects the changes in the number of issued deferred share units (DSUs) from the most recent year ended October 31, 2017 to the date of this MD&A:

	Number of DSUs
Balance as at October 31, 2017 and January 31, 2018	1,314,778
Balance as at the date of this MD&A	1,314,778

On August 14, 2017, Sernova's Board of Directors also approved an amendment to the Company's Option Plan & Deferred Share Unit Plan (the "Amended Plan") to increase the number of DSUs available by 660,222 to a maximum of 1,975,000. These additional DSUs were conditionally approved and granted subject to the Company obtaining shareholder approval and TSX Venture Exchange approval ("Exchange approval"). Subsequently, on March 19, 2018, the Board approved two further amendments to the Incentive Plan, subject to shareholder and Exchange approval, being: (a) an increase to 15% of the rolling number maximum of Common Shares available for reserve under the Incentive Plan for exercise of Options pursuant to the Option Plan component of the Incentive Plan; and (b) a further amendment to the DSU Plan component of the Incentive Plan to further increase the number of DSUs available by an additional 2,821,797 DSUs to a maximum fixed number total of 4,796,797 DSUs. The new maximum fixed number total of 4,796,797 DSUs represents 3% of the Common Shares at the date hereof.

No additional options or DSUs were granted post the financial year ended October 31, 2017 and to the date of this MD&A.

## 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.

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™ for treatment of



## SERNOVA CORP.

### MANAGEMENT'S DISCUSSION AND ANALYSIS

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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. In November 2017, the Company received an interim payment in the amount of €226,603 (\$331,770). 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. A payment in the amount of US\$185,778 (\$249,611) was received by the Company in December 2016.

The Company entered into a three year lease effective September 1, 2017. Notwithstanding the term, the Company has the right to terminate the lease after the first anniversary by providing 90 days' written notice. As at October 31, 2018 gross minimum payments amounted to \$122,595.

### 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, 2018 was \$73,695 due to key management personnel (October 31, 2017 – \$64,520).

Compensation to key management personnel for the three months ended October 31, 2017 and 2016, was as follows:

	Three months ended January 31,	
	2018	2017
Salaries, benefits and consulting fees	\$ 103,896	\$ 96,336
Director fees and benefits	25,496	24,985
DSU's issued for director compensation	14,660	27,039
Share-based compensation	56,875	34,797
Total	\$ 200,927	\$ 183,157

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.

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## MANAGEMENT'S DISCUSSION AND ANALYSIS

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**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
2018	Net loss	\$ 766,355			
	Net loss per share	\$ 0.00			
2017	Net loss	\$ 317,524	\$ 638,431	\$ 705,793	\$ 977,731
	Net loss per share	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.01
2016	Net loss	\$ 676,450	\$ 691,917	\$ 964,947	\$ 166,308
	Net loss per share	\$ 0.00	\$ 0.01	\$ 0.01	\$ 0.00

The higher loss in the first quarter of 2018 is reflective of the Company's continued investment in manufacturing expenses and patent developments.

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, 2017 and 2016.

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 behaviors, 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

## **SERNOVA CORP.**

### **MANAGEMENT'S DISCUSSION AND ANALYSIS**

**FOR THE THREE MONTHS ENDED JANUARY 31, 2018 AND 2017**

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share-based payment transactions are discussed in Note 7 of the audited consolidated financial statements for the years ended October 31, 2017 and 2016.

#### **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 required to be applied for years beginning on or after January 1, 2018. The Company has assessed there is no impact from the amendment of this standard on the Company's consolidated financial statements, and accordingly these interim condensed financial statements have been prepared in accordance with the July 2014 version of IFRS 9 Financial Instruments.

##### *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. The new standard is required to be applied for years beginning on or after January 1, 2018.

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The Company has assessed there is no impact of this standard on the Company's consolidated financial statements, and accordingly these interim condensed financial statements have been prepared in accordance with IFRS 15 Revenue from Contracts with Customers.

*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 is currently monitoring the development of this standard and assessing the impact that adoption of this standard may have on the consolidated financial statements.

## **SERNOVA CORP.**

### **MANAGEMENT'S DISCUSSION AND ANALYSIS**

**FOR THE THREE MONTHS ENDED JANUARY 31, 2018 AND 2017**

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#### **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 listed 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, 2017 and 2016 as filed on SEDAR.

#### **Investment Risk**

- *Volatility of share price, absence of dividends and fluctuation of operating results.*
- *Dilution.*

#### **Reliance on Third Parties for Supply and Manufacture of Products**

#### **Issuer Risk**

- *Early stage development and scientific uncertainty.*
- *We depend heavily on the success of our Cell Pouch™ platform.*
- *HemAcure consortium: forward looking statements. 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.*
- *Additional financing requirements and access to capital.*
- *We heavily rely on the capabilities and experience of our key executives and scientists and the loss of any of them could affect our ability to develop our products.*
- *Clinical trials are long, expensive and uncertain processes and Health Canada, FDA, European Union or other regulatory jurisdictions may ultimately not approve any of our products. We may never develop any commercial applications or products that generate revenues.*
- *Patents and proprietary technology.*
- *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.*
- *Employee misconduct or other improper activities.*
- *Lack of product revenues and history of losses.*
- *Conflict of interest.*
- *We are likely a "passive foreign investment company", which may have U.S. federal income tax consequences for U.S. shareholders.*
- *It may be difficult for non-Canadian investors to obtain and enforce judgements against us because of our Canadian incorporation and presence.*

## **SERNOVA CORP.**

### **MANAGEMENT'S DISCUSSION AND ANALYSIS**

**FOR THE THREE MONTHS ENDED JANUARY 31, 2018 AND 2017**

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- *As a foreign private issuer, we are not subject to certain United States securities law disclosure requirements that apply to a domestic United States issuer, which may limit the information which would be publically available to our shareholders.*

#### **Industry Risk**

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

#### **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](http://www.sedar.com).