Sernova Company Overview

Founded: *2006,* ***TSX(V)*** *"**SVA.V**" ;* *www.sernova.com*

Sernova Corp.
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Sernova Corp is a clinical stage company, developing disruptive platform technologies to treat chronic diseases through a regenerative medicine approach. Sernova's primary focus is in developing products for the treatment of patients with insulin-dependent (TI) diabetes, haemophilia A and Thyroid disease.

Sernova's novel approach uses therapeutic cells placed into an implanted medical device to produce proteins or hormones which are in short supply or missing from the body due to the underlying disease state. The ***Cell Pouch System™***, is an implantable, scalable medical device about the size of a business card which provides a natural "organ-like" environment for the long term survival and function of therapeutic cells such as insulin producing islets to treat diabetes. The ***Therapeutic Cells*** placed into the device may be natural (human) donor cells, or cells that can be a source to treat millions of patients including stem cell derived insulin responsive cells or xenogeneic cells. Sernova uses proprietary ***local immune protection technologies*** which protect therapeutic cells within the Cell Pouch™ from immune system attack reducing or eliminating the need for daily anti-rejection drugs. Sernova's approach is designed to make future therapeutic cell replacement a simple outpatient procedure that can be performed in virtually any hospital setting. Using a medical device and therapeutic cell strategy to treat chronic diseases, Sernova is positioned for significant revenue upon commercialization of its "disruptive paradigm-shifting" platform technology.

Sernova's team is focused on development of the Cell Pouch System™ for diabetes to treat both Type-1 and Type-2 patients who become insulin dependent –representing a treatable population of an estimated 40M patients worldwide currently taking insulin. Sernova is also focused on development of the Cell Pouch System™ for the treatment of Hemophilia A through use of corrected patient's cells placed in the Cell Pouch™ which is then expected to release Factor VIII at a constant rate.

TECHNOLOGY HIGHLIGHTS

- **The Standard of Care** for patients with reduced or missing critical hormones or proteins such as insulin is often monitoring blood levels and injecting these proteins multiple times a day with a consequence of poor compliance and serious side effects resulting in over $150B/yr hospital costs for diabetes alone. Cell therapy is an alternative for patients with chronic diseases; however, there is no currently approved device to house and protect these cells in the body and no method to make the therapy a simple outpatient procedure. Instead, often cells are injected multiple times into blood vessels in an extremely expensive (>$100,000) and risky procedure, where many cells die through blood-derived inflammation and clotting, resulting in the need for repeat operations. Hence, the current standard of care for local cell therapy is limited by expensive procedures, poor cell survival and inappropriate delivery coupled with a lack of donors.
- **Sernova's Cell Pouch System™** is a versatile, scalable implantable medical device made of materials approved for permanent use in the body, designed by biomedical engineers and biologists. Placed under the skin or in other locations, it develops organ-like characteristics (including vascularization) for survival and long term function of therapeutic cells. A natural environment where therapeutic cells are housed within a tissue matrix, rich in microvessels is expected to conserve cell number, and promote natural function - increasing cell survival, while significantly increasing the number of treatable patients beyond those with severe disease.
- **Sernova's Therapeutic Cell** technologies involve the use of natural donor cells, stem cell derived insulin responsive cells or xenogeneic cells to replace cells in the body that no longer produce the therapeutic proteins.
- **Sernova's Local Immune Protection Technologies** placed within the Cell Pouch™ with therapeutic cells is expected to eliminate the need for systemically administered toxic and expensive anti-rejection drugs ($10-15,000/yr).

FIRST THERAPEUTIC APPLICATION - DIABETES

The Cell Pouch™ has been contract manufactured in accordance with the strict guidelines of ISO13485, as mandated by the FDA. In preclinical safety and efficacy studies, the Cell Pouch™ with islets has been shown to be safe and to control sugar levels in small (isograft – similar cell transplants) and large animal transplantation models of diabetes including an autograft model (self-islets are

placed into the Cell Pouch™) and an allograft model (donor islets are placed into the Cell Pouch™). Sernova's technologies have been independently proven under collaboration at the University of Alberta in a marginal islet mass study showing that a small dose of islets can make diabetic animals insulin independent at the 100 day time point. Several of Sernova's important preclinical studies have been funded in part by agencies such as the National Research Council (IRAP) of Canada. In addition to these studies, the Cell Pouch™ has been shown to be biocompatible in a series of FDA mandated preclinical studies (ISO10993).

Sernova Corp., received Health Canada Approval to conduct a Phase I/II human clinical trial assessing the safety and efficacy of Sernova's Cell Pouch™ with transplanted insulin-producing islets in patients with insulin-dependent diabetes. The primary endpoint of safety and biocompatibility has been demonstrated. Results have been presented at the International Pancreas and Islet Transplantation Association and at the 2015 American Diabetes Association Meeting. The Company is preparing for a U.S. clinical study of the Cell Pouch for diabetes at a major transplantation center.

ADDITIONAL PRODUCT OPPORTUNITIES/PARTNERING/M&A

While in this initial clinical study, subjects receive the latest antirejection medications to protect the islets, Sernova plans to conduct future clinical trials using local immune protection technologies. Furthermore, with the success of the Cell Pouch™ to date, Sernova is developing technologies to provide an unlimited source of locally immune protected cells including stem cell derived insulin responsive cells and xenogeneic cells to treat the 40M patients currently taking insulin worldwide.

The Company is currently also developing a product for Haemophilia A as member of a European Consortium (HemAcure) which has recently received approximately 5.6M EU ($8.5M CAD) funding from the European Union with a successful, highly prestigious European Union Horizon 2020 grant. The grant is to develop the product for clinical trials in patients with Hemophilia A and is expected to reduce or eliminate the need for multiple weekly infusions of Factor VIII. The current market for Factor VIII which must be infused thrice weekly for prophylactic treatment is approximately $5.0B/yr. Sernova plans to develop other indications using the Cell Pouch System™ to treat diseases such as Thyroid disease, with approximately 250,000 patients/yr who could benefit from a cell therapy approach. The company is seeking corporate partners for these therapies and plans to in-license additional complementary technologies.

INVESTOR VALUE PROPOSITION AND EXIT STRATEGY

The table below shows a comparison of diabetes technologies. Sernova's Cell Pouch System™ technology platform is unique to anything currently on the market or in development. This has generated strong interest from potential pharmaceutical corporate partners.

Sernova's Cell Pouch™ Offers a Unique Investment Proposition vs. Other MedTech Diabetes Management Programs

	Endogenous Insulin Production	Internal, Self-contained	Number of Components	Human Insulin	Developmental Stage
Sernova - **Cell Pouch™**	✓	✓	1	✓	Ph. I/II
Medtronic - **MiniMed 530G**	✗	✗	6	✗ / ✓	Marketed
Animal Corp. (J&J) **HHMS (hypoglycemia -hyperglycemia minimizer system)**	✗	✗	4	✗ / ✓	Ph. II/III

SERNOVA'S MANAGEMENT/BOARD/ADVISORY BOARD

Stellar Management Team: President and CEO since May 2009 – Dr. Philip Toleikis: Former VP Pharmacology R&D, Angiotech Pharmaceuticals, where he was part of the team that developed the multi-billion dollar drug-eluting stent and other drug-eluting medical devices; Chief Financial Officer, Ralph Deiterding: CPA, CA, CMA is a finance veteran with over 20 years of experience, primarily in senior finance roles at Toronto Stock Exchange listed software vendors; Senior Director R&D - Delfina Siroen: BSc. Hon. MSc. with over 20 years in managing academic and corporate R&D teams; Business Development – Nick Borrelly: 25 years corporate development (Ciba-Geigy, Novartis and Sanofi-Aventis).

Board of Directors: Chairman Frank Holler – CEO and partner BC Advantage Funds; Jeffery Bacha – CEO Delmar Pharmaceuticals, Inc.; Bruce Weber – V.P Clinical, Regulatory and QA Innovia LLC; James Parsons, CA; Dr. Philip Toleikis, President and CEO Sernova Corp.

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