



## **Sernova Corp about to start FDA cell pouch diabetes trials**

*As a general rule, the most successful man in life is the man who has the best information*

### **Disruptive innovation**

Economist Joseph Schumpeter introduced innovation economics in his 1942 book *Capitalism, Socialism and Democracy*. Schumpeter said that industries must incessantly revolutionize the economic structure from within by innovating with better or more effective processes and products, as well as constantly improving their market distribution.

We can define, or limit the term "innovation" to a product, or process that's original, that's more effective, and as a new application better meets new requirements or existing market needs.

The term, disruption, describes a process whereby a smaller company with fewer resources is able to successfully challenge established incumbent businesses by, a.) displacing an established technology with a better one or b.) inventing a ground-breaking product that creates a completely new industry.

In his book "The Innovator's Dilemma" Harvard Business School professor Clayton Christensen coined the term 'disruptive innovation.' A disruptive innovation displaces an existing market, industry, or technology and produces something new, more efficient and worthwhile.

Disruptive innovations do this in three ways:

- By harnessing new technologies
- By developing new business models
- By exploiting old technologies in new ways

Michael Raynor in his book "The Innovator's Manifesto" says all disruptive innovations stem from technological or business model advantages.

*"History is replete with examples of disruptive innovation, dating back to ancient times. Examples include the compass, the printing press, currency, gunpowder... Imagine that you are Kodak, a company based largely on film, and someone develops digital imaging, or that you are a mainframe computer company like IBM or DEC, and advances in processors lead to the development of inexpensive but powerful personal computers. In our own lives, we recognize how cable or satellite TV has displaced air antennas and how cell phones have displaced landlines."* Disruptive innovation as a driver of science and medicine, J. Larry Jameson

Disruptive innovations have the potential to truly reshape the world in which we live and work.

### **A better mousetrap**

In 1882, Ralph Waldo Emerson stated; *"If a man has good corn or wood, or boards, or pigs, to sell, or can make better chairs or knives, crucibles or church organs, than anybody else, you will find a broad hard-beaten road to his house, though it be in the woods."*

In 1889, Emerson was credited with having said; *"If a man can write a better book, preach a better sermon, or make a better mousetrap than his neighbor ..."*

Today the common phrasing is of course a metaphor about the power of innovation - 'Build a better mousetrap, and the world will beat a path to your door.'

'Better' is a relative term. Every business, in every sector, is trying to build a 'better mousetrap.' Unfortunately, just like the over 4,000 patents for mouse traps, most are not better, they are just different in some small way.

As far as real mousetraps go there has never been, at least for most of us, a better way of killing mice than the spring loaded snap of the trap caused by a mouse trying to take the bait off a trigger plate. Sure, glue on a piece of cardboard might be an improvement for some who worry about getting their fingers caught (and don't care about a swift humane kill), or maybe a 'mouse house' trap for those who get queasy and don't want to see a dead rodent. But these are not big enough changes to want to make the majority of us change from the existing, perfectly capable technology.

Most often those who claim to have invented the better mousetrap, real or metaphorically speaking, haven't - there just isn't enough of a technological

change to force consumers, businesses or institutions to want to or need to make a change. Call it incremental technology looking for a market.

The opposite end of the scale would be a change so great, a technological change so much more efficient, so much more attractive a switch is made without question – from 8-tracks to cassettes, to CDs. From black and white TV to color. From bulky poor quality movies on VHS tapes to slim, lightweight high quality optics on DVD's. And of course programmable TVs with high def (and movies on demand) came along and kicked the crap out of the DVD market. These examples are all innovations that built upon an existing technology and truly created better mousetraps that were universally accepted as such.

Failing to create a clear competitive advantage, doing almost exactly the same thing as your competition, differentiating yourself by only a small tweak to the existing dominate market share technology is no way to succeed or even survive in business.

When you hear about a 'better mousetrap' ask yourself:

Better for who - do people really need or want a better mousetrap? Is this new mousetrap market growing, or shrinking?

## **Regenerative medicine**

Regenerative medicine means replacing, engineering or regenerating human cells, tissues or organs with the goal being to re-establish normality for conditions that currently are beyond repair.

An example of a highly disruptive technology in regenerative medicine is where living therapeutic cells placed within an implanted medical device manufacture and release required medicines into the body as needed.

For diabetes, this technology has the potential to disrupt the entire multibillion insulin and insulin pump market as the therapeutic cells can read blood sugar levels and manufacture and release all the hormones required to appropriately control blood sugar. The same can occur in other therapeutic areas such as hemophilia where Factor VIII can be produced by therapeutic cells within an implanted device rather than being infused multiple times weekly.

*"Disruptive innovations, like we've seen in other industries, can bring complex and expensive health care products and services to greater levels of*

*affordability and accessibility.*” Jerome Grossman, MD and Jason Hwang, MD, MBA, The Innovator’s Prescription

## **A Pure Regenerative Medicine Play**

The promise of regenerative medicine is to treat disease and injury by replacing, regenerating or rejuvenating various parts of the human body that have been damaged by chronic disease, traumatic injury, heart attack, stroke, or aging. Treatments include both in vivo (studies and trials performed inside the living body) and in vitro (treatments applied to the body through implantation of a therapy studied inside the laboratory) procedures.

**“The real promise of regenerative medicine is the ability to provide cures for degenerative diseases, not just treat their symptoms.”**

It has to be pretty clear by now that regenerative medicine, although still in the early stages, is in the process of changing the practice of medicine.

These therapies will not only change healthcare, but will also lead to commercial success for the company and success in the market for investors.

One regenerative medicine company that’s currently off investors radar screens is Sernova Corp. (TSX-V: SVA, OTCQB: SEOVF, FSE: PSH).

However, with all Sernova has going on for it, the academic partnerships and R&D alliances, the company will begin to attract serious market attention, and possibly big pharma attention, in 2018.

Sernova Corp. is a clinical stage regenerative medicine company developing their Cell Pouch System™ for the treatment of chronic debilitating metabolic diseases such as diabetes, blood disorders including hemophilia and other diseases treated through replacement of proteins or hormones missing or in short supply within the body.

Sernova Corp. has developed the subcutaneous Cell Pouch™ and has specifically designed it to overcome the issues with previous implanted devices for cell transplantation.

Sernova’s implantable prevascularized macro-encapsulated Cell Pouch™ is a versatile and scalable, first-in-class medical device made entirely of FDA approved materials. The Cell Pouch System™ provides a natural “organ-like” environment rich in tissue matrix and micro-vessels. This is the ideal

environment for therapeutic cells to thrive which then release proteins and/or hormones as required.

Sernova's extensive preclinical safety and efficacy studies have shown this device to be both safe and effective, while being sparing of islets, supporting its design and function. The Cell Pouch™ being thin and typically smaller than a business card, fits easily under the skin with virtually no visibility.

Sernova Corp.'s Cell Pouch™, using human donor islet cells to produce insulin, will begin formal U.S. Food and Drug Administration (FDA) directed clinical testing in Type I/II diabetes in the second half of 2018.

Phase I clinical human testing with porcine-derived islets and formal human studies using stem cell-derived islet cells will follow.

Sernova has entered into partnerships with the University of Toronto (a stem cell-derived diabetes technology licensing/alliance), Harvard University and the University of Chicago.

Sernova has also entered into R&D alliances with leading regenerative medicine and disease-specific organizations like the University of Toronto-affiliated [Centre for Commercialization of Regenerative Medicine and the Juvenile Diabetes Research Foundation](#).

Sernova's Cell Pouch™ potential is not limited to just islet cell transplantation in diabetes. Sernova has an R&D collaboration ongoing to develop cell therapies for treating [hemophilia A](#) (already funded from the European Commission's Horizon 2020 program), and a separate alliance with the University of British Columbia focused on thyroid disorders.

Regenerative medicine could potentially provide lasting solutions to some of the world's leading chronic diseases. That will massively impact the medical industry in coming years. The regenerative medicine market, still in its infancy, offers a genuine opportunity for investors.

Big pharmaceutical companies are beginning to show increased interest by making various acquisitions and engaging in partnership programs with startup research companies.

*"The rapid aging of the global population and the increasing prevalence of obesity is leading to a significant and growing rate of inflammatory and degenerative diseases of all types. These demographically driven changes are generating significant interest from large, multi-national pharmaceutical*

*companies now targeting small biotechnology start-ups engaged in developing diagnostics and treatments for these degenerative diseases."*

By the year 2020, baby boomers - people aged 65 and up - will outnumber children under age 5 globally. Also, by the year 2020, the Department of Health and Human Services predicts the market for regenerative medicine will reach \$300 billion.

Companies, such as Sernova Corp., are the leaders in preclinical research and many, like SVA is, are entering Phase I/II clinical trials. These company's become significant targets once they successfully get their products to a stage warranting the attention of the big players.

From SVA's most recent Management Discussion and Analysis (MD&A) Report comes the following.

"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 anti-rejection 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 Sernovas 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/.

- 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."

A busy year indeed.

The magnitude of the present opportunity for an investment into Sernova is equaled only by the enormous potential return once one of SVA's therapies reaches the market, or more likely draws the attention of big pharma.

*"A new branch of medicine will develop that attempts to change the course of chronic disease and in many instances will regenerate tired and failing organ systems."* Leland Kaiser, recognized futurist and acknowledged authority on the changing American healthcare system

### **A better 'mousetrap'**

The Edmonton Protocol is a method of implantation of pancreatic islets into the portal vein of the recipient's pancreas along with a steroid free anti-rejection drug regimen. The pancreatic islets are sourced/extracted from pancreases removed from recently deceased adult donors.

Each recipient receives islets from one to four donors. The islets are infused into the patient's portal vein, and are then kept from being destroyed by the recipient's immune system through the use of two immunosuppressant drugs as well as an antibody drug specifically used in transplant patients.

A search has been on for an alternative site for islet transplantation as well as for an optimal medical device in which to implant the islets. Several subcutaneous devices have previously been developed for islet transplantation but from a preclinical and clinical perspective the results from these products have been generally disappointing.

Sernova Corp. (SVA.v) has developed the subcutaneous Cell Pouch™ specifically designed to overcome the issues with previous implanted devices for cell transplantation. Sernova's extensive preclinical safety and efficacy studies have shown this device to be both safe and effective, while being sparing of islets, supporting its design and function.

### **Conclusion**

Harnessing the power of therapeutic cells to repair or replace cells, tissues or organs that are damaged by trauma or disease means we are entering an era where treatments for some of the world's most devastating diseases are developed.

Lab manufactured therapeutic cells hosted in the human body, in SVA's prevascularized Cell Pouch System™ monitoring, regulating, manufacturing and secreting the necessary hormones, factors and proteins to control diabetes and hemophilia would be a major accomplishment, and a truly disruptive innovation.

Schumpeter said that industries must incessantly revolutionize the economic structure from within by innovating with better or more effective processes and products.

Sernova Corp's disruptive innovation, it's better 'mousetrap,' is going to do just that.

For these reasons Sernova Corp TSX.V – SVA (OTCQB: SEOVF, FSE: PSH), is on my radar screen. Is it on yours?

If not, maybe it should be.

Richard (Rick) Mills  
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Richard owns shares of Sernova Corp. TSX.V - SVA