Ahead of the Herd Newsletter - 2018 Issue Four
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As a general rule, the most successful man in life is the man who has the best information

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This week's newsletter has two feature articles and a short teaser about a new, soon starting to trade, blockchain/bitcoin company - **Blockchain Idea coming!**

Our first article in this week's newsletter is titled **'Regenerative medicine: Healing the body by healing itself.'**

Webster's defines regenerative medicine as "the restoration or the growth by an organism of organ or tissue, that has been lost, removed or injured." The field of regenerative medicine focuses on the replacement or revival of tissues and organs, using all of the different technologies available: drugs, biopharmaceuticals (any drug extracted from a biological source), medical devices and cells.

All regenerative medicine seeks to repair/replace damaged cells or tissues in order to restore normal function, thus slowing or even stopping the effects of the pathology the patient is suffering from. Stem cell research plays a central role in regenerative medicine, since stem cells can be transformed into any of the body's 200 cell types and theoretically, live as long as the body does. Stem cells can repair diseased or damaged cells and lead to new cell growth.

The advances made in stem (therapeutic) cell therapy and regenerative medicine over the past few years have been astounding. While scientists still have a ways to go in understanding how stem cells - the building blocks of life - function in order to heal diseases that up to now have only been handled by drugs and surgery, the field is opening to new discoveries practically every day, making regenerative medicine one of the sweetest spots for Ahead of the Herd investors to be in right now.

Our second article is **'US clinical trial puts Sernova one step closer to diabetes cure.'**

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Regenerative medicine: Healing the body by healing itself

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What is regenerative medicine?

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A brief history

Regenerative medicine was first mentioned in a 1992 article which stated: "[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." However, the more widespread use of the term is attributed to William Haseltine, the founder of Human Genome Sciences, a biopharmaceutical company, who recognized that stem cells sourced from human embryos have a unique ability to differentiate (split) into all the different cell types in the human body, a process known as pluripotency. This ability opened up a huge new potential to develop regenerative therapies across a broad swath of the medical spectrum.

Early successes included the first transplant of a windpipe (or trachea) at a hospital in Barcelona in 2008, and the transplant in 2014 of a 1.3 by 3.0-millimeter sheet of retinal pigment epithelium (cells that line the body surface) that were differentiated into the eye of an elderly woman suffering macular degeneration.

The history of regenerative medicine cannot be split (no pun intended) from the history of stem cell research, which goes back much further.

In the 1880s the discovery that some cells have the ability to produce other cells led to attempts to fertilize mammalian eggs outside the human body. About 20 years later scientists found that some cells could generate blood cells, and then in 1968, the first bone marrow transplant was performed. Other key developments in the history of stem cell research, courtesy of explorestemcells.co.uk, include:

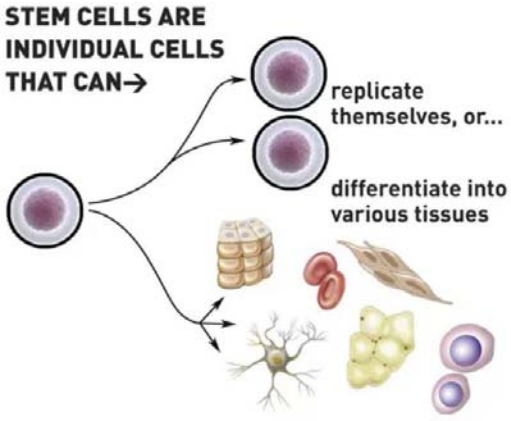
- 1978: Stem cells were discovered in human cord blood
- 1981: First in vitro stem cell line developed from mice
- 1988: Embryonic stem cell lines created from a hamster
- 1995: First embryonic stem cell line derived from a primate
- 1997: Cloned lamb from stem cells
- 1997: Leukaemia origin found as haematopoietic stem cell, indicating possible proof of cancer stem cells

Even more important events followed shortly thereafter, including the 1998 discovery of the first embryonic stem cells, and a decade later, the finding that manipulating mouse tissues could produce different cell types e.g. cells from bone marrow could produce liver cells. This meant that scientists could potentially exert a higher amount of control over how stem cells divide and proliferate.

Stem cells: What's the big deal?

To understand this question, one needs to be acquainted with some basic

biology. Every cell has the same set of DNA, but different genes are active in each - say a nerve cell and a blood cell. Embryonic stem cells are considered the “purest” type of stem cell. Formed right after conception, embryonic stem cells have the ability to transform into any other type of cell in the body - they are pluripotent. By contrast, adult stem cells can only split into the different cell types from the tissue they originated from, which limits their usage. Also, embryonic stem cells can be relatively easily grown in a lab, while adult stem cells are rare in mature tissues, so isolating them is challenging, and ways of expanding their numbers have yet to be worked out, explains an excellent stem cell primer from the National Institutes of Health. However one important advantage of adult stem cells is they are less likely to be rejected by the body, versus embryonic stem cells, which means the patient may not have to go on immunosuppressive drugs to help the stem cells to survive.



In 2006 a sort of hybrid stem cell was invented, the induced pluripotent stem cell (iPSC), which are adult stem cells that have been genetically reprogrammed to become like an embryonic stem cell. Although more research is needed to determine the exact differences between iPSCs and embryonic stem cells, scientists are finding them useful for developing drugs and modeling diseases, with the hope of using them more in transplantation medicine.

The concept of stem cell therapy is fairly basic, in that stem cells are injected into the diseased tissue (say a dying brain) allowing for healthy replacement cells to grow. Stem cells can also make repairs to damaged cells and replace missing elements such as hormones. e.g. insulin.

Benefits of stem cell therapy

Compared to drug therapies or surgery, stem cell therapy is a far more natural and less invasive way of treating diseases, ailments and the inevitable effects of the aging process. An example is stem cell therapy used in the treatment of arthritis and other forms of joint pain. Performed as an outpatient procedure, recovery times are minimal, and daily routines can be maintained. Side effects from the use of opiates, sleeping pills and other potent pharmaceutical drugs are no longer relevant.

Applications: Everything from teeth to cows

Over the years stem cell therapy and regenerative medicine have combined to produce a number of fascinating applications. Below are just a few recent ones:

Heart disease

It is extremely encouraging to see stem cells being researched to treat heart disease, which along with cancer is the most likely fatal disease to strike people as they age past 50. Nearly 2,600 Americans die of cardiovascular disease each day, or one person every 34 seconds. Small animal studies involving embryonic stem cells, cardiac stem cells from the heart, bone marrow-derived stem cells, cells that give rise to the interior lining of blood vessels, and umbilical cord blood cells have all been investigated as possible sources for regenerating damaged heart tissue. A few studies have also been carried out in humans during open-heart surgery, demonstrating that stem cells injected into injured heart tissue can improve cardiac function.

Cancer

Stem cells have been shown to replace cells in the bone marrow that can cause cancer. St Catharines Standard tells of a patient who tried stem cell therapy following a second round of chemotherapy to fight myeloid leukemia. At Juravinksi Hospital and Cancer Centre she received a stem cell transplant while also receiving immunosuppressive drugs to aid in the cells' survival. After 100 days, no signs of cancer were found in her body, and the disease has been in remission for five years.

Researchers at Dartmouth's Norris Cotton Cancer Center are currently devising strategies to target glioma stem cells in order to treat a particularly aggressive type of brain tumour that has one of the worst cancer survival rates. The tumors are attacked by identifying a pathway that is essential for maintaining glioma cancer stem cells, reports Science Daily.

Alzheimer's disease

Just this week Celltex Therapeutics Corp. and Texas A&M's Institute for Regenerative Medicine announced an intellectual property licensing deal involving research on a potential stem cell therapy for Alzheimer's disease. According to the Houston Chronicle, the therapy involves a substance known as exosomes produced by a type of stem cell isolated by researchers. Exosomes are thought to be able to cross the blood-brain barrier, unlike

most drugs, which is why many experimental drugs to treat Alzheimer's disease often fail.

Diabetes

Type 1 diabetes is thought to be an excellent candidate for stem cell therapy because patients who suffer from the disease are lacking a single cell type known as the beta cell. Researchers are looking at either using stem cell derived cells as "factories" that produce beta cells, or using stem cells to support beta repair. Stem cells can also be guided through a series of steps into cells that produce proteins or hormones required by the body. These stem cells can be guided to produce either progenitor cells which then develop into glucose responsive cells when transplanted into a medical device in the body or more fully differentiated cells which produce insulin on an immediate basis when transplanted into a medical device within the body. A number of investigators are working on these technologies. The goal is to have the body produce insulin normally so that the patient does not have to rely on daily insulin injections to control blood sugar levels.

Teeth

Stems cells aren't usually thought to be useful in dentistry, but that is beginning to change thanks to new research. Emi Shimizu, a researcher at Rutgers School of Dental Medicine, has just received a $1.5 million grant to pursue research into how stem cells could be used to regenerate dental pulp rather than removing it - the usual course of action in performing a root canal. As described by Medical Xpress, "her work involves isolating patient stem cells, which can be drawn from skin or hair, and cultivating them to form the vascular network that comprises the nervous system of dentin, the hard bony tissue beneath tooth enamel."

In Britain researchers are working on a new type of filling that could prevent root canals in the first place. The fillings contain materials that enable them to stimulate stem cells in the pulp tissue beneath the bony dentin layer, enabling the decayed pulp to be restored. If the new fillings are used early enough, the dead pulp could regenerate, eliminating the need for a root canal.

There is also promising research into using stem cells to actually regenerate teeth, which could eventually prevent a common dental procedure: filling a hole in a tooth caused by a cavity. A team of bioengineers at King's College, London discovered that they could boost teeth's natural healing ability by mobilizing stem cells in the dental pulp. Tapping into an earlier-discovered

molecular pathway that is essential for stem cell development in other parts of the body, the scientists realized that exposing damaged teeth to drugs that stimulate the pathway could also encourage the activity of stem cells in dental pulp. Their theory has been tested on mice and rats, but not yet humans.

Livestock

The use of stem cells of course is not limited to the human body. While beyond the scope of this article, one interesting use of stem cells could see the breeding of specialized traits in cows. Science just reported that after a couple of decades of trying, scientists have finally managed to derive embryonic stem cells from cows and keep them in a pristine state without dividing. Access to the bovine stem cells could result in "designer breeds" that produce more milk, more tender meat, or animals that are more resistant to diseases.

The market for regenerative medicine / stem cell therapies

Science aside, the market for regenerative therapies is huge. In 2016 regenerative medicine generated $17 billion in revenue, and is expected to triple to $50.5 billion by 2025. The North American regenerative medicines market holds 39% of global market share, according to a recent report.

The global stem cell market is growing equally rapidly, with a compound annual growth rate of 10.5% between 2017 and 2025, states another forecast. According to that report, the market was valued at $5.2 billion in 2016 and is expected to reach $13.7 billion in 2025. It predicts induced pluripotent stem cells will be the fastest growing market due to their applications in regenerative medicines, drug screening, disease modeling and organoid (an organ produced in vitro) generation.

Conclusion

The new and exciting field of regenerative medicine is ripe for investment opportunities for those able to separate the wheat from the chaff, so to speak. While stem cell research promises plenty of potential cures, there have also been failures and many charlatan companies whose treatments are little more than placebos. The New York Times noted that "enthusiasm for stem cells sometimes outstrips the science." Other obstacles include producing consistent and high-quality therapies, receiving federal approval (President George W. Bush prohibited the use of federal funds to create new embryonic stem cell lines in 2001, a decision that was reversed by Obama)

and persuading insurers to cover treatments.

On the other hand, most of the research in regenerative medicine is being led by academics and done by small companies. The amount of research and clinical trials that need to be done often involves too much capital to take them all the way to FDA approval, meaning they will be looking to either partner with larger companies or be bought out. This is when the real money is to be made by investors.

I've been keeping my eye on the regenerative medicine space for the past several years and I see it as one of the most potentially rewarding fields for Ahead of the Herd subscribers. Is regenerative medicine, and a potential investment opportunity, on your radar screen?

If not, maybe one should be.
Richard (Rick) Mills
aheadoftheherd.com

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US clinical trial puts Sernova one step closer to diabetes cure

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Last week I read a shocking post on one of my social media feeds. The author was a diabetic who displayed a photo of a bill from Walgreens and two boxes of insulin. Three vials of Humalog cost the man $807.96, which lasts one month. At that rate, his annual insulin tab is just under US$10,000 a year, and this is with health insurance coverage. He calculated the price of insulin has been marked up 500% since it was first introduced in the 1920s. “It’s insulin, not tiger blood. This is BS and needs to change,” reads the post from the man who lives in North Carolina. It ends with the hashtag #LiquidGold.

Patients who have been diagnosed with diabetes, Type 1 or Type 2 (about 30% who take insulin) not only have to contend with the high cost of insulin which in the US is onerous, but the daily ritual of injecting themselves with insulin to control their blood sugar levels. People with diabetes must carefully monitor their blood sugar throughout the day and take multiple doses of insulin based on food intake, exercise, stress, illness, etc. A miscalculation or unexpected variable leading to high or low blood sugar levels are daily threats leading to accumulating long term consequences. Only about a third of Type 1 diabetics achieve their long- term glucose targets.

Insulin injections take the place of natural insulin which is normally produced by islets in the pancreas. Those with Type 1 diabetes have a condition whereby the pancreas does not make enough of the hormone insulin, while Type 2 diabetics’ blood sugar level is too high because the body doesn’t produce or use insulin normally. Over time, people with either condition can develop serious complications including heart disease, strokes, kidney problems, nerve damage and eye problems.

But what if the cells (islets) that release insulin could be transplanted into the body within an implantable delivery mechanism, allowing the body to produce natural insulin? Such a device would render insulin injections unnecessary, thereby vastly improving the lives of people with diabetes.

That is the goal of Sernova Corporation (TSXV:SVA; OTCQB: SEOVF; FSE: PSH), a London, Ontario-based company which in December was granted IND clearance by US Federal Drug Administration (FDA) to conduct a human clinical trial for its Cell Pouch technologies, designed to treat diabetes, hemophilia and thyroid disease.

The Cell Pouch

The diabetes trial is a major milestone for Sernova, which has been developing the Cell Pouch since 2009. The device is essentially an implanted

housing vehicle for therapeutic cells that produce and deliver insulin, as needed. The cells, which can either be stem cell derived or sourced from organ donors, are implanted into the Cell Pouch to produce proteins or hormones that are in short supply or missing from the body, a result of the disease the patient is suffering from.

About the size of a credit card, the Cell Pouch is surgically implanted under the skin, where it creates an “organ-like” environment that allows the therapeutic cells to integrate within the body. The surgery can be a simple outpatient procedure.

Sernova’s President and CEO, Dr. Philip Toleikis and his team early on realized they needed to create an environment that incorporates tissues and blood vessels rather than “walling them off” which is what usually happens when a medical device is implanted in the body becoming surrounded by scar tissue, a process known as fibrosis. The scar tissue could trap the therapeutic cells, preventing them from integrating with the rest of the body, and they eventually die.

Sernova’s Cell Pouch™ forms a natural vascularized environment for long-term survival and function of the therapeutic cells which release into the bloodstream requiring but missing proteins or hormones like insulin.

The technology would be beneficial if it provided a simple reduction in the number of insulin injections a patient must take; however, there is the possibility that it could even essentially ‘cure’ the disease through natural release and regulation of insulin.

The Cell Pouch is also an ideal delivery vehicle for cells which produce factor VIII, a blood-clotting protein absent in patients with hemophilia and thyroid cells which produce thyroid hormones that are in short supply in patients with thyroid disease.

Sernova has shown its technology to be safe and effective in multiple small and large animal preclinical trials, and it has also been proven in a first in human clinical trial in Canada which demonstrated safety of the device, survival of human islets (a grouping of therapeutic cells) and the presence of insulin from islets implanted under the skin within the Cell Pouch - a world’s first.

“We believe the Cell Pouch platform is the first such patented technology proven to become incorporated with blood vessel enriched tissue-forming tissue chambers without fibrosis for the placement and long-term survival

and function of immune protected therapeutic cells," Sernova stated in a July 24th, 2017 news release.

"The important point is that we designed the device early on to create a natural and ideal tissue environment for all therapeutic cells. Sernova's technologies form a platform technology for potential treatment of multiple diseases," Toleikis told Ahead of the Herd in a recent interview. He stressed that Sernova is likely two or more years ahead of other regenerative medicine companies trying to do similar work, a number of which have been unable to clear the fibrosis hurdle that Sernova has cleared.

"We have definitively shown two critical points with all of our preclinical studies and with human islets in humans. First, our Cell Pouch can keep human islets alive and highly vascularized. And the other thing that we have shown in a year-long study is that our device does not fibrose," added Toleikis, who studied different combinations of drugs and medical devices to improve the functioning of the latter while Vice President of R&D, Pharmacology and Drug Screening when he was at Angiotech Pharmaceuticals which developed one of the first drug-eluting coronary stents, a multi-billion dollar technology.

"We believe we are the first company to show that human islets can survive and become vascularized within a tissue matrix housed in a medical device that's implanted under the skin."

The trial

The next step for Sernova was to get approval from the US Federal Drug Administration (FDA) to conduct a human clinical trial for a group of patients in the United States, utilizing the Cell Pouch. On December 11, 2017 Sernova announced it had been granted a notice of allowance from the FDA for a new clinical trial using patients with Type 1 diabetes that have hypoglycemia unawareness.

Hypoglycemia unawareness is a complication of diabetes whereby the patient is unaware of a deep drop in blood sugar levels because the body fails to trigger a secretion of epinephrine, which generates symptoms of hypoglycemia such as palpitations, sweating and anxiety. The condition can result in prolonged exposure to hypoglycemia, resulting in a seizure, loss of consciousness or brain damage. It's estimated that around 30% of diabetics have hypoglycemia unawareness.

The company-sponsored trial is to investigate the ongoing safety as well as efficacy of the Cell Pouch with a yet-to-be-released number of hypoglycemia

unaware patients. The patients will have the Cell Pouch implanted, with the first objective being to assess the safety and tolerability of islet transplantation into the Cell Pouch, and secondly, the efficacy of the treatment. The patients' progress will be tracked for about six months, after which a decision will be made whether to transplant a second dose of islets. Those patients will then be further followed for a year. Thus, the trial enables understanding of the effects of potential multiple doses of cells within the Cell Pouch.

The trial is being backed by a significant grant from the Juvenile Diabetes Foundation - the world's largest supporter of diabetes research. The grant went through a six-month due diligence process, including high-level academic reviews, and is an important validation of the company's research, said Toleikis.

"The review process involved peer review of the clinical protocol, and receipt of the support indicated that the study is considered important, that the indication of hypoglycemia unawareness is an important unmet need in these patients and that the Cell Pouch preclinical data is strong," he said.

Key attributes of the new trial include refined surgical techniques involved in implanting the Cell Pouch, means to ensure high quality and purity of the islets, controlled dosing of islets, taking multiple measures of efficacy and assessment of several potential doses of cells to understand the effect of islet dosing.

The Holy Grail for diabetes?

Toleikis sees the trial for hypoglycemia unaware patients as the first pool of patients using the Cell Pouch that if successful could eventually mean expanded trials in Type 1 as well as Type 2 patients, a market that represents up to 60 million patients worldwide. This is especially true if stem cell derived technologies - which are cells that can differentiate into specialized glucose responsive insulin producing cells - are implanted into the Cell Pouch as an unlimited supply of cells as Sernova's technologies advance.

While not widely publicized, Sernova has obtained a world-wide exclusive license for a stem cell derived technology developed by luminaries Drs. Gordon Keller and Cristina Nostro for the treatment of diabetes through the University Health Network, a Toronto-based medical research organization. The ability to use stem cells is important for Sernova because it means the company would eventually not have to rely on organ donors for obtaining

therapeutic cells; moreover, stem cells are considered to be easier to implant and more survivable than pancreas-derived islets.

“The hypoglycemia unawareness market itself is a significant market in the United States, but we are also working on unlimited supplies of cells such as a stem cell-derived technology that can then go into the Cell Pouch. If successful, that particular technology may be used to treat the general population of diabetic patients,” said Toleikis.

“We see our Cell Pouch technology with human donor islets as an importantl indication to help hypoglycemia unaware patients, but we also see that indication and validation as a launch pad supporting our work with other types of cell technologies such as the glucose responsive insulin-producing stem cell technologies or even encapsulated porcine [pig] technologies.”

Further details of the study will be made public when institutional ethics board (IRB) review is completed, a process which occurs at the clinical sites following FDA clearance. At its technologies advance, Sernova plans to conduct trials with several of its diabetes technologies: the first will have the patients take donor islets protected by immunosuppressive drugs which help the islets to survive in the body. A second, separate later anticipated trial (not yet approved) expects to involve patients who have the Cell Pouch implanted but do not take immunosuppressive drugs. Those patients will have Cell Pouches equipped with therapeutic cells that provide local immune protection to reduce or eliminate the need for anti-rejection drugs. If the second trial is proven effective, Sernova may have a practical ‘cure’ for diabetes.

“For the larger patient population with diabetes who may not have severe hypoglycemia unawareness, our goal is to develop a product where patients will receive locally immune protected cells within the Cell Pouch that will produce insulin and all the hormones as required to control blood sugar levels,” said Toleikis. “This is the Holy Grail of diabetes treatment – to free these individuals from constant worry.”

What it means for individuals with diabetes

Diabetic patients could see a considerable improvement in their quality of life should the Cell Pouch technologies continue to prove to be safe and to show efficacy in clinical trials.

“We’re anticipating that with appropriate islet dosing, a period after the islets are transplanted into the Cell Pouch and become vascularized, they will start to function, releasing insulin to take over glucose control as the

patients reduce their insulin doses," said Toleikis. "The end goal is that the islets begin to control blood sugar levels and the injections tapered down to the point where they are no longer necessary."

If that were to happen and the sugar levels were controlled in a normal way, these individuals may also benefit from a reduction of accumulating microvascular side effects of diabetes, which include eye, kidney and nerve damage, as well as heart attack, stroke and amputations.

"That would be ground-breaking - a highly disruptive, significant improvement in the quality of life of those patients," said Toleikis, adding that "a de facto 'cure' for diabetes could significantly reduce hospitalizations and worldwide healthcare costs that are becoming a significant burden for worldwide government healthcare budgets."

"We anticipate that if regenerative medicine products prove out as we continue to move forward, they will be the largest medical products ever in the history of medicine to treat patients and, likely, one of the most significant achievements in therapeutic treatment of disease in improving the quality of life of millions of patients."

The timeline

Asked how long it could be between getting the first patient enrolled in the clinical trial, conducting this and other trials needed for regulatory approval for marketing approval of the first product, Toleikis said the exact timeline depends on many factors but gave an estimate of three-four years or so depending on the outcome of the trial and regulatory requirements. For these hypoglycemia unawareness patients, if the results show significant benefit, the company has the potential to apply for fast track status for the therapy in this population.

Toleikis noted the company is interacting with pharmaceutical companies that have stem cell technologies and overall interest in regenerative medicine that could dovetail with the Cell Pouch delivery system. Virtually every major pharma company such as Merck, Takeda, Novo Nordisk, and Sanofi have publicly shown strong interest in the new wave of regenerative medicine therapeutics, an indication that regenerative medicine is being taken very seriously.

"Sernova can be considered the hub of the wheel if not the entire wheel of the processes that are going on for regenerative medicine requiring replacement of proteins or hormones in the body. We are bringing all the pieces of the regenerative medicine puzzle together including the prevascularized device, the therapeutic cells and local immune protection of

the cells. We want to work with pharma and medical device companies in the development and marketing of our products and are actively seeking collaborations," said Toleikis. "If one thinks about it, medtech companies are experts in devices and may not have cell therapy experience and pharmaceutical companies may not have medical device experience. Sernova's expertise crosses both arenas but we don't yet have the ability to market the products or the deep pockets for the pivotal trials. This mutual need makes a collaboration between Sernova and these companies a potential 'marriage made in heaven" in a win-win relationship towards commercialization of these multi-billion dollar products."

A cure for hemophilia?

Sernova has not only made startling progress lately with respect to a potential 'cure' for diabetes, it has also made great strides in its other main product development arena, hemophilia.

Sernova is a member of the Horizon 2020 granted HemAcure consortium which has united academic institutions from Germany, Italy and the UK with Sernova's corporate experience and mission in developing a product to treat hemophilia A patients with a cell therapy product within the Cell Pouch.

The overall objective of the HemAcure project is to develop and refine the tools and technologies for a novel, curative ex vivo (outside the body) gene therapy in cells placed in the implanted Cell Pouch to treat hemophilia A that could ultimately lead to improved quality of life for patients. The EU's Horizon 2020 program has funded the HemAcure project with €5.6 million (approximately CAD$8.06M, US$6.3M). The most recent tranche of funding was cleared in July, 2017 based on the encouraging mid-term results reported to the European Union. In addition to the JDRF grant, receipt of the highly prestigious Horizon 2020 grant is a strong validation of Sernova's technologies.

Sernova's goal is to do the same thing for patients with hemophilia as for diabetic patients, in clinical trials using the Cell Pouch.

"With the HemAcure team we are working on a product repairing the patient's own cells, called an autograft therapy." Toleikis explained. "We take a blood sample from the patient. We then isolate a certain cell type called an endothelial cell and insert the gene for factor VIII so those cells start to produce factor VIII. We can then expand or multiply those cells and transplant them into the Cell Pouch that's under the skin. The idea is for those cells to produce factor VIII on a constant basis which becomes therapeutic when it enters the bloodstream."

Having a sufficient amount of factor VIII constantly released into the bloodstream can significantly reduce the symptoms of hemophilia, which include heavy bleeding from minor cuts and more seriously, internal hemorrhaging that can take place in joints (especially knees, ankles and elbows) and into tissues and muscles. Bleeding can also occur in vital organs putting a patient's life in danger.

Although effective treatment of the symptoms is available through frequent infusions, there is no cure for hemophilia A at present and therapy has to be individualized to each patient. Currently patients require lifelong infusions with factor VIII several times a week to compensate for the missing clotting factor.

The global total hemophilia market was valued at US$9.3 billion in 2015. Approximately 20,000 people in the United States, 10,000 in Europe and approximately 2,500 in Canada have a moderate or severe form of hemophilia A. Annual costs for the treatment of the disease for each patient may range from $60,000 to $260,000 for a total cost of between $2-5B per year just in North America and Europe.

Derisking

A regenerative medicine company like Sernova is in a way similar to a resource company in that the valuation of the company and its stock price is intimately tied to de-risking. In Sernova's case, this derisking comes from multiple sources. One is about working on multiple products. Sernova has three diabetes products, one current hemophilia product and a thyroid disease treatment product in its pipeline. The other derisking approach Sernova has taken is its interest in cutting deals with pharma and medtech companies to help advance its programs to commercialization status. Meeting milestones in its product development pipeline as well as initiating collaborations with corporate partners are each expected to contribute in a major way to the company's valuation.

"I am very excited about 2018 and the coming years," said Toleikis. "We have spend years building the foundation of our technologies and it is starting to show in a big way. We have validated our technologies in major preclinical studies, and have demonstrated first in human safety and survival of cells within the Cell Pouch. We have proven that the Cell Pouch is a viable device for cell survival and are now aggressively moving forward in US clinical trials with confidence."

Conclusion

Investors in Sernova have been patiently waiting as the company has developed and tested their regenerative medicine products. I believe that investor patience is finally being rewarded as Sernova proves its technologies are safe and effective, with results that could be life-changing for diabetics, hemophiliacs and any other patients requiring therapeutic cell transplants.

We believe Sernova is the only company in this space with the combination of technologies to enable 'cures' to these serious diseases. Where other companies are concentrating on the "payload" (cells) that get implanted into the body, Sernova has the only known delivery device that prevents fibrosis - this is the key to ensuring that the therapeutic cells survive and do their work. Sernova's success could represent a true medical breakthrough. How many companies can that be said about? For these reasons Sernova is on my radar screen. Is SVA on yours?

If not, it should be.

Richard (Rick) Mills
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Blockchain Idea coming!

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Dear Reader,

You'd have to have been living under a rock over the last year to not have noticed the explosion of investor interest in blockchain technology and its most familiar manifestation: bitcoin. Ahead of the Herd has been following the developments closely, including the incredible run up in the value of bitcoin and subsequent pullback, after South Korea outright banned the popular cryptocurrency. We have been skeptical of the bitcoin bubble many think it is (and have been waiting for things to settle down), but we also recognize the incredible opportunities that blockchain presents. It has been compared to the invention of the Internet nearly 30 years ago. That caught my attention, so here is a blockchain and bitcoin primer, followed by news of an incredible upcoming blockchain investment opportunity you might not want to miss out on.

What is blockchain?

The easiest way to think of blockchain is a spreadsheet that is duplicated thousands of times across a network of computers. The network is designed to regularly update this spreadsheet. A great example of a simple blockchain is Google Docs, where a document can be shared and updated by an infinite number of people at the same time. The advantages of such a system are that the blockchain database isn't stored in any one location - making it virtually unhackable - while its records are public and easily identifiable.

The first blockchain was bitcoin, whereby computer nodes "mine" bitcoin by solving computational puzzles. Nodes that solve the puzzles are awarded bitcoins. Bitcoin was the first "cryptocurrency" since it is encrypted for security and can be substituted for fiat currencies to purchase certain good and services. There are currently about 1,400 other cryptocurrencies in circulation.

While the most obvious uses of blockchains involve financial transactions (Eg. money transfers that cut out the middleman, the banks), other potential applications include:

- Smart contracts, where distributed ledgers enable the coding of simple contracts when certain condition are met. This was the rationale for the cryptocurrency ethereum.
- The shared economy. What if you could hail a ride without using a centralized service like Uber? Blockchain opens the door to peer-to-peer payments, completely cutting out shared economy providers like Uber, AirBnB and eBay.
- Supply chain auditing. The current system of supply chain management relies on companies to disclose where they get their products and how they're made. A distributed, public ledger could easily certify the progeny of a product, which is particularly important in proving whether something like a diamond has been sourced ethically.

Bitcoin mania

As everyone knows, the growth in cryptocurrencies over the past year has been phenomenal. A chart of the global coin market shows the total market cap of cryptocurrencies at under USD$20 billion from 2013 to 2017, then rising to $23 billion in April 2017. From there cryptocurrencies spike, reaching a high of $749 billion in January 2018, then retreating to the current value of around $332 billion. Bitcoin, the most familiar and used cryptocurrency, started the year at around $1,000 and finished 2017 just under $15,000 - a gain of 1,322%. Ethereum rose in value by over 2,500% in 2017.

How do we capitalize?

While many, including Goldman Sachs, think that bitcoin is a bubble about to pop - equating it to the 17th century Dutch "tulip mania" - the reality is that crypto currences and blockchain technologies have great utility and are here to stay. The global blockchain market is expected to grow by 42.8% (CAGR), reaching $13.96 billion by 2022.

I've identified an excellent blockchain company that is led by a world class team of cryptocurrency developers, blockchain operators and forensic & financial experts with deep relationships throughout North America and Japan, the leading cryptocurrency market.

The Canadian company has four revenue streams: bitcoin mining, "mining as a service", forensics & data analysis, and blockchain software platform development. Their "mining as a service" model offers customers access to 50,000 servers, and their fourth revenue stream involves partnering with

select companies to develop “custom-made” blockchain-based software solutions.

Finally, this company has already formed a number of key blockchain partnerships, with all kinds of new contracts and takeovers coming - all with the potential to increase shareholder value significantly. In short, our company is no pretender. It has a unique business model, diversified streams of revenue, and a top-notch team of proven blockchain pioneers to pull it all off. I can’t say much more, other than to stay tuned for our next newsletter, where we’ll be featuring our first blockchain company. I hope you’ll be as excited as I am to welcome them to the Ahead of the Herd stable.

Rick Mills
Ahead of the Herd