

# THE National Investor



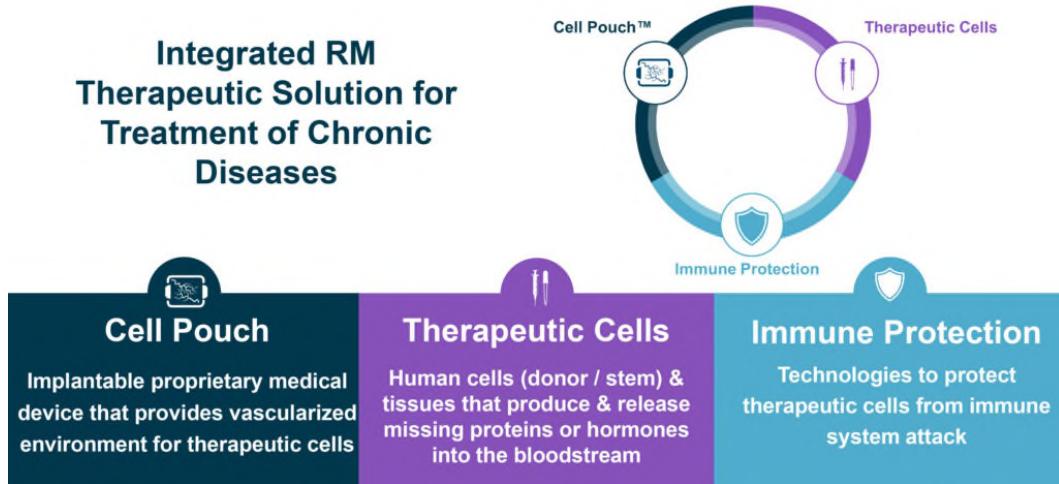
Winter, 2021

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Company Profile

## **COMPANY PROFILE: SERNOVA CORP. (TSXV-SVA; OTCQB-SEOVF)**

### **Sernova's Platform Approach**



\* The New Year has commenced with Sernova Corporation *on fire*; as of this writing its shares have increased FIVE-FOLD within just several weeks' time!

\* Though several other better-known and larger biotech companies have *some* of the pieces of a potential GAME-CHANGING overall, *single* regimen to defeat the scourge of Type One diabetes, **Sernova's Cell Pouch System™** is the farthest along *in human trials* of them all.

\* Notwithstanding Sernova's surge already through the first two weeks of 2021, the company remains VASTLY undervalued compared to real (and imagined) peers...and even now, investors are looking at the possibility that C\$300 million market cap or so Sernova can be sitting on MANY BILLIONS of dollars' worth of a valuation if it is the first to commercialize *or monetize* its science/technology.



Chris Temple

From the desk of Chris Temple, Editor & Publisher

*The National Investor*

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Whether in bull or bear markets, long-term success for individual investors has always primarily come from **discovering and buying good companies when they are cheap.**

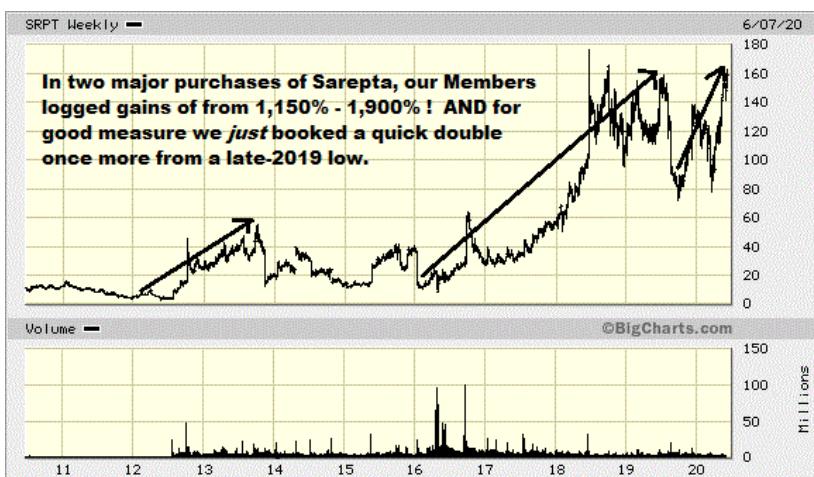
Sometimes it's a household name or some other large company that for a time is "unloved" for whatever reason on Wall Street. Many a time, we have picked off such companies at a low level and done quite well.

The *real* fun, though, is when we can find a **company that almost nobody knows about.** Advances in science and technology... more efficient means of transportation and communication. . . pending CURES for diseases rather than just better treatment. . . and so many more themes are continually sought after. When you find the right combination of management, support, market need and the rest in a young company, the rewards (and not just monetary) can be *astounding!*

As I teach in one of my FREE tutorials on stock picking/research (easily accessible on my web site), sometimes great investment ideas are right under our noses one way or another as we go about our everyday lives. Who among us, for instance, does *not* remember the decades-long run of the late actor and comedian Jerry Lewis and his annual Labor Day telethons? For many years our hearts broke for "Jerry's kids" who were beset by one form or another of the scourge Muscular Dystrophy.



Years ago my "homework" brought me into contact with a tiny biotech start-up whose science on RNA-based therapeutics showed great promise. Sure enough, shares of **Sarepta Therapeutics** hit the big time back in 2012, when trials in adolescent patients who have Duchenne Muscular Dystrophy **actually showed that Sarepta's drug was allowing some of them to produce dystrophin and GROW muscle tissue!**



Biotechnology and other medical and health-related breakthroughs, from an investment perspective, are not just exciting and potentially VERY rewarding. *They are opportunities as well that have little if anything to do with the broader economy and stock market.* So arguably more than in any other sector of the market, health care/biotechnology companies are driven chiefly by their success...or failure. Often, these kind of stocks do well on their own news even in a *falling* overall market.

As this is written I have other “story stocks” in this area among my recommendations: companies working on everything from Alzheimer’s disease (a VERY successful “return trip” in this one as well recently, after quadruple-digit gains here, too, a few years back)...cutting-edge technologies to detect and treat bladder cancer...the neatest anti-aging science I’ve uncovered (*this company*, in fact, is in a collaboration with Sernova, among other things) ...and MOST recently, a company going on my recommended list (*for Members only*) whose disruptive technology will make the hated mammogram *obsolete* while making the early detection of breast cancer more accurate.



**But of all the various “story stocks” on my recommended list now, none is currently more explosive, nor closer to my heart, than is Sernova Corporation.**

While the many photos of the late comedian Lewis and any number of Muscular Dystrophy sufferers over the years are the pictures burned into my mind concerning Sarepta’s story, *the one at left occupies my thoughts in telling Sernova’s story.* That is my son Stephen, who died just over a year ago due to long-term complications of Type One diabetes. Two of my other children have Type One as well; and thus far happily have theirs under good control, *notwithstanding the never-ending cloud it casts over their lives.*

**So it goes without saying that when I first heard about Sernova several years ago, I was all ears!**

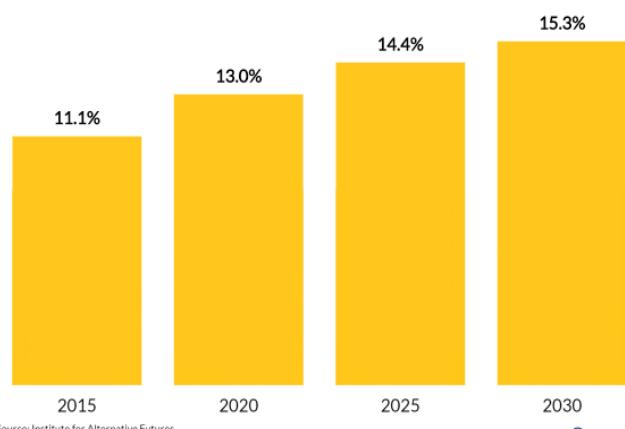
## **SERNOVA CORPORATION: AN INTRODUCTION**

The idea that a *major* breakthrough in ending (for the most part) the scourge of Type One diabetes especially might be at hand is **HUGE**. Diabetes (all types) is the seventh-leading reported cause of death in America, where over 35 million people are afflicted in total of a *worldwide* total of over 460 million people.

Of the number in America, some 1.3 million people have Type One; sometimes referred to as well as “Juvenile onset” diabetes, as this *far* worse form usually manifests itself in children/younger people. The incidence of all cases of diabetes has been on a steady upward trajectory.

### **The Projected Diabetes Rate in the United States**

Percentage of US Population with Diagnosed and Undiagnosed Cases



**Ominously, it is no longer the case that this disease is just hereditary.** The occurrence of Type One/juvenile onset in people whose family history is void of diabetes has *exploded*. It is expected that this will contribute to even more acceleration in Type One cases, to as many as five million people (in the U.S. alone) by 2050. And as you likely know, the regimen of care for Type One cases is *far* more involved and serious than for “Type two” that usually manifests later in life and can be largely negated in many cases by diet, exercise, simpler pharmaceuticals and related lifestyle changes.

## Type 1 Diabetes : First-in-Human Study



### Study Design

2015 • Diabetes subjects with hypoglycemia unawareness

- Open-label; single-arm
- Donor islet transplantation 2-24 weeks post Cell Pouch™ implantation
- Primary endpoint
- Safety post Cell Pouch™ implantation and 1 month post islet transplantation

### Cell Pouch™ and Islet Safety Met

- Safety successfully met for the Cell Pouch™
- Cell Pouch™ histology assessed by independent pathologists blinded to the treatment
  - Islets housed within a natural tissue matrix
  - Islets are well-vascularized
  - Islet safety successfully met
  - Islets show evidence of insulin, somatostatin, & glucagon
  - Cell Pouch™ and islet biocompatibility met
  - Proof of islet protection from immune system attack

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When I first heard about Sernova Corporation several years ago, I was understandably interested in following the company. For years, our family—as most that have one or more diabetes sufferers—had heard of the potential of an “artificial pancreas” or some such thing. Pretty much everyone was in early stages, though; and none as far as being in human trials, *except those that were beginning to take shape with Sernova*.

**What prompted me to add Sernova at last to my recommended list in the Fall of 2019 (at around C26 cents per share, I can happily say!) was getting my head more fully around Sernova’s developing success in human trials of its Cell Pouch.** No other company then or since was matching the entirety of the developing Cell Pouch System™ though—as I will describe in a bit—some have done great work on developing insulin-producing stem cells to be used in such a setting, *potentially*.

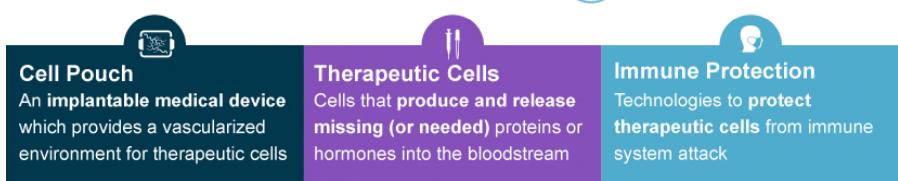
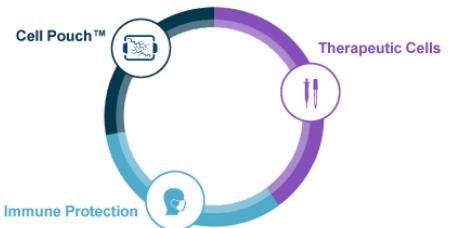
Also prompting me to pull the trigger on Sernova when I did was the September 3, 2019 announcement by Vertex Pharmaceuticals (NASD-VRTX) that it was paying \$950 million to acquire privately-held Semma Therapeutics; see <https://investors.vrtx.com/news-releases/news-release-details/vertex-acquire-semma-therapeutics-goal-developing-curable-cell>. Semma had been working, among other things, on developing “pancreatic islet cells” that could produce insulin; but by several measures is not as far along, as I (and others) see things, as Sernova.

And with such a **HUGE** valuation gap between Sernova (then a mere C\$40 million or so market cap, compared to the \$950 million cash Vertex paid for Semma) I was of a mind that *one of these days* the markets would wake up to the little London, Ontario-based Sernova which seemed to be putting all the pieces together.

## Sernova's Approach



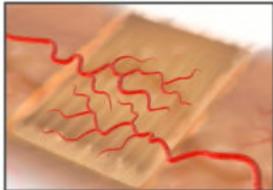
**A Total Regenerative Medicine Solution for the Therapeutic Treatment of Chronic Diseases**



# OVERVIEW – BASIC TECHNOLOGY

## Biologically Compatible Delivery Process

### Cell Pouch Implantation & Therapeutic Cells Delivery Process



Proprietary Cell Pouch is placed deep under the skin, allowing for vascularization & creating a natural environment for long-term function of therapeutic cells

Therapeutic cells are transplanted directly into the vascularized tissue chambers of the proprietary Cell Pouch

Therapeutic cells release missing proteins or hormones in the bloodstream to correct biological dysfunction

Sernova's Cell Pouch System™ is an implantable device that could provide a *functional cure* for Type 1 diabetes and other chronic metabolic diseases (though this Special Issue will focus on diabetes, the Cell Pouch System™ is also in pre-clinical work to treat Hemophilia A and thyroid disease.) Indeed, as those of us who have followed Sernova with increasing excitement know—and the company's C.E.O. and President Dr. Philip Toleikis has pointed out—**Sernova appears in the lead to bring to Type One diabetes sufferers the most game-changing develop since the discovery of insulin exactly a century ago!**

The Cell Pouch System™ goes far beyond some improvements in treatment that have come about in recent years; among them insulin pumps, better monitoring regimens for blood glucose levels, etc. This system of *regenerative medicine* goes beyond the mere better treatment or management of diabetes.

Sernova's pouch is implanted in the body and **becomes the “home” for cells that will produce insulin**; something which the pancreas, of course, for diabetes patients no longer does at all, or in sufficient amounts. A number of ingredients must come together in the end for this cell pouch to be viable, and approved ultimately for development for diabetes patients: among them are safety (no issues or adverse effects from implantation), efficacy (that the cells introduced into the pouch *work* to meaningfully reduce the blood sugar level swings of diabetes, etc.) and that an overly burdensome NEW issue isn't created in the process, of the body trying to reject this foreign pouch (the three ingredients you saw on the earlier graphic.)

Having already demonstrated the *safety* of its cell pouch in clinical work, **Sernova scored perhaps its biggest-ever breakthrough on July 17, 2019 just before I recommended the company.** As you can read, in part, at <https://sernova.com/press/all/?year=2019>, "...Sernova's Cell Pouch transplanted with islet cells demonstrated initial safety, as well as key efficacy measures, including glucose-stimulated blood levels of C-peptide, insulin, and additional measures of glucose control in the first study patient with type-1 diabetes and severe hypoglycemia unawareness." **This was the first time**

**that any such *in-human* trials of any regimen reported such results of transplanted cells substantially reducing “sugar spikes” in the blood, leading to blood levels of the markers showing that insulin-production has been reinstated, etc.**

“I am pleased with these interim results in the first implanted patient,” said Dr. Piotr Witkowski, Director of Pancreatic, and Islet Transplant Program at the University of Chicago and the Sernova study’s principal investigator, on that news. “The first dose of islets transplanted into the Cell Pouch has shown safety and early indicators of potential efficacy. We found some glucose-stimulated C-peptide and insulin present in the bloodstream, which are the gold standard indicators of islet function. Our team continues

the research and looks forward to reporting longer-term results in additional patients as the trial progresses.” (Emphasis added.)

## Sernova: Innovator & Leader



Publicly traded, clinical-stage RM therapeutics solution innovator & leader:

- > Cell therapy therapeutics solution platform treating chronic diseases & enhancing daily QOL
- > Integrated RM therapeutic solution (Cell PouchTM + therapeutic cells or tissue + immune-protection)
- > Broad platform application potential: multiple large market indications
- > Cell Pouch overcomes current barriers associated with therapeutic cells survival & function by forming organ-like environment for the cells to produce missing proteins, hormones, etc.
- > Diabetes lead program & 1<sup>st</sup> company with RM therapeutic product showing insulin production & early clinical efficacy indicators for type 1 diabetes (T1D). Active US Phase I/II clinical trial.
- > Pre-Clinical proof-of-concept demonstrated for hemophilia A & thyroid disease



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And added Dr. Toleikis, “The preliminary clinical data achieved in this patient with our pre-vascularized implanted Cell Pouch represent an early clinical validation for our regenerative medicine technologies as we pursue safe, efficacious, and transformative treatments for patients with hypoglycemia

unawareness in type-1 diabetes. With these data from our current clinical trial, in conjunction with our advancing hemophilia A, hypothyroid, and diabetes stem cell programs, we believe Sernova is closer to achieving significant advancements in regenerative medicine treatment.”

Since that time, Sernova has been slowly but surely adding the additional, needed pieces to the puzzle of developing its goal of **an Integrated RM (Regenerative Medicine) therapeutic solution** on its way to that *functional cure* for Type One diabetes. As I will describe further along, this has included working on the two elements not focused on as much by other companies: *the delivery system itself* (Sernova’s Cell Pouch System™ is *well* ahead of pretty much everyone in this regard especially) and a means to have *a built-in immune protection* so that those in whom the Cell Pouch is implanted in the future do not have to take added immune system-suppressing drugs, as with other transplants.

## Immune Protection



### Conformal Coating Technologies:

- Sernova’s proprietary cellular conformal coating technology - developed and optimized with years of research
- It consists of a thin biocompatible porous polymer hydrogel coating surrounding therapeutic cells (islets, stem cells)
- Proven to allow for physiological transfer of insulin and glucose unlike other encapsulation technologies
- Sernova is preparing for use within its Cell Pouch for islets, stem cell derived cells for multiple applications
- The potential to eliminate the need for anti-rejection medications significantly increases the number of treatable patients for Sernova’s clinical products

### Gene-Editing Technologies:

- Sernova entered in a collaboration to evaluate the potential of Sernova’s pluripotent stem cell-derived pancreatic islet beta cells, and hemophilia cells engineered with AgeX’s UniverCyte technology, to evade human immune detection.
- UniverCyte uses a modified form of HLA-G, a potent immunomodulatory molecule, which in nature protects an unborn child from their mother’s immune system. AgeX’s modified HLA-G has the potential to allow for long-term, stable and high expression of the immunomodulatory effect.
- The complementary combination of technologies could enable the transplantation of therapeutic cells in patients with T1D in an off-the-shelf manner using Sernova’s Cell Pouch, without human leukocyte antigen (HLA) tissue matching or concurrent administration of immunosuppressive medications

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# 2021 STARTS OFF WITH A BANG! -- DEVELOPMENT PROGRESS; WHAT COMES NEXT

Sernova's first press release of the New Year this past Friday, January 15, was a biggie! The company announced (see <https://sernova.com/press/all/?year=2021>) that Dr. Witkowski had just presented additional positive preliminary safety and efficacy data at the 2021 American Society of Transplant Surgeons Winter Symposium. Sernova's Cell Pouch™ transplanted with insulin producing cells in patients with type 1 diabetes continues, he reported, to show "persistent islet function and clinically meaningful improvement in measures of glucose control."

## US Ph I/II 90-Days Post Transplant

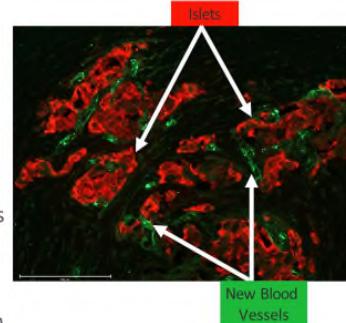


### Achievement of Secondary Endpoint

*"Survival of endocrine tissue in the Cell PouchTM (defined by positive staining of islets during histological analysis) [ Time Frame: 90±5 days post-transplant for sentinel Cell PouchTM ]"*

*Independent Pathologist reported:*

- > abundant viable, organized islet cells
- > intimately associated with blood vessels
- > within a collagen matrix
- > islet cells strongly express insulin
- > Indicator of transplanted islet health in the therapeutic Cell Pouches remaining in the subject
- > Ability to produce insulin and deliver to the bloodstream
- > Previously demonstrated by reported findings of blood levels of both glucose-stimulated & fasting C-peptide plus other efficacy indicators



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Also, as you can see in that latest news, **five of the near-term goal of seven patients are now implanted** as the current trial continues; the remaining two are finalizing their screening process before being implanted.

One of the most noteworthy things about the most recent progress report is that one patient (presumably, of course, the one who has been implanted the longest) **has now gone nine months with NO supplementary injected insulin to augment what the Cell Pouch and its islets is producing!** Again, Sernova is the FIRST to such a milestone as this. Needless to say, if the newly-added implantees can see this result duplicated in them and without any safety issues cropping up—the Finish Line to finding this functional cure will be in sight.

The company will be working through 2021 to not only manage *these* patients, but to **finish the work needed on the immune suppression piece of the total puzzle.**

Besides the work that Sernova has been doing/reporting on that itself is starting to lead at last to a greater recognition, it is others trying to elbow their way into this space that is turning up the heat—and attention—on everyone. As I explained to my Members at the end of last year as Sernova was starting to awaken from a long slumber, the recent I.P.O. at the beginning of December of Sigilon Therapeutics

(NASD-SGTX) brought a new player (with an instant \$1 billion-plus market cap) new entrant into, chiefly, the development of stem cells/islet cells to treat both Hemophilia A and Type One diabetes.

And again, a follow-on effect was to cause at least some medical experts and investors/analysts alike to look at the whole landscape of such companies out there as they looked into Sigilon; **and to begin to realize what an uncovered and undervalued player Sernova is.**

## SERNOVA IN THE LEAD; BUT CHEAPER THAN “RIVALS”

Even as the spurt in Sernova's share price through the first two weeks of the New Year has taken its market cap to around C\$300 million or so, the company stands out like a sore thumb *still* in comparison to those deemed its chief “rivals.” It remains valued at far less than do Semma Therapeutics and Sigilon (at over \$1 billion, as noted) especially. And more important, it is farther along to coming up with that *complete functional cure*.

### RM Diabetes Competitive Landscape



Clinical Efficacy Data: Therapeutic C-peptide Levels Measured in Bloodstream	Device Vascularization Islet Engraftment Demonstrated in Humans	Local Immune Protection Technology	Financial Metrics (USD Millions)
<p>Phase I/II initiated late 2018 in T1D patients with HU<sup>1</sup>; initial data demonstrates bloodstream C-peptide in T1D patient after 90-days post implant &amp; other efficacy indicators<sup>2</sup></p>	<p>Interim data demonstrated highly vascularized tissue chambers in human patients &amp; abundant surviving islets robustly producing insulin<sup>3</sup></p>	<p>Immuno-suppression is needed under current clinical trial regimen<sup>4</sup>. Local immune protection technologies secured.</p>	<p><b>\$64.8M</b> As of December 2020 Sernova's market cap</p>
<p>PEC-Direct initiated Phase I/II in 2017 in high risk T1D patients; initial data released in 2019 demonstrated cells produce sub-therapeutic C-peptide<sup>5</sup></p> <p>PEC-Encap initiated Phase I/II in 2014, paused due to poor engraftment<sup>6</sup> &amp; restarted in 2019<sup>7</sup></p>	<p>PEC-Direct vascularizes directly<sup>8</sup> &amp; is verified in human trial<sup>9</sup>;</p> <p>PEC-Encap has surface diffusion<sup>10</sup> but their trial was “paused” due to low levels of engraftment<sup>11</sup> – to date human vascularization data is lacking</p>	<p>PEC-Direct program requires long-term immunosuppression<sup>12</sup>;</p> <p>PEC-Encap program may not require immunosuppression<sup>13</sup> – to date human validation has not been demonstrated</p>	<p><b>\$240 M</b> November 2018, raised \$80 M Series D financing – undisclosed valuation<sup>14</sup>; total raised ~\$240 M to date<sup>15</sup></p>
<p>Expected to enter the clinic by 1H of 2020 for hypoglycemia unawareness; a broader trial for adult T1D patients is planned for 2020 H2<sup>16</sup></p>	<p>Pre-Clinical PoC data in pigs demonstrated the vascularization capability of stem cell encapsulating device<sup>17</sup> – to date human vascularization data has not been generated</p>	<p>Semma's proprietary delivery system is designed to protect cells from the immune system<sup>18</sup> though human validation is lacking to date</p>	<p><b>\$950 M</b> August 2019, Vertex acquired Semma for a \$950 M cash payment<sup>19</sup></p>

1. ClinicalTrials.gov; 2. Company Press Release; 3. Company Press Release; 4. JDCA; 5. Company Press Release; 6. Company Press Release; 7. Company Website; 9. Company Press Release; 10. Pitchbook Estimate; 11. Company Press Release  
HU: Hypoglycemia Unawareness; T1D: Type 1 Diabetes.

[ 11 ]

Along the way, Semma's early attempts to implant its “pouch”-like device in patients has reportedly been plagued by fibrosis (scarring) and other challenges when implanted in patients.

As for Sigilon, it seems to have good science/technology where its cell therapies are concerned. However, it has no “pouch” or similar device; *and in early trials, simply injects cells into patients' abdomens.*

# Cell Pouch Solves Device Conundrum



## The Device Conundrum

*"We thought the cells would be the hard part and focused our efforts there. It's obvious now having a functional device will be the limiting factor and there are few current options."*

Big Pharma executive at 2020 JPM

## The challenging device issues and hurdles conquered by Sernova:

- Scalability - Vascularization - Natural cell environment
- Fibrosis - Cell engraftment - Biocompatibility
- Versatility: human cells & tissue, stem cell derived islet cells

The newest reported upstart I have *just* heard of is a private company called Sana Therapeutics, with offices in Cambridge, Massachusetts, San Francisco and Seattle. It has raised \$900 million over the last couple years for its cell therapy offerings; *again, however, with no Cell Pouch-like or other delivery platform*. It has yet to start in-human clinical trials.

[13]

is clear: While several companies in addition to and including Sernova have various offerings where islet/stem cells are concerned, NOBODY is as far along when it comes to the delivery mechanism, etc. as is Sernova. So understandably—and, I suspect, part of what is driving this sudden surge of interest that is unfolding—some of us see it as merely **a matter of time before Sernova is acquired by a larger company** that 1. Has, perhaps, its own regenerative cell regimen and 2. Wants to beat *its* larger rivals to market by having Sernova's delivery platform.

The common denominator

## ***A COMPELLING INVESTMENT THESIS AND "RISK-REWARD" DYNAMICS***



For any start-up/research-oriented company, a LOT has to go *right*. More companies over time fail than those which succeed for one or more reasons: everything from inept management and a lack of money to see things through, to the lack of legitimate expertise in its area, to misreading *the need* for its product/technology and more.

In the case of any such company—and realizing the *general* inherent risks of investing in such small companies—I always advocate we approach them and **make investing decisions simply as Benjamin Franklin would have done**.

Franklin famously advocated that in any important decision, one simply write opposing pros and cons on a piece of paper opposite one another—weight them as necessary, as to importance—and make a decision based on the preponderance of either positive or negative factors.

In my view, making a decision in this way as to investing in Sernova Corporation's shares is a no-brainer (keeping in mind, of course, that until the company *monetizes* its work in one way or another it is still properly classified as *speculative*.) The field in which it is clearly in the lead—in coming up with that functional cure for Type One diabetes—is VAST. Making the comparison to our happy experience with Sarepta—where one birth (commonly, male) out of every 7,000 or so globally is beset with the muscle-

wasting disease that company now has two drugs being sold to better treat—*the universe of patients globally with Type One diabetes is MANY times larger.*

## Diabetes Market Opportunities



		IP Status 2020 Potential Patient Population		Potential Commercial Opportunity			
		(before market access considerations)					
Device / Method Patent		T1D Severe HU with Human Donor Islets	T1D Severe HU with iPSC	All T1D with iPSC	T1D Severe HU with Human Donor Islets	T1D Severe HU with iPSC	All T1D with iPSC
U.S.	Granted	~0.65 K Total Transplants	~240 K Patients	~1.6 M Patients	\$65 – 130 M (per year)	\$5 – 9.5 B (in total)	?
EU5	Granted	~0.5 K	~195 K	~1.3 M	\$40 – 75 M	\$3 – 6 B	?
APAC	Granted CHN & JPN only	~3.0 K	~1.0 M	~7.3 M	~\$225 M		~\$15 B?
Total	Sernova has a global IP portfolio across all key markets	~4.2 K Transplants	~1.4 M Patients	~10.2 M Patients	\$340 – 450 M (per year)	\$24 – 31 B (in total)	?

HU = Hypoglycemia Unawareness HypoHgly. = Hypoglycemia

[10]

As you see above, Sernova—bolstered by a substantial patent portfolio in every major country/region of the world—is in the cat bird seat to earn a meaningful chunk of **a global market that could run into the many billions of dollars**. How it does this... who, if anyone, it does this with... and related questions remain to be answered. But as the market has clearly told us, in part in recognition of the latest clinical progress reported just last week, Sernova has already been considerably “de-risked.”

It also helps reduce the risk here that the company *already* is under the watchful eye of would-be partners and rivals. Last Summer, the company announced that it had formed a Global Advisory Board, by which it seeks to bring on leading talent to help with development as well as representing the company to the industry. The first member named was Dr. Anke M. Schulte, an internationally acclaimed expert in diabetes and cell therapy regenerative medicine *and a 19-year veteran of Sanofi, a global pharmaceutical leader*. It would not be too much of a stretch here to muse about Dr. Schulte’s eyes and ears on Sernova giving her former company more of an inside look at things than others may have!



However we want to handicap different scenarios by which Sernova could one day monetize its work and its leading science/edge specifically on its Cell Pouch System™ (whether by commercializing all this itself or—more probable, in the opinion of Yours truly, as it is acquired or “partnered” somehow with a larger company) we need to also honestly ask *what could go wrong*.

\* **Management’s skill set** – As Dr. Toleikis (at left) pointed out in an on-line presentation from a few days ago to the H.C. Wainwright Bioconnect 2021 Virtual Conference, Sernova’s management has all the necessary tools—to work on the device itself, as well as therapeutic and immunology experience—as has been validated to

*date by the company's clinical success.* Among your other "homework" on the company you'll want to do as an informed investor, I encourage you to learn about Philip and his team at <http://sernova.com/company/#Management>.

In short, Yours truly is and has been quite confident in management's scientific and technical expertise to, if anything, *broaden* Sernova's lead in the race for a functional cure for Type One diabetes and be the first management team to monetize such a thing in a big way.

\* **Funding** – Sernova is in good shape for the foreseeable future to finance its work. In late September it closed an oversubscribed private placement (which several of my Members here at *The National Investor* happily participated in.) The company also received a grant not long ago of \$5.6 million euros for the further work on its Hemophilia A regimen in Europe.

All told, I see virtually no risk of the company running out of money to do its work, especially following this latest surge of interest in the market. I daresay that if/when the time comes that the company needs to do another capital raise, demand will be *brisk*.

\* **Immune response suppression** – As *briefly* touched on a bit earlier, the final, meaningful "third part" of the total picture for the Cell Pouch regimen is immune suppression; finding a way that the device and islets themselves will be protected, with no need to have an implanted patient take immune-suppressing drugs.

**Here the company has two different irons in the fire:** one with AgeX Therapeutics (NASD-AGE) on that company's *fascinating* UniverCyte technology (announced late last Spring) and a collaboration announced August 4 with the University of Miami at Coral Gables, Florida for the commercial rights to its novel conformal coating immune protection technologies. News and the interesting details on both of these arrangements can be viewed at <http://sernova.com/press/all/?year=2020>

\* **The work ahead is more "tweaking" than anything** – When you read (and read *again!*) the news of last Friday, you should come away with the appreciation the rest of us have: that Sernova is in the late innings of this game to bring its Cell Pouch System™ across that proverbial Finish Line. Thus, a lot of the "de-risking," as I alluded to earlier, is in the rear-view mirror. Now it is a matter of putting the relatively fewer improvements and finishing touches on the overall device/regimen.

As Dr. Toleikis held in that Wainwright presentation in discussing this aspect and the continuing trials with the added patients underway for 2021, "Importantly this is not a study where there will be a binary outcome." Already, the device has been well tolerated and safe...no

## Clinical Study Update



### ENROLLMENT:

5 of the 7 patients have now been enrolled, implanted with Cell Pouches and are actively advancing through the transplantation phase of the study

Pre-screening is ongoing for the final two patients and full enrollment of the study is anticipated to be completed in the first quarter of 2021

### SAFETY (Primary Endpoint):

- > Following implantation, consistent incorporation of the Cell Pouch with vascularized tissue providing a suitable environment for transplant of islets (insulin-producing cells)
- > No incidence of Severe Adverse Events (SAEs) related to the Cell Pouch or islet transplant

Highlighting some of the trial efficacy findings with focus on clinical benefits to the T1D patients, the following trends have also been observed.

### EFFICACY (Secondary Endpoint):

- > Ongoing detection of bloodstream levels of C-peptide in treated patients
- > Reduction in injectable insulin use
- > Reduction in levels of HbA1c as a measure of long-term glucose control
- > Reduction in severe hypoglycemic episodes

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fibrosis...no rejection...and the company's overseeing Independent Safety Board in the last year gave the green light to continue.

**The markers of efficacy are there as well:** the KEY one being the first patient long ago evidencing those C-peptide blood levels and—most recently—the announcement that he has not required ANY additional injected insulin.

Nothing is, of course, *guaranteed*; nor a reality until the company (and/or an acquirer/partner) reaches a final, F.D.A.-approved application. But after all the progress to date, it's hard to imagine at this point what could go so badly wrong as to *meaningfully derail* the company.

**\* Market recognition** – For a while, many of us wondered whether the world (meaning, the investment markets that were mostly sleeping through Sernova's story and progress of the last 18 months especially) would pass Sernova by. *The accelerating attention given the company since last month has put that worry to rest.*



**what I will tell the broader audience reading this report is what I just told my paid Members as well: and that is, I see Sernova going up by several more multiples.** That is based in part—as I have discussed herein—to it still being too cheap compared to several rivals, NONE of whom are as far along in *their* "journey to the Finish Line."

**So for present purposes at least, Sernova remains a BUY.**

Bear in mind as well that—notwithstanding the likelihood that some who have jumped on will want to lock up quick profits and sell, likely leading to volatility—we have more than the story/progress ongoing here. **We also have what is refreshingly and belatedly the investment world waking up.** That has been helped along now in the U.S. by Sernova listing on the OTCQB; this opens the company to greater institutional and analyst coverage, among other things, especially with its rising share price/market cap. *And management plans to go for a full up listing to the NASDAQ as well.*

**So in summation**, Sernova as I see things has already done the lion's share of the research and clinical work needed to de-risk its Cell Pouch System™. Both the medical community and investment markets have their eye on the company in a greater way than ever. *The Finish Line can now be pretty clearly seen up ahead.*

Though most of you reading this who are *not* regular, paid Members of *The National Investor* (you can fix that by visiting me at <https://nationalinvestor.com/subscribe-renew/>) missed the year-or-so long opportunity to get into Sernova at *a fraction* of its current price, **I believe you can see that it is now priced at a fraction of the company's ultimate value.**

**So the opportunity here remains every bit as compelling.**

## ***KEEPING UP WITH SERNOVA'S STORY AND PROGRESS***

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\* I strongly urge you to take the 24 minutes and watch that presentation Dr. Toleikis *just* gave at the H.C. Wainwright Bioconnect 2021 Virtual Conference. You will need to register (FREE) at <https://journey.ct.events/view/3a577711-041b-48a3-8b1c-0d47129bb30c> after which you can watch the recording.

Having been with Philip and his C.F.O. David Swetlow last February at the NobleCon Conference in Hollywood, Florida—and otherwise being on a few different calls with him since I've known him—I can tell you he *really* knocked the cover off the ball here! To be sure, I think much of the sudden surge in interest in Sernova was fairly due to Philip so expertly wrapping up the whole story on that Wainwright conference. *You'll be sorry if you don't watch and let Dr. Toleikis himself "seal the deal" for you.*

\* Spend some time as well getting to know the company at <http://sernova.com/>. Get on their mailing list and follow their occasional announcements on Twitter at <https://twitter.com/SernovaCorp>. Or @SernovaCorp.

I will, of course, have ongoing updates on the company as warranted, whether in my twice-monthly newsletter or, as appropriate, any of my between-issues shorter alerts. For more information, you can visit me at <https://nationalinvestor.com/>. And if you are not already, be sure you are on MY mailing list and that you follow me as well (see below.)

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**Don't forget that those of you so inclined can follow my thoughts, focus and all daily !!!**

\* On Twitter, at <https://twitter.com/NatInvestor>

\* On Facebook at <https://www.facebook.com/TheNationalInvestor>

\* On my You Tube channel, at [https://www.youtube.com/channel/UCdGx9NPLTogMj4\\_4Ye\\_HLLA](https://www.youtube.com/channel/UCdGx9NPLTogMj4_4Ye_HLLA)

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*A Reminder...or quick "Primer"*

## **HOW TO PURCHASE SHARES OF SERNOVA CORPORATION IF YOU ARE A U.S. INVESTOR USING A U.S.-BASED BROKERAGE ACCOUNT**

For those of you who are not already used to buying shares of companies such as Sernova Corporation that are *listed* primarily in Canada, I want to give you a quick and easy "tutorial." It's MUCH easier than you think, if you have never done so, to buy such companies in any U.S. brokerage account. *Indeed, as I have explained in one of my investor tutorials, it's just as easy and inexpensive to buy shares in a Sernova Corporation as it is to buy Apple!*

Many larger Canadian and other foreign companies have primary listings on more than one major exchange. For those listed on the New York Stock Exchange or the Nasdaq as well as Toronto, you need only buy/sell using the U.S. market. Generally, there would be no reason to check prices and such on the Toronto Exchange first.

More often than not, smaller companies—for both cost and logistical reasons—do not LIST their shares on a major U.S. exchange. **But they are still easily TRADABLE in the U.S. via the Nasdaq's OTC Market.** All you need to know is the company's symbol; unlike most U.S.-listed companies, it will always be a five-letter symbol ending with an "F."

In Sernova's case, its ticker symbol on the OTCQB System in the U.S. is **SEOVF**, while on the Toronto Venture Exchange (TSXV) it is **SVA**.

**The main consideration in buying shares of Canadian stocks via the U.S. OTC market is that SOMETIMES--if you look at the OTC quote FIRST--you are not getting as fresh and accurate a price as you would if you went to the Toronto Exchange.** This is because with most, the majority of their activity is on the Canadian market where it is listed; sometimes hours can go by between trades on the OTC, if the company you're looking to buy isn't actively traded at the time. Thus, you simply need to insure, via a simple process, that you are neither overpaying for a stock when you buy it, nor getting less than you should when you sell. That is easy to accomplish. (**NOTE:** As this Report is being released, the U.S. volume has picked up substantially as well in the recent past; but I *still* recommend you follow this simple exercise.)

The most reliable and current quotes for shares of companies such as Sernova are to be found *first* on the Canadian Exchange where they are primarily LISTED. Prices and volume activity are updated all through the trading day on the TSXV just as they are on the N.Y.S.E. or Nasdaq, and are generally fresh/instantaneous.

**I will use the following example to show the simple process that will normally take you LESS THAN TWO MINUTES to enter a trade to buy Sernova's stock via the OTC market in the U.S, in a typical U.S.-domiciled brokerage account:**

1. First check the Canadian quote for the company, via its ticker symbol on the TSXV, which is SVA. You'll find this at the Exchange's web site, <https://tmx.com/>. Plug in "SVA." We'll say for purposes of this lesson that the current asked price for IME's shares is C\$1.24, its closing price on Friday, Jan. 15 (in Canadian currency.)

2. Next determine what that price is **in U.S. currency**. If you don't follow exchange rates on a daily basis, you can get a fresh picture by going to Kitco's web site, at [www.kitco.com](http://www.kitco.com) (or your own favorite one that lists currency differentials; there are many.) Near the bottom of Kitco's front page, you will find a table of various currency exchange rates. *At this writing the Canadian dollar, rounded off, is worth 78.6 cents in U.S. currency.*

3. Do the math as to what SVA's U.S. asked (selling) price on the OTC market should be:

C\$1.24 per share  $\times$  .786 = **US\$0.975** per share.

4. Finally, **enter a LIMIT ORDER** to buy the number of shares of Sernova you want in your U.S. brokerage account at or very near that price. Personally, I would first start with US 98 cents per share. If the order doesn't fill right away, bump it up by a tenth of a cent once or twice until it does (these days, most online brokers will allow you to use tenths of a cent in pricing.) *You would use the company's 5-letter symbol, which is SEOVF.*

It's that simple! And, of course, you would do much the same thing when it was time to sell some of your holdings. But in the case of a sale, you would focus on the bid price listed on the TSXV's site for the company in question.

As always, if you have any comments or questions, let me know!

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