

# Corporate Investor Deck

February, 2022



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**Sernova Corp.** is a **Regenerative Medicine** clinicalstage company developing therapeutic products for **chronic debilitating diseases.** 

The Company's proprietary **Cell Pouch System™** consists of an implantable device containing immuno-protected therapeutic cells capable of sustainably producing missing therapeutic proteins and hormones.

Sernova's lead product treats type 1 insulin-dependent diabetes (T1D). It utilizes insulin-producing cells placed into its Cell Pouch, which is implanted and naturally vascularized, allowing cells to provide a continuous supply of insulin with the goal of reducing or eliminating the need for insulin injections.

# Sernova Corp

Sernova's approach for its **cell therapy** platform is focused on creating a true 'functional cure' for chronic diseases like T1D, vs. only treating the symptoms with burdensome and lifelong administration of prescription medication. The platform has potential application for multiple indications.

### **Investment Highlights – Cell Pouch System**



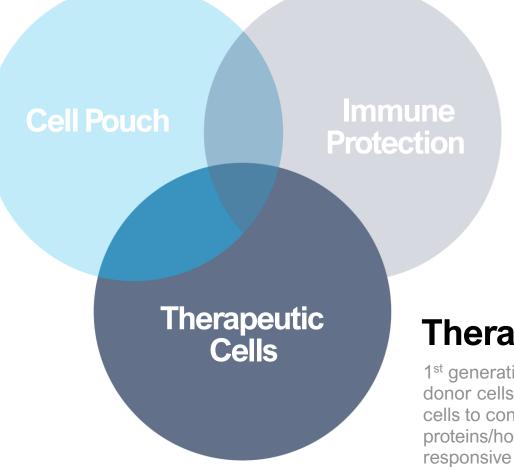
Proprietary Cell Pouch System™	<ul> <li>Proprietary implantable device containing therapeutic cells for organ-like environment</li> <li>Once implanted, is naturally vascularized allowing self-sustaining cell survival for years</li> <li>2<sup>nd</sup> generation allows for immuno-protection abrogating the need for immunosuppressives</li> </ul>
Immune-protected Cells Producing Missing Proteins	<ul> <li>Cell Pouch currently utilizes human donor pancreatic islets</li> <li>Next generation products will utilize insulin producing stem cell-derived islets</li> <li>Cells are completely susceptible to natural regulation but physically restricted by Cell Pouch</li> </ul>
Lead Indication: Type 1 Diabetes (T1D)	<ul> <li>T1D Phase 1/2 study well underway; progressing to Phase 3 study</li> <li>Preclinical POC using human cells demonstrated for Hemophilia A and Thyroid Disease</li> </ul>
POC Established in Human Clinical Trials	<ul> <li>Preliminary data from first 6 T1D study patients shows potential for 'functional cure' and complete insulin-independence for extended periods of time</li> <li>1<sup>st</sup> patient has completed study protocol and now insulin independent for &gt; 21 months (Jan/22)</li> </ul>
Well-funded, Experienced Leadership	<ul> <li>Management team with deep expertise in regenerative medicine and combination therapies</li> <li>Strong cash position of \$27M provides ample runway. Up to \$45M available from warrants.</li> <li>Aspirations for US-based Nasdaq listing in 2022</li> </ul>

# Platform Approach: Finding Functional Cure for Chronic Diseases

Integrated Regenerative Medicine Solution for Treatment of Chronic Diseases

### **Cell Pouch**

Proprietary implantable medical device that provides vascularized environment for therapeutic cells to survive for long periods of time – creating an organ-like environment



#### Immune Protection

2<sup>nd</sup> generation devices utilize technologies to protect therapeutic cells from immune system attack – reducing or eliminating need to immunosuppressives

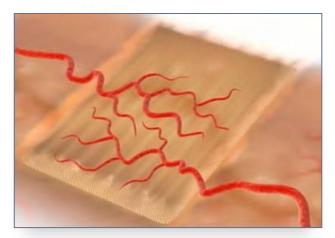
### **Therapeutic Cells**

1<sup>st</sup> generation product utilizes human donor cells, and 2<sup>nd</sup> generation with stem cells to continually produce missing proteins/hormones and cells fully responsive to endogenous regulation

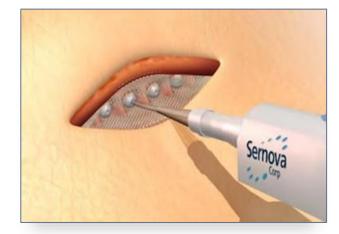
### **Cell Pouch Containing Therapeutic Cells**



Biologically compatible delivery process – allows natural vascularization



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



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

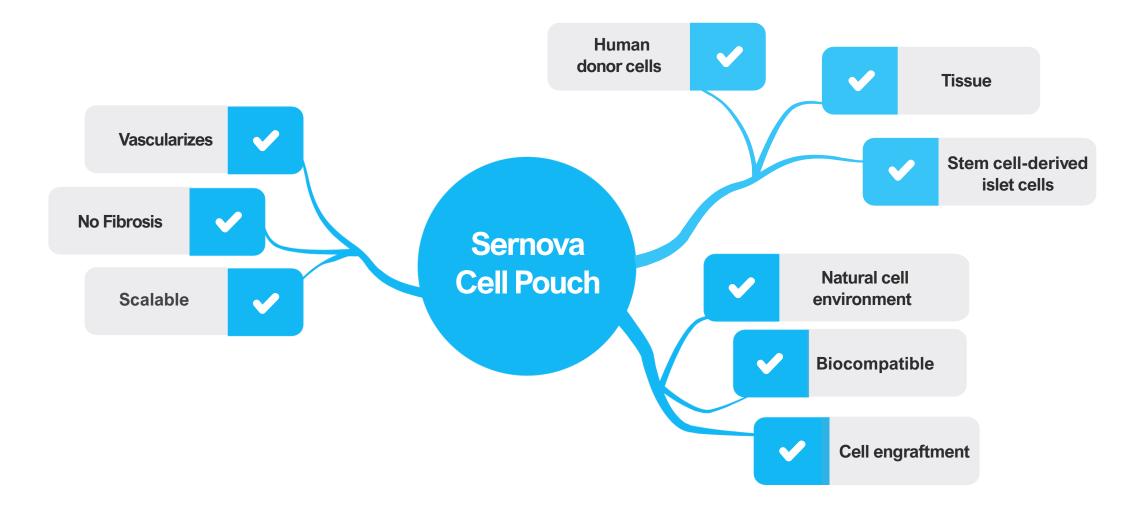


Therapeutic cells are responsive to endogenous regulation and release missing proteins or hormones into the bloodstream to correct biological dysfunction

### **Cell Pouch has Overcome Limitations of Previous Attempts**



Sernova has created an organ-like environment with the goal of providing 'functional cure'



### **Pipeline – Life Cycle Iterations and Multiple Indications**



Product Candidate	Therapeutic Cell Source	Immune Protection	Indication	Pre-Clinical	Phase 1/2	Phase 3	Market Approval Application
Cell Pouch System	Human donor islet cells	Immunosuppressives					
2 <sup>nd</sup> Gen System	Human donor islet cells	Local immune protection	Type 1 Diabetes				
3 <sup>rd</sup> Gen System	Stem cells	Local immune protection					
Cell Pouch System	Corrected patient cells	Autogeneic cells	Hemophilia A - Severe				
2 <sup>nd</sup> Gen System	Allograft immune protected stem cells	Local immune protection	Hemophilia A – All patients				
Cell Pouch System	Thyroid cells	Autogeneic cells	Thyroid Diseases / Hypothyroidism				
2 <sup>nd</sup> Gen System	Allograft immune protected stem cells	Local immune protection	Thyroid Diseases / Hypothyroidism				



**GLOBAL DISEASE = GLOBAL MARKET** 

## DIABETES



**Diabetes** is one of the module prevalent **diseases** pervasive **medical problems**, impacting society and everyday **quality of life** today.

**463 million people** are affected worldwide with Diabetes; another estimated 179 million people have it without knowing it. **By 2045**, projections show this number rising to some **700 million diabetics globally**.

Sernova's Cell Pouch System for Type 1 Diabetes will enter a commercial market of ~\$30 billion and could have true blockbuster potential. It could potentially provide a future free from insulin injections for millions of patients.

#### **Diabetes statistics**

**\$760B** Health Expenses related to Diabetes

**\$845B** 

Projected Health Expenses related to Diabetes in 2045

\$34.8B Global human insulin market for 2019

10% Prevalence of T1D



# LEAD DIABETES INDICATION

### Hypoglycemia Unawareness Among Type 1 Diabetic Patients

Hypoglycemia Unawareness – most critical unmet need in T1D

Affects 15% of T1D patients (~240k patients in the US)

Clinically defined as a person's inability to recognize the symptoms of low blood sugar before they become severe or even fatal

Patients do not experience hypoglycemia warning symptoms (i.e. palpitations, anxiety, excessive sweating, light headedness)



Harmful effects: diabetic ketoacidosis (DKA), coma and death

### Phase 1/2 Study Design



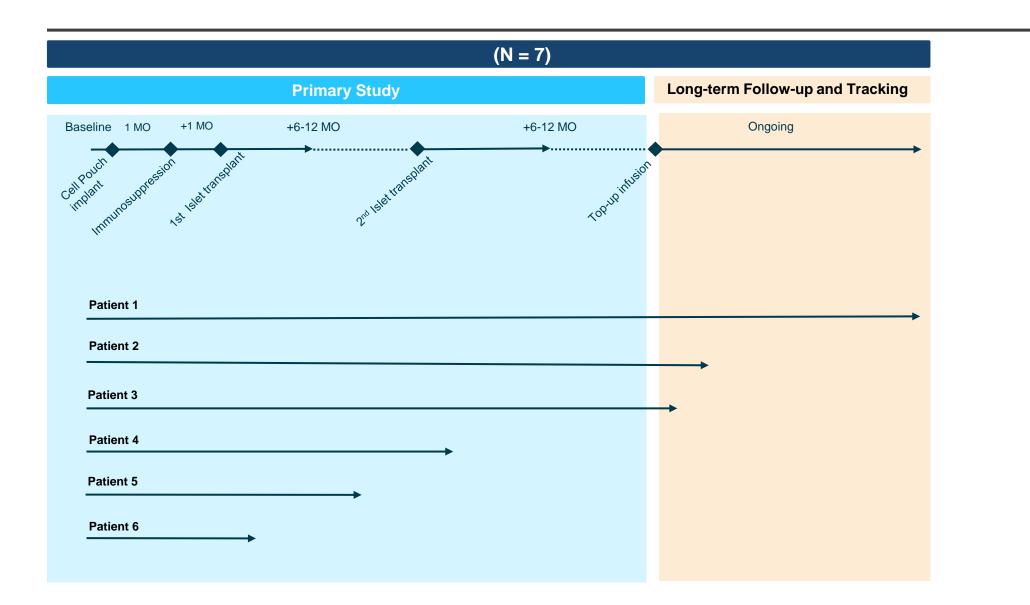
#### 7 Patients with Type 1 Diabetes (T1D)

#### **Study Overview**

Study Design	<ul> <li>Company sponsored open label single-arm, single-center study</li> <li>Enroll 7 insulin dependent T1D patients with Hypoglycemia Unawareness</li> <li>Cell Pouch implant followed by human donor islets transplant to Cell Pouch</li> <li>Standard of care for immunosuppressives</li> <li>PI: Dr. Piotr Witkowski, Assoc. Professor of Surgery; Director, Pancreatic and Islet Transplant Program; Univ. of Chicago</li> </ul>
Key Inclusion Criteria	<ul> <li>T1D patients with history of severe hypoglycemic events</li> <li>No glucose-stimulated systemic C-peptide</li> </ul>
Key Objectives and Endpoints	<ul> <li>Key Objectives</li> <li>Demonstrate the safety &amp; tolerability of islet transplantation into the Cell Pouch</li> <li>Establish islet cell quality criteria that accurately characterize the islet product and are predictive of clinical transplant outcomes into the Cell Pouch</li> <li>Primary endpoint <ul> <li>Safety and tolerability</li> </ul> </li> <li>Secondary endpoints <ul> <li>Survival of endocrine tissue in Cell Pouch</li> <li>Proportion of subjects with a reduction in severe hypoglycemic events</li> <li>Proportion of subjects with HbA1c reduction &gt;1mg</li> <li>Over 20 additional endpoint analyses</li> </ul> </li> </ul>

### Phase 1/2 Study Design

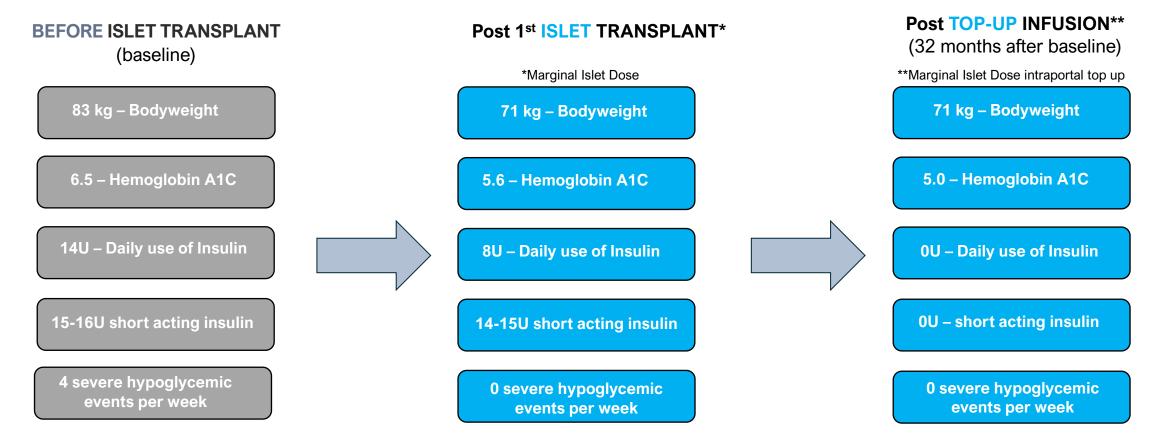




### Case Study: Longest Patient Insulin Independent for >20 Months



Dr. Witkowski presents patient data at international conferences



#### Post-transplant Glucose Tolerance Tests

The tests consistently showed increase in blood levels of C-peptide, a biomarker for insulin presence in the bloodstream from transplanted islets

Consistent enduring blood levels of C-peptide & ongoing evidence of islet engraftment & durable therapeutic effect detected post Cell Pouch transplant

### Patient #1 – Impact Statement



After completing the safety, tolerability and efficacy study of Sernova's Cell Pouch for clinical islet transplantation and as the first transplant candidate, I can easily state how absolutely wonderful life is to be free of always thinking of how to manage my diabetes. After having T1D for 47 years with approximately 21,535 injections of various cow/pig, synthetic insulins, 34,310 finger sticks, 1,460 urine tests, 15 years on the pump, carbohydrate counting, blood tests, low blood sugar reactions, and doctors...doctors and more doctors' visits, I have now been free of the need for injectable insulin for 15 months. My Sernova team of invaluable scientists, doctors, engineers, and Dr. Witkowski, and the University of Chicago's support staff have done this truly amazing feat right in the middle of a worldwide pandemic! My only wish is that it could have been June 2021 done sooner.

# Sernova

### Summary of First Transplanted Patients in Phase I/II Clinical Trial (Protocol PROSVA201701)

РТ	Daily Insulin Use (Units)	C-Peptide (ng/ml)		Severe Hypoglycemic Events		HbA1c (%)		CGM Time in Range	
	Δ From Baseline	Baseline	Post-Tx	Baseline	Post-Tx	Baseline	Post-Tx	Baseline	Post-Tx
А	↓ 100%*	Undetectable	Normal	Frequent	Zero	6.5	5.4	88.9%	99.6%
В	↓ 100%*	Undetectable	Normal	Occasional	Zero	9.2	5.3	22.3%	95.5%

\*Patients A & B are Insulin Independent – Ongoing for 22 and 3 months, respectively (Jan 2022)

CGM: Continuous Glucose Monitoring C-Peptide: A measure of insulin production Post-Tx: Following completion of last protocol-defined islet transplant.

- The ongoing safety and tolerability of Cell Pouch has been maintained in all study patients
- The other enrolled study patients have received Cell Pouch implants and are at various stages of protocol-defined islet transplants and follow-up
- A 7<sup>th</sup> study patient has been identified

### T1D Phase 1/2 Findings Presented To-Date



The Sernova Cell Pouch System is the <u>first</u> regenerative medicine to demonstrate a subcutaneous transplanted device to achieve persistent islet cell graft function in T1D patients

#### Safety Assessments<sup>1</sup>:

- 6 patients now successfully implanted and transplanted with Cell Pouch and islet cells
- Cell Pouch well-tolerated with excellent safety profile
  - Cell Pouch implant durations up to 32 months (and continuing)
  - Islet cell transplant functional survival duration up to 30 months (and continuing)
- No incidences of SAEs determined to be probable or highly probable to the Cell Pouch
- Safety findings continue to meet the primary endpoints

#### **Efficacy Observations**<sup>1</sup>:

- Clinical benefit has been reported by the investigator in case studies, in the most advanced study subjects
  - Sustained blood levels of C-peptide (biomarker of functional insulin production by transplanted islet cells)
  - Reduction of HbA1c (indicator of long-term glucose control)
  - Overall improvement in glucose control (assessed by CGM) including reduction/elimination in hypoglycemia unaware events
  - Reduction/elimination in the need for daily insulin injections
- Investigator reported improved islet engraftment and patient outcomes with a smaller (marginal) dose of islets in the Cell Pouch
- The most advanced patient has successfully completed the study protocol and remains insulin independent >21 months (Jan/22)
  - Remaining 5 patients continue to advance in the study at various stages

#### 1<sup>st</sup> patient remains insulin independent >21 months (@ Jan/22)

### **Cell Pouch Diabetes Program – Progress & Upcoming Events**



#### Internal and External Advancement of Development and Commercialization Strategy

#### **Current Phase 1/2 Clinical Study**

- Completion of study enrollment; completion of patient follow-up and study report
- Additional top-line data expected in 2022

#### **Expand Clinical Development**

- · Preparation for pivotal Phase 3 study with islet cells
- Advancement into the clinic using Conformal Coating Technology with human islets with the goal to eliminate immunosuppressives

#### Advance stem cell preclinical collaborations with Cell Pouch in diabetes into formal partnership announcement

• Clinical development of immune protected stem cell technology in Cell Pouch for <u>all insulin-dependent diabetic patients</u>

#### Advancement of relationships with potential Medtech partners

- Development of surgical tool kit for minimally invasive placement of Cell Pouch and therapeutic cells
- Establish marketing and distribution partner for Cell Pouch System and surgical tool kit

#### **Conducted Independent Physician and Payor Survey**

- Overall conclusion Cell Pouch System would be a significant contribution to current diabetes treatment
- Market could support potential pricing in the \$100,000 \$200,000 range per course of treatment per patient

### **Conformal Coating Technology for Cell Pouch Immune Protection**



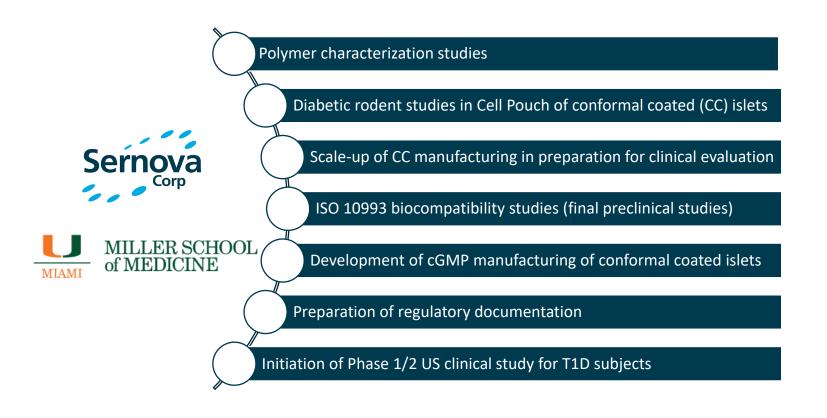
Potential to eliminate the need for immunosuppressives

#### **Conformal Coating**

Conformal Coating Technology developed and optimized with >12 years of research at the University of Miami

- Selectively permeable
  - Immuno-protective to prevent rejection
  - Allows for physiological transfer of insulin and glucose unlike other encapsulation technologies
- Consists of a thin biocompatible polymer hydrogel coating that surrounds therapeutic cells (donor islets, stem cell-derived islets)
- Used within Cell Pouch to coat islet cells and stem cell derived cells for multiple indications
- Potential to eliminate the need for immunosuppressives

#### University of Miami / Sernova Collaboration Plan





	Conformal Coating with Cells	Cell Pouch + Cells
Safety in non-human primates	$\checkmark$	$\checkmark$
Efficacy with donor islets in T1D preclinical models	$\checkmark$	$\checkmark$
Efficacy with T1D stem cell-derived islets in T1D preclinical models	$\checkmark$	$\checkmark$
Safety in humans with T1D	Not Applicable	$\checkmark$
Efficacy in T1D humans with donor islets	Not Applicable	$\checkmark$
Efficacy in T1D humans with stem cell-derived islets	Not Applicable	

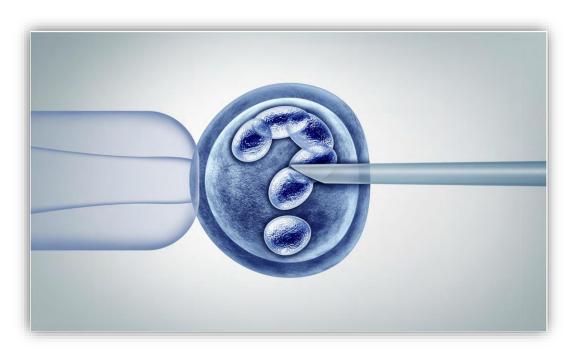
#### Immuno-protection Summary

- Due to its 'shrink wrap' proximity to the cells, the volume of cells for transplantation into the Cell Pouch is unaffected
- Unlike other encapsulation technologies allows for normal movement of nutrients / glucose / insulin in and out of cells
- Allows normal glucose-stimulated insulin response (glucose tolerance test) in vitro and in vivo
- Produces insulin independence for islets and stem cell-derived islets (technology to provide an <u>unlimited supply</u> of cells)
- Safety demonstrated in non-human primate models
- Anticipate to start human studies in 2023

### Gene Editing for Stem Cells in Cell Pouch - Immune Protection



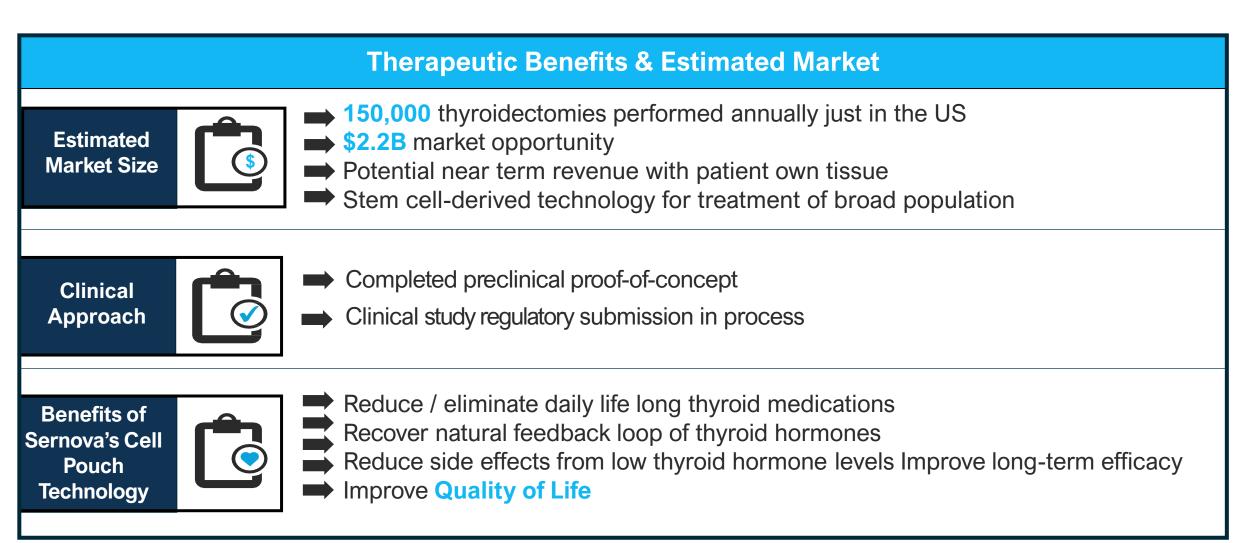
AgeX technology for potential off-the-shelf islet cell transplantation product



- AgeX collaboration ongoing to confirm the potential of Sernova's pluripotent stem cell-derived pancreatic islet beta 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 protects a developing fetus from the mother's immune system.
- **Combination** of UniverCyte with Cell Pouch could create an off-the-shelf product for transplantation of therapeutic cells in patients with T1D without the use of immunosuppressives.



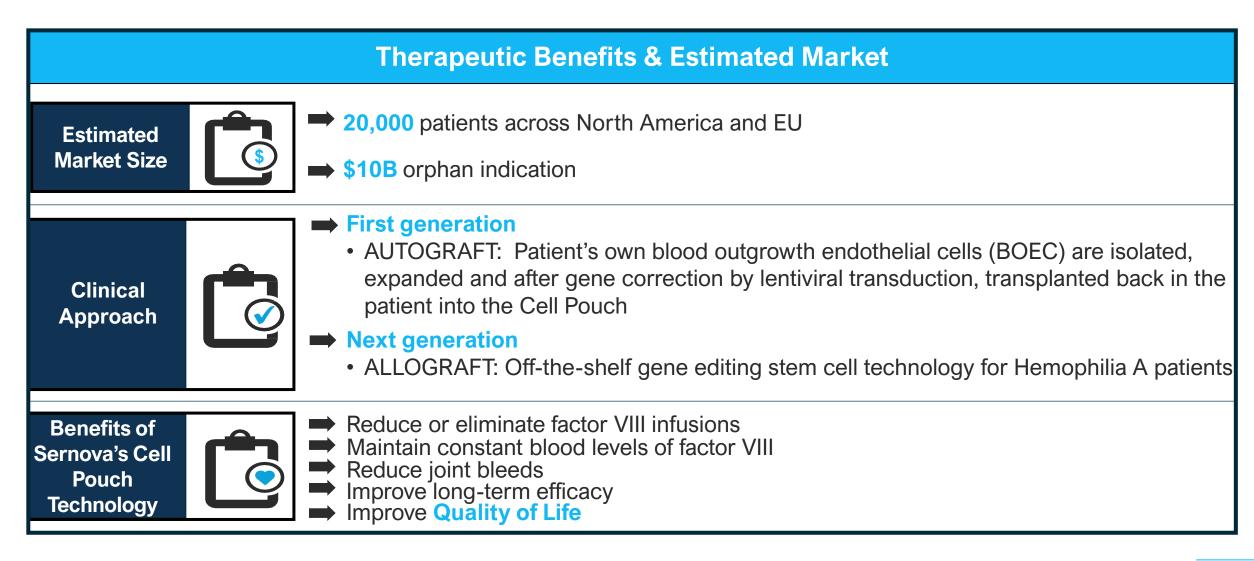
## **Cell Pouch System Thyroid Program**



### **Cell Pouch System Rare Disease Program**

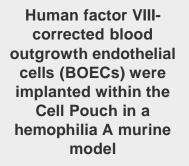


Hemophilia A

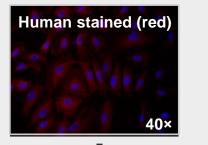


### **Hemophilia A Indication**

#### Preclinical Safety & Efficacy of Hemophilia Cell Therapy in the Cell Pouch



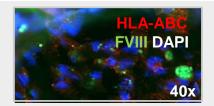
Confirmed Release-tested BOECs



Non-transplanted Cell Pouch Awaiting Cells



T – Transplant area of Cell Pouch P – Peritoneum



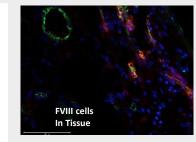
**Cell Pouch Transplanted with Cells** 



Improvement in clotting with Cell Pouch and Factor VIII producing cells

E 0.8-

099 0.6 0.4 0.4



FVIII corrected human BOECs arranged into blood vessels within the vascularized Cell Pouch at 4 months post-transplant (mouse model) Human corrected BOECs transplanted into the Cell Pouch improved clotting in hemophilia A, providing scientific rational for next step development

### **Sernova Share Information**





In millions except share price

Share Prices and Market Cap as of February 2, 2022



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