The Path To A Regenerative Medicine Cure

BIOLInvestor Forum
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Forward-Looking Statements

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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 Pouch™ + 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\textsuperscript{st} 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**
Sernova’s Platform Approach

Integrated RM Therapeutic Solution for Treatment of Chronic Diseases

Cell Pouch
Implantable proprietary medical device that provides vascularized environment for therapeutic cells

Therapeutic Cells
Human cells (donor / stem) & tissues that produce & release missing proteins or hormones into the bloodstream

Immune Protection
Technologies to protect therapeutic cells from immune system attack
Worldwide IP / Patent Portfolio

*International patents & patent applications portfolio in multiple patent families with broad application & continued expansion:*

- Composition & use of medical devices for delivery & cell transplantation
- Glucose responsive insulin secreting stem cell technologies
- Local immune protection technologies

*Broad geographic coverage:*

- North America
- South America
- Europe
- Asia
# Sernova Pipeline

<table>
<thead>
<tr>
<th>CELL POUCH CANDIDATE</th>
<th>PRE-CLINICAL</th>
<th>PHASE I</th>
<th>PHASE II</th>
<th>PHASE III</th>
<th>DEVELOPMENT STAGE</th>
<th>INDICATION</th>
</tr>
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<tbody>
<tr>
<td>HUMAN DONOR ISLETS, SYSTEMIC IMMUNE PROTECTION</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PHASE I/II INITIATED DEC 2018</td>
<td>HYPOGLYCEMIA UNAWARENESS</td>
</tr>
<tr>
<td>LOCALLY IMMUNE-PROTECTED STEM CELL DERIVED CELLS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ANTICIPATED 2ND APPROVAL FOR DIABETES</td>
<td>ALL INSULIN DEPENDENT DIABETIC PATIENTS</td>
</tr>
<tr>
<td>CORRECTED PATIENT CELLS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PRE-CLINICAL</td>
<td>SEVERE HEMOPHILIA A PATIENTS</td>
</tr>
<tr>
<td>ALLOGRAFT IMMUNE-PROTECTED CELLS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>EARLY DEVELOPMENT</td>
<td>BROADER HEMOPHILIA A PATIENTS</td>
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<tr>
<td>THYROID CELLS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PRE-CLINICAL</td>
<td>THYROIDECTOMY PATIENTS FOLLOWING HYPERTHYROIDISM</td>
</tr>
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</table>

**T1D**

**Hemophilia A**

**Thyroid**
# Diabetes Market Opportunities

<table>
<thead>
<tr>
<th>IP Status</th>
<th>2020 Potential Patient Population (before market access considerations)</th>
<th>Potential Commercial Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>T1D Severe HU with Human Donor Islets</strong></td>
<td><strong>T1D Severe HU with iPSC</strong></td>
</tr>
<tr>
<td><strong>Device / Method Patent</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>U.S.</strong></td>
<td>✔ Granted</td>
<td>~0.65 K Total Transplants</td>
</tr>
<tr>
<td><strong>EU5</strong></td>
<td>✔ Granted</td>
<td>~0.5 K</td>
</tr>
<tr>
<td><strong>APAC CHN &amp; JPN only</strong></td>
<td>✔ Granted</td>
<td>~3.0 K</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>Sernova has a global IP portfolio across all key markets</td>
<td>~4.2 K Transplants</td>
</tr>
</tbody>
</table>

HU = Hypoglycemia Unawareness  
Hypgly. = Hypoglycemia
### RM Diabetes Competitive Landscape

#### Clinical Efficacy Data:

**Therapeutic C-peptide Levels Measured in Bloodstream**
- Phase I/II initiated late 2018 in T1D patients with HU: initial data demonstrates bloodstream C-peptide in T1D patient after 90-days post implant & other efficacy indicators.

#### Device Vascularization

**Islet Engraftment Demonstrated in Humans**
- Interim data demonstrated highly vascularized tissue chambers in human patients & abundant surviving islets robustly producing insulin.

#### Local Immune Protection Technology
- Immuno-suppression is needed under current clinical trial regimen. Local immune protection technologies secured.

#### Financial Metrics (USD Millions)
- As of October 2020: Sernova’s market cap
  - $48 M
- November 2018: ViaCyte raised $80 M Series D financing at an undisclosed valuation; in total ViaCyte has raised ~$240 M to date.
  - $240 M
- August 2019: Vertex acquired Semma for a $950 M cash payment; in total Sigilon has raised ~$195 M to date.
  - $950 M
- March 2020: Sigilon announced $80.3 M Series B financing at an undisclosed valuation; in total Sigilon has raised ~$195 M to date.
  - $195 M

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HU: Hypoglycemia Unawareness; T1D: Type 1 Diabetes.
Therapeutic Cells

Therapeutic Cell Options

- **Human donor cells** enable early safety / efficacy testing in the clinic for indications & patients with unmet needs & advanced disease (i.e. diabetes HU patients). Supply is limited; however, they enable **Cell Pouch validation** in preparation for stem cell technologies.

- **Stem cell derived cells** enable expanded availability to an **unlimited supply of cells** for large market opportunities (i.e. all T1D patients & other indications)

Stem Cell Derived Technologies

- **Exclusive worldwide license** to a diabetes stem cell derived technology unlocking potential access to all T1D subjects & 30% of TD2 who convert to insulin use

- **Big Pharma collaboration** on other best in class stem cell derived technologies to advance **partnering opportunities**
### Immune Protection

- **Transplanted therapeutic cells must be protected from a natural immune system attack** response.
- While established systemic transplantation immuno-suppression (anti-rejection) drugs can be effective, **local immune protection (LIP) is optimal**. LIP alternatives present different opportunities & challenges.
- **Multiple approaches** under consideration to **optimize indication match, therapeutic solution delivery** & benefit, & eliminate the need for drugs & their associated side effects.

<table>
<thead>
<tr>
<th>IMMUNE PROTECTION APPROACH</th>
<th>SYSTEMIC (S) or LOCAL (L)</th>
<th>DEVELOPMENT PROFILE</th>
<th>SERNOVA ACTIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immuno-suppression drugs</td>
<td>S</td>
<td>Proven, Achieved</td>
<td>Medium, Low, Low</td>
</tr>
<tr>
<td>Immuno-protected macro device</td>
<td>L</td>
<td>Failed, Achieved</td>
<td>Medium, High, Medium</td>
</tr>
<tr>
<td>Cell encapsulation (conformal coating)</td>
<td>L</td>
<td>Proven, Near term</td>
<td>Low, Low, Low</td>
</tr>
<tr>
<td>Cell tolerance (gene editing)</td>
<td>L</td>
<td>TBD, Mid term</td>
<td>Under Evaluation, Under Evaluation, Medium</td>
</tr>
</tbody>
</table>
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
Strategic Development Approach

Development + Testing Cycle

Systematic stepwise “building-block” process deployed to:
- minimize unknown variable interdependencies
- de-risk development outcomes

vs. “all-in-one” failures by other RM cell therapy companies
The Reality: Diabetes is one of the most prevalent diseases & pervasive medical problems impacting society & everyday quality of life (QOL) today

- 463 million affected worldwide and nearly 10% of these individuals have T1D
- T1D represents a potential commercial opportunity of $30B+ for Sernova

The Hope: A functional cure for everyone suffering from diabetes

The Problem: Lack of integrated RM therapeutic solution

The Future: Blockbuster potential for Sernova’s platform which could establish a new standard of care for diabetes treatment & management. Potential to be the biggest therapeutic advancement in diabetes treatment since insulin discovery 100 years ago.

(1) source: International Diabetes Federation
Diabetes Clinical Progress Summary

Pre 2018
- Completion of first-in-human proof-of-concept study for diabetic condition HU
- Clinical protocol & regulatory package development for US Ph I / II clinical trial for diabetic HU condition (T1D Study)
- FDA IND clearance to commence T1D Study
- T1D Study funding grant awarded by JDRF
- Prominent diabetes clinical investigator Dr. Witkowski joins T1D Study
- UChicago IRB approval obtained
- Clinical Trial & Consulting Services (CTI) engaged as T1D Study CRO
- Medtronic contracted for T1D Study CGM
- T1D Study patient screening & recruitment initiated, 1st patient enrolled

2018
- Cell Pouch implantation into first T1D Study patient
- Human islet cells transplantation into Cell Pouch in first T1D Study patient
- T1D Study positive early safety & efficacy indicators observed
- Enduring level of fasting C-peptide in bloodstream observed
- Positive DSMB Review & Recommendation for Continuation of Ph I/II clinical trial
- Positive Efficacy Endpoint – Survival of Endocrine Tissue
- Ongoing T1D Study patient enrollment, treatment & follow-up

2019

2020
Hypoglycemia unawareness (HU), the most critical unmet need in diabetes, affects 15% of T1D patients (~240K patients in the US alone)

- clinically defined as a complication of diabetes in which the patient is unaware of a deep drop in blood sugar
- patients do not experience hypoglycemia warning symptoms (palpitations, anxiety, excessive sweating, light headedness)
- harmful effects: diabetic ketoacidosis (DKA), coma & death

1st study population for Sernova's integrated RM therapeutic solution for lead indication of insulin-dependent diabetes
Study Design: Company-sponsored IND. Open-label, single-arm study. Human donor islets are transplanted into the Cell Pouch after implantation & stable anti-rejection medication activity has been established.

Primary Objective: To demonstrate the safety & tolerability of islet transplantation into the Cell Pouch for the treatment of HU in T1D subjects with a history of severe hypoglycemic episodes.

Secondary Objectives: To establish islet release criteria that accurately characterize the islet product & are predictive of clinical transplant outcomes into the Cell Pouch, demonstrated through defined efficacy measures:

- Survival of endocrine tissue in the Cell Pouch
- Proportion of subjects with a reduction in severe hypoglycemic events
- Proportion of subjects with a reduction in HbA1c >1mg%
- Over 20 additional endpoint analyses will occur

Status: Study Active & Ongoing

- IND allowance by FDA & protocol approved by IRB
- Multiple subjects implanted & transplanted
- Positive early findings announced
- Patient enrolment & recruitment ongoing
Incidence & severity of adverse events associated with Cell Pouch were monitored:

- **No incidences of AEs** determined to be probable or highly probable to the Cell Pouch
- **Cell Pouch well-tolerated & safe** during the implant & the time of transplant
- **No reactions** to the Cell Pouch implant
- Cell Pouch **well-incorporated with vascularized tissue** & deemed suitable to receive the islet transplant

**CONCLUSION:** Safety findings met the first measure of the primary endpoint

**WHY IS THIS IMPORTANT?**
Demonstrated Cell Pouch safety is a prerequisite for its use in multiple therapeutic indications
US Ph I/II Case Study Early Findings

US Ph I/II Safety, Tolerability, Efficacy Study

First Patient Observed Data Presented by Clinical Investigator*

Early Efficacy Findings

<table>
<thead>
<tr>
<th>Islet Transplant Status:</th>
<th>Before</th>
<th>3 Mo. After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bodyweight</td>
<td>83kg</td>
<td>73kg</td>
</tr>
<tr>
<td>Hemoglobin A1C</td>
<td>6.5</td>
<td>5.6</td>
</tr>
<tr>
<td>Daily Use Of Long Acting Insulin Tresiba</td>
<td>14U</td>
<td>8U</td>
</tr>
<tr>
<td>Daily Use Of Short Acting Insulin</td>
<td>15 – 16</td>
<td>14 – 15</td>
</tr>
<tr>
<td>Severe Hypoglycem. Events</td>
<td>4 per week</td>
<td>1 per week</td>
</tr>
</tbody>
</table>

90-day post-transplant glucose tolerance test (i.e. patient given a high sugar drink) was administered over several hours:

- showed increase in blood levels of C-peptide
- showed increase in blood levels of insulin

**WHY IS THIS IMPORTANT?**

C-peptide is a biomarker confirming insulin production by cells

**SUBSEQUENT FINDING:** Enduring blood levels of fasting C-peptide & ongoing evidence of islet engraftment & durable therapeutic effect detected post-second Cell Pouch islet dose

*Presented at IPITA Q3 2019 in Lyon, France
US Ph I/II Case Study Early Findings

Improvement in ALL CGM Parameters

**Baseline CGM**
- More excursions, hyper/hypo events
- Less time in range

**CGM POST CELL POUCH ISLET TRANSPLANT**
- Less excursions, hyper/hypo events
- More time in range

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>Post-transplant</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Glucose Value (mg/dL)</td>
<td>285</td>
<td>231</td>
</tr>
<tr>
<td>Low Glucose Value (mg/dL)</td>
<td>50</td>
<td>66*</td>
</tr>
<tr>
<td># Glucose Excursions</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td># High Excursions</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td># Low Excursions</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>37</td>
<td>31</td>
</tr>
</tbody>
</table>

* Lowest excursion was 66mg/dL and this occurred only once.
US Ph I/II 90-Days Post Transplant

Achievement of Secondary Endpoint

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

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
**Earlier First-in-Human Study**

**Study Design**
- T1D subjects with HU & a history of severe hypoglycemic episodes
- Open-label, single-arm
- Donor islet transplantation 2 – 24 weeks post Cell Pouch implantation
- **Primary Endpoint:** Safety post Cell Pouch implantation & 1-month post islet transplantation

**Cell Pouch and Islet Safety Endpoints 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 were well-vascularized
  - Islet safety successfully met
  - Islets show evidence of insulin, somatostatin & glucagon
  - Cell Pouch & islet biocompatibility met
  - Proof of islet protection from immune system attack

**Cell Pouch™ Clinical Histology**
Insulin staining islets with microvessels

First-in-World Successful Proof-of-Concept

SD
Hemophilia A Program

Benefits of Sernova’s Cell Pouch with factor VIII releasing cells:

- Reduce / eliminate factor VIII infusions
- Maintain constant blood levels of factor VIII
- Reduce joint bleeds
- Improve long-term efficacy
- Improve QOL

Estimated Market

- ~20 K patients across North America & EU
- ~$10 B orphan indication

Standard of Care

- Patients receive regular infusions of missing clotting factors (i.e. factor VIII)
  - Infusions are highly expensive & burdensome
  - Select patients develop inhibitors, reducing the effectiveness of infusions

Therapeutic Goals

- Improved efficacy with prophylactic treatment; reduced cost; improved patient QOL; reduction of side effects

Sernova Approach

- Gene corrected own patient cells into the Cell Pouch (EU5.6M Horizon 2020 Consortium Grant)
- Potential treatment for all patients
  - Stem cell releasing factor VIII product

Status

- Completed pre-clinical proof-of-concept
  - Cell manufacturing process developed
  - Corrected patient cells survive & produce factor VIII in pre-clinical hemophilia model
- Further development being scoped
Thyroid Disease Program

Benefits of Sernova’s Cell Pouch with Thyroid releasing cells:

- Reduce / eliminate daily long-term thyroid medications
- Recover natural feedback loop of thyroid hormones
- Reduce side effects from low thyroid hormone levels
- Improve long-term efficacy
- Improve QOL

Therapeutic Benefits

Estimated Market

- 150,000 thyroidectomies performed annually in US
- ~$2.2 B market opportunity

Standard of Care

- Patients require lifelong thyroid hormone replacement therapy
- Various oral / IV / other therapies may also be needed depending on underlying condition

Therapeutic Goals

- Improved efficacy with prophylactic treatment; improved patient QOL; reduction of side effects

Sernova Approach

- Thyroidectomy patient healthy tissue isolated & transplanted into the Cell Pouch
- Patient cells survive within the Cell Pouch & produce thyroid hormone

Status

- Completed pre-clinical proof-of-concept
- Clinical program under development
NEXT STEPS – Action Plan

- Develop licensed/acquired local immune-protection technologies for therapeutic cells
- Advance local immune-protected diabetes stem cell technology in preparation for First-in-Man (FIM) study
- Expand existing strong worldwide multi-family patent portfolio

- Complete T1D Study patient enrolment
- Continue T1D Study patient treatment & follow up
- Ongoing T1D Study safety & efficacy data evaluation
- Strategic pharma / medtech collaboration(s) expansion

- HemAcure study results conference presentation & publication
- Market & product positioning assessment
- Regulatory & Clinical plan development

- Complete Pre-Clinical studies
- Prepare & submit FIM regulatory package
Management Team

Dr. Philip Toleikis
PRESIDENT & CEO
- 20+ years experience in biotech management & product development in pharmaceutical & combination products.
- Previous Angiotech VP R&D (achieved $2 B market cap; product revenue $200 M per year).

David Swetlow CPA, CA
CFO
- 20+ years experience in life sciences (biopharma, combination products & devices) & high-tech industries, including Ondine, Protox, QLT, Xillix.
- Various senior management, board & advisory roles. Nasdaq & TSX experience.

Delfina M. Mazzuca-Siroen
SR. DIRECTOR & HEAD OF R&D / CLINICAL
- 20+ years senior management roles in R&D, clinical, regulatory, product development.
- Biochemistry, translational cell biology, device & transplantation expertise.
- Publications & patents author / co-author.

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