

SymbioCellTech (SCT)

Dec. 2019

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SymbioCellTech, LLC (SCT)



A Durable, Stem Cell-Enabled, Biologic Therapy for Diabetes in Humans and Companion Animals

- Delivered in a simple out-patient procedure
- Free from significant adverse effects
- Capable of halting the negative lifestyle impact of diabetes
- Scalable for world-wide distribution



SCT's Mission



To provide a Durable Cure, using Stem Cell-based Technologies for

- Insulin-Dependent Type 1 Diabetes in Patients and
- Companion Animals: Dogs, Cats with Insulin-Dependent Diabetes
- **Type 2 Diabetes** in Patients and in Companion Animals
- <u>Future: Other Chronic Disorders:</u> Microvascular Disorders treated with Stem Cell-derived **Exosomes** (see IP)
- <u>Future</u>: Prevention and Treatment of Acute and Chronic Renal Failure.

Current Epidemiology and Costs of all Types of Diabetes

422 Million people live with diabetes worldwide

10,000 People die from Diabetes every day

\$1.3 Trillion (1.8% of the global GDP) are spent each year worldwide on Diabetes



WHO, 2012; CDC 2010; NEJM 367(14):1332, 2012; <u>The</u> <u>Lancet Diabetes and Endocrinology 5(6):423, 2017</u>

USA

- **CDC** (Center of Disease Control) estimates 40% of U.S. population is diabetic or pre-diabetic
- Annual Costs for diabetes care have increased by 40%
- 34% of all diabetics are on injected Insulin; this delivery mode is sub-optimal for lifestyle, long-term health and prevention of complications
- Costs for ~ 2 M Type 1 diabetics in US \$11+ B/yr
- In addition to the human population, there is a significant Veterinary Market for diabetic companion animals (dogs, cats)

Underlying Causes of Diabetes



Dysfunction of Insulin Production and/or Utilization

- <u>Pancreatic Islets</u>, in particular Beta (β) cells produce too little Insulin or none at all
- Body can become resistant to Insulin
- Pancreas ultimately "burns out" which causes diabetes

Type 1 Diabetes aka "Insulin-dependent"

- autoimmune mediated
- often diagnosed during childhood, previously called "Juvenile Diabetes"
- antibodies from "self" attack pancreas until β islet cells no longer produce insulin

Type 2 Diabetes aka "Adult Onset"

- pancreas makes too little Insulin as body becomes resistant to it
- largely an acquired ailment in Western cultures, "lifestyle disease"
- 26% of Type 2 diabetics ultimately become Insulin-dependent
- 5 other critical hormones produced by pancreas become dysregulated in diabetes
- Prolonged unregulated glucose levels lead to array of co-morbidities
- Physiologic feedback loops become dysfunctional leading to end-organ damage and death

<u>Type 1 DM</u>: Technical Challenges to Achieving Insulin Independence



Immune Attack

- The immune system of a Type-1 diabetic attacks and destroys insulin-producing pancreatic β islet cells
- Any newly transplanted pancreatic islets must be protected from persistent immune attack
- The use of immunosuppression drugs has severe side-effects and should ideally be avoided
- Islet encapsulation devices fail due to foreign body reactions

Neo-Vascularization

- New blood vessels must be formed and connect to transplanted islets for long-term survival in the body
- Without neo-vascularization pancreatic islet cells die from inadequate blood supply, nutrients, oxygen, energy stores (ATP), etc.

Donor Scarcity

- Physiologically competent islets are difficult to culture, grow, or mass produce in a lab
- Up to 5 cadaveric donors are needed to produce enough islets for a single recipient
- Scarcity of donors limits the ability to produce sufficient numbers of islets for worldwide islet transplant therapy

Physiologic Insulin Delivery

- Healthy islets measure glucose at millisecond intervals and secrete insulin directly into the portal system of the liver in real time
- Suboptimal insulin delivery, amount, and timing leads to organ failure and premature death (regularly seen with current injected Insulin)

SCT's Technology and Current Status



Neo-Islet: Stem Cell-Enabled Therapy for Type I Diabetes



MSC +

"Ignored" by the immune system

β Cell Produces insulin

Produces insulin when blood-sugar n is high

Neo-Islet

Cell cluster - MSCs "cloak" β Islet cells against immune attack while allowing production of quality insulin

Mesenchymal Stem Cells (MSCs)

- Adult Stem Cells
- Immune-Privileged
- Protect and Repair Other Cells
- Provide Neo-vascularization
- Immuno-Modulating
- Anti-Inflammatory Actions
- Proven to be safe in humans
- No Ethical Concerns

- SCT's Neo-Islet therapy overcomes key technical challenges.
- Diabetic mice treated with Neo-Islets were cured of Type I diabetes (see Appendix).
- Diabetic pet dogs treated with Neo-Islets under an FDA INAD have better blood sugars and need much less insulin (*see Appendix*). SCT is in talks to license this successful application.
 - SCT has submitted an Pre-IND packet to the FDA and will have Pre-IND meeting in Sept. 2019.
- SCT is preparing for Phase I/II Clinical Trials following FDA Human IND approval.

Two SCT Landmark Publications





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The details of SCT's Neo-Islet technology were first published in the journal, *Stem Cells Translational Medicine* and featured on the cover of the July 2017 issue. **It was the "most downloaded/read paper in 2017-2018."** (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5689775/)

"An absolutely superb paper in every way. Outstanding hypothesis, thoroughly convincing data to validate it, and tremendous potential to provide a dramatic new treatment for millions of patients."

> ~ **Darwin Prockop, MD PhD** - Professor of Molecular and Cellular Medicine, Stearman Chair in Genomic Medicine, and Director of the Texas A&M University College of Medicine Institute for Regenerative Medicine.

> > - Key Opinion Leader (KOL) in Cell Therapy -

Details on SCT's proof of principle, FDA guided study in dogs with T1DM were published Sept 2019 in the journal *PlosONE* :

"Interim report on the effective intraperitoneal therapy of insulin-dependent diabetes mellitus in pet dogs using 'Neo-Islets,' aggregates of adipose stem and pancreatic islet cells (INAD 012-776)." (https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0218688).

<u>Clinical Trial:</u> Envisioned Outpatient Procedure





<u>Clinical Trial:</u> Outpatient Procedure [INAD 012-776], 5,000 allogeneic NIs/kg Bwt i.p.



NI Infusion to sedated Dog

15 min. post Infusion



<u>Type 2 DM, Solution</u>: Therapy with Neo-Islets and Medications



TREATMENT GOALS:

- Prevention of Insulin Dependency & associated Progression of Disease: interrupt the vicious cycle of ever increasing Insulin needs
- Reduction of Insulin Resistance
- Halting and Reversal of End Organ Failures and Premature Death (Stroke, Heart Attack, Kidney Failure [50% of all dialysis patients are diabetic], Amputations, Abortions, serious Infections, Weight Gain, Blindness, others)

RATIONALE for INTERVENTION with Neo-Islets and oral Agents

- Transplant Neo-Islets into Omentum as for T1DM before patient is Insulin Dependent: achieves Insulin Delivery into Liver and not via subcutaneous injection. The latter increases Insulin Resistance, Obesity, requiring ever higher doses of injected Insulin and progressive End Organ Damage.
- Omentum becomes new endocrine Pancreas and is responsive to oral agents: Reestablishes adequate Blood Glucose Control.
- Patient must adopt lifestyle changes.

SCT Intellectual Property



SCT Patents: filed in US, Canada & Europe

(1) <u>Filed Dec 2014</u>: - "NEO-ISLETS COMPRISING STEM AND ISLET CELLS AND TREATMENT OF DIABETES MELLITUS THEREWITH" # US 3285-P12723.4US; 62/264,238

(2) Other patents based on stem cell derived exosomes and microvascular diseases have been filed but not published.

(3) SCT has a robust pipeline of stem cell based technologies and therapeutics.

Inventors: Christof Westenfelder, Anna M. Gooch, et al.

IP Strategy:

- SCT's trade secrets include technologies relating to the preparation, culture, storage, and expansion of "Neo-Islets" that will be evaluated for patentability as part of SCT's overall IP strategy.
- New SCT technologies are evaluated for strategic value and patentability on an ongoing basis.

"Neo-Islet" Regulatory Pathway



Investigational New Drug (IND) Application

- Pre-Clinical Animal Studies
- Chemistry, Manufacturing and Control (CMC)
- Human Clinical Trial Design

After IND Approval

- Phase I/II Human Trials
- (Market approval post human trials)

Regulatory Advisors and CROs

- Jo-Anna Reems, PhD Director of Cell Therapy and Translational Medicine Facility, University of Utah
- **IQVIA** preferred regulatory consultant for California Institute for Regenerative Medicine (CIRM)
- RoosterBio leading Bioprocess Design and Acceleration Company for Cellular Technologies and Scale Up

The SCT Team



Christof Westenfelder, MD, FACP Co-Founder and CEO	Serial Life Science entrepreneur, extensive experience in Cell Therapy & Regenerative Medicine, Professor of Medicine and Physiology at the University of Utah, and former Chief of Nephrology, George E. Wahlen VA Medical Center.		
Axel Zander, MD Co-Founder and VP	Emeritus Professor of Medicine and Former Chief of the Bone Marrow Transplantation Center at the University of Hamburg in Germany, Visiting Professor, Huntsman Cancer Institute at the University of Utah School of Medicine.		
Anna Gooch, PhD Chief Scientific Officer	Fifteen years experience in Cell Therapy research and commercialization. Doctorate in cellular, viral and molecular biology with special expertise in adult stem cell therapies, early phase clinical trials and operations.		
G. Russell Reiss, MD Chief Operating Officer	Twenty years experience in stem cell research and commercialization, founder Utah Center of Excellence for Cell Therapy and Regenerative Medicine, former Medical Director University of Utah Cell Therapy Facility & Cord Blood Bank, board certified Cardiothoracic Surgeon.		
William P. Tew, PhD Director of Business Development	Forty years experience developing and commercializing Life Science research products, medical devices, and biopharmaceuticals. Former research faculty at Johns Hopkins University School of Medicine where he served as Associate Provost and Assistant Dean of Technology Licensing.		

Market Opportunity: T1DM and T2DM





of US adults are pre-diabetic



The Lancet, Volume 387, Issue 10027, P1513-1530, April 09, 2016 and The WHO Global Report on Diabetes 2016

Competitive Landscape







Daily insulin injection

- The most common treatment today
- Significant negative lifestyle impact
- Premature organ failure and death
- Syringe or pump



Pancreas/Islet Transplant

Solves the lifestyle issue, but.....

- 1. Scarcity of donors up to 5 donors per treatment. (Islet cells can not be expanded in culture)
- 2. Need anti-rejection drugs which cause damage to kidneys, infections and cancer.



Cross Section of Encaptra' Drug Delivery System

Embryonic Stem Cell Research

- Semma, Harvard, MIT and other institutions
- Attempts at solving donor-scarcity issue
- Do not solve immune-system-attack issue
- Ethical concerns
- Could grow into malignant cancer
- Still need anti-rejection drugs



Micro-Encapsulation

- Attempt at reducing anti-rejection drugs
- Does not solve donor-scarcity problem
- Requires artificial foreign-body implantation
- Islets eventually fail due to poor oxygenation



"Encaptra" Drug Delivery

- ViaCyte (San Diego).
- Requires artificial foreign-body implantation
- Relies on fetal precursor cells (ethical concerns, immature technology, and potential tumor development)
- Numerous devices per patient. (The body requires up to 1 Billion beta cells, but a single "Encaptra" device holds only 24 thousand. So, a large number of devices must be implanted under the skin



Macro-Encapsulation

- Beta-O₂ (Israel)
- Attempt at reducing anti-rejection drugs
- Attempt at solving the oxygen-depletion problem
- Does not solve donor-scarcity problem
- Requires artificial foreign-body implantation
- Does not solve negative lifestyle problem.

(Requires daily oxygen refills with syringe)

Current Estimated Timeline





Milestones Achieved in the last Quarter



Pre-IND has been submitted. A successful Pre-IND meeting was held Sept 5, 2019.

Dog Redose:

Permission from WSU IACUC has been granted for redose.

WSU-02 has been recently redosed, and results thus far are encouraging. VSH-02 will be redosed soon.

A <u>data room</u> to help facilitate necessary due diligence on fundraising has been populated and can be made available upon request to serious potential investors.

Publication: a manuscript of the dog data has been submitted, peer reviewed and published.

(https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0 218688)

Financial Needs



• Short Term Funding

- SCT, to fund operational costs, including the ongoing dog study, is currently offering and has partially funded a Convertible Note of
 - Up to \$3,000,000 from accredited investors
 - Simple interest rate of 8.0% per annum compounded annually
 - 2 year maturity
 - Conversion discount rate of 10%
- Bridge Funding
 - SCT is in need of \$7-10M to fund IND application work.
- Series A
 - SCT is offering a \$20-30M Series A round to a fund human Phase I clinical Trial at \$50/share.

Series A Raise



- \$20-30M Series A Preferred Round
- Last unit price \$50/unit
- Total capital raised \$10.5 M
- Current Capital Structure (Total units outstanding 810,304)
 - Founders 43%
 - Employees 16%
 - Early investors 33%
 - University of Utah Tech & Venture Commercialization 50,000 units
 - Units not outstanding 189,696
- Use of Capital Execution of IND Application and approval to begin human clinical trials
- Anticipated Series B to complete Phase I/II human trials
- Potential exit event upon favorable Phase I/II clinical results



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The following Appendix slides provide:

- Background on Diabetes and the specific problems that must be overcome;
- Background on MSCs' ability to modulate the immune system and other of their cell supportive roles;
- Findings of relevant studies that support the Conclusion that SCT's technology is currently, and ultimately will be successful, both in the veterinary and human markets.

<u>Appendix:</u> Type 1 DM, The Problem: Insulin Deficient, "Juvenile" Diabetes mellitus







Normal Process:

Islets in the pancreas make and secrete insulin after a meal FIRST into the liver. From there, the remaining 50% of Insulin reaches muscle, fat and other organs, transferring blood sugar into cells as fuel to maintain normal energy metabolism.

The Disease:

Not enough Insulin: The body's immune system attacks insulin producing beta cells of the pancreas resulting in auto-immune disease.

The Treatment:

Unless insulin levels are restored,

hyperglycemia and potentially fatal metabolic abnormalities rapidly occur and progressive End Organ Damage develops: eyes, kidneys, heart, amputations, infections, stroke, abortions.

 ~ 50% of all patients on dialysis or who receive a kidney transplant have diabetes

<u>Appendix:</u> Type 1DM: Current Therapies vs. SCT's Neo-Islets (NIs)

Standard Current







Optimal Current:

Insulin-Independence

Pancreas transplants

 (>60,000 to date); donor
 scarcity, need for anti rejection drugs: damage
 kidneys, infections, cancers

COST: up to \$ 300,000.-

 Islet transplants (~2,000 to date); up to 5 donors needed, often repeatedly, lifelong antirejection drugs

COST: ~ \$ 270,000.- UCSF

 Both Therapies and other Cell-based Technologies still face major hurdles

Ideal: "Neo-Islets" Insulin-Independence

- Provides physiological Insulin secretion and delivery, but without the need for Anti-rejection Drugs
- Provides adequate culture expansion of functional beta/islet cells, addressing the scarcity of pancreas donors
- COSTS projected: ~ 1/3rd of Optimal Current Therapies

"NEO-ISLET" Technology overcomes major hurdles

<u>Appendix:</u> Results – *Euglycemia** in NOD Mice





From Westenfelder, et al., Stem Cells Transl Med. 2017;6(7):1631-1643.

NIs From Unrelated Donors Eliminate Need for Insulin Without Antirejection Drugs

- NOD mice are the ideal rodent model for Type-1 diabetes
- All mice naturally developed auto-immune Type-1 diabetes
- All mice were functionally cured (euglycemic) within weeks of treatment
- Sera from cured mice elicited no IgG antibody response proving Neo-Islets are shielded against allogeneic immune attack

**Euglycemia* = normal blood glucose levels

Appendix Results: No Hypoglycemia*



From Westenfelder, et al., Stem Cells Transl Med. 2017;6(7) 1631-1643.

NIs Do Not Cause Hypoglycemia

- Critical safety feature; insulin secretion is normally regulated
- Indicates normal, auto-regulating, physiologic blood glucose sensing and insulin delivery by Neo-Islets
- Neo-Islets eliminate risk of insulin overdose seen with self-administered exogenous insulin

Hypoglycemia* = dangerously **low blood glucose level

Appendix Results: Long-term Glucose Control



From Westenfelder, et al., Stem Cells Transl Med. 2017;6(7):1631-1643.

NIs Function Long-term and Require Both Cell Types

- Comparison groups of STZ-Diabetic C57BI/6 Mice
- Long-term data show Neo-Islet treatment is durable
- Continued normal, physiologic blood glucose sensing and insulin delivery by Neo-Islets
- All other groups became moribund (ultimately sacrificed)



STZ-Diabetic Mice

Appendix Results: Human Neo-Islets





Human-cell-Derived NIs Eliminate the Need for Insulin

- Comparison groups of STZ-Diabetic NOD/SCID Mice
- Neo-Islets durably eliminate need for insulin
- Continued normal, physiologic blood glucose sensing and insulin delivery by Neo-Islets (nearly normal Glucose Tolerance Test)

[Unpublished Data]

<u>Appendix Results:</u> Proof of in vivo Redifferentiation of Insulin Producing Dog Cells



Glucose Stimulated Insulin Secretion (GSIS) of Dog derived NIs (cNIs) before and after implantation in mice. GSIS per cNI of freshly formed cNIs vs. cNIs retrieved from euglycemic (from cNIs), STZ-diabetic, cNI-treated NOD-SCID mice 9 weeks post cNI administration. *, P < 0.05 compared to 5 mM glucose; **, P < 0.01 compared to pre-administration.

Appendix: FDA INAD Companion Animal Study



- SCT has attained an FDA Investigational New Animal Drug (INAD) approval to conduct a canine Neo-Islet pilot study in pet dogs, ultimately leading to a marketable companion animal therapy.
- One result of conducting such a study in companion animals, which are not in a controlled research environment, is that more real world data have been obtained that also translate to the human Diabetes. Dogs, and indeed most of the dogs that SCT has successfully treated, have an autoimmune form of Diabetes and comorbidities.
- Initial preliminary data are positive and confirm that Neo-Islet administration is feasible, safe and durable in a large mammal.
- Positive results of SCT's dog trial have led to Neo-Islet therapy being identified by a global veterinary company as a break-through, innovative technology for their "new business" division. A term sheet for a licensing agreement has been executed, and terms of a licensing agreement has been agreed on. A second veterinary company has reached out to ask for licensing rights as well.

Appendix Results: FDA INAD Companion Animal Data



VSH-01

VSH-02

WSU-01 WSU-02

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Dog	Reduction in daily insulin dose	Reduction in serum glucose
VSH-01	14% (P<0.0001) baseline to 15 months post Rx	106 mg/dL (P<0.0001) to 15 mos.
VSH-02	50% (P<0.0001) baseline to 13 months post Rx	92.5 mg/dL (P=0.03) 13 mos.
WSU-01	20% (P<0.0001) baseline to 6 months, but not after 7 months	96.6 mg/dL (P=0.0015) 12 mos.
WSU-02	37% (P<0.0001) baseline to 9 months post Rx	41 mg/dL (P=0.009) 9 mos.

From Gooch, et al., PLoS One. 2019 Sep 19;14(9):e0218688

Efficacy of Repeated NI Dosing



Unlike in diabetic mice, although insulin requirements and glucose levels are improved in the NI-treated dogs, they are not yet insulin independent which is the ultimate goal.

<u>Rationale</u>: Redosing is a procedure that is routinely carried out in patients receiving islet transplants, and is required for establishing or reestablishing euglycemia. Preclinical studies where we redosed incompletely controlled diabetic mice successfully achieve insulin independence (See below).



<u>Appendix:</u> Type 2 DM (90% of all diabetics): Pathogenesis/Pathophysiology





Normal Process:

Islets in the Pancreas make and secrete Insulin after a meal FIRST into the Liver. From there, remaining ~ 50% of Insulin reaches Muscle, Fat and other Organs, transferring Blood Glucose into Cells as Fuel to maintain normal Energy Metabolism.

The Disease:

Defective and eventually inadequate Insulin Secretion. Because of systemic Insulin Resistance islets get exhausted despite the use of oral antidiabetic drugs. High Blood Glucose levels result.

The Treatment:

Unless Life Style Changes (obesity, lack of exercise, diet) are effectively addressed and Blood Glucose levels are improved with oral agents, patients will need ever higher doses of injected Insulin, increasing OBESITY and INSULIN RESITANCE. Progressive End Organ Damage and Early Death develop: blindness, kidney failure, heart attacks, amputations, infections, stroke, abortions, other.

~ 50% of all Patients on Dialysis or who receive a Kidney Transplant have Diabetes

<u>Type 2 DM, Solution</u>: Therapy with Neo-Islets and Medications



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- Prevention of Insulin Dependency & associated Progression of Disease: interrupt the vicious cycle of ever increasing Insulin needs
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- Transplant Neo-Islets into Omentum as for T1DM before patient is Insulin Dependent: achieves Insulin Delivery into Liver and not via subcutaneous injection. The latter increases Insulin Resistance, Obesity, requiring ever higher doses of injected insulin and progressive End Organ Damage.
- Omentum becomes new endocrine Pancreas and is responsive to oral agents: Reestablishes adequate Blood Glucose Control.
- Patient must adopt lifestyle changes.



In anticipation of marketing the dog product, and of scale up for human use, and with the aim of increasing efficiency and reducing cost of production, SCT is currently conducting scale up testing of other cell expansion systems. Below is an example of expected cost reduction and scale up using Corning's CellCUBE expansion system.

Cost of Production comparison for expansion of <u>one</u> cell type using Corning's 12 layer hyperstacks (HS; current system) vs. Corning CellCUBES.

Note that 2 cell types are needed per product, and formation of NIs in CUBES must be tested. Most cost effective vessel for the size of dog is noted in blue.

	Cost	Cost Per 5	Cost Per	Cost Per	expected	Cost
	Per	kg dog (\$)	12 kg dog	70 kg	cell yield/	per
	Vessel		(\$)	human (\$)	vessel	million
	(\$)					cells
						(\$)
traditional	1,058.63	2,117.26	4,234.51	25,407.07	3.00E+08	35.29
12 L HS						
10 layer	1,883.10	3,766.20	5,649.30	32,012.71	4.25E+08	44.31
CUBE						
25 layer	2,652.99	2,652.99	2,652.99	18,570.96	1.06E+09	25.03
CUBE						
100 layer	6,809.88	6,809.88	6,809.88	13,619.76	4.25E+09	16.02
CUBE						