

# SymbioCellTech (SCT)

*A Regenerative Medicine Company*

February 2020

# SCT was founded in Utah in 2012

## The TEAM:



**Christof Westenfelder, MD, FACP**  
Co-Founder and CEO

Serial Life Science entrepreneur, extensive experience in Cell Therapy and Regenerative Medicine, Professor of Medicine and Physiology

**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

**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

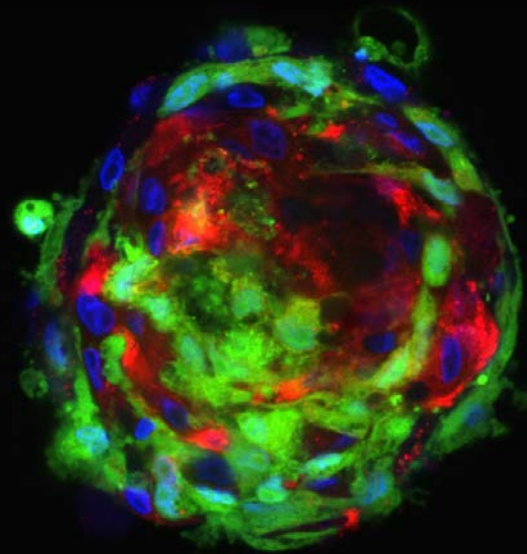
Twenty years experience in stem cell research and commercialization, founder Utah Center of Excellence for Cell Therapy and Regenerative Medicine, former Medical Director University of Utah Cell Therapy Facility & Cord Blood Bank, board certified Cardiothoracic Surgeon.

**William P. Tew, PhD**  
Previous 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.

***“Stem Cell-enabled functional Cure of Type 1  
Diabetes mellitus: from Bench to Dogs to the Clinic”***

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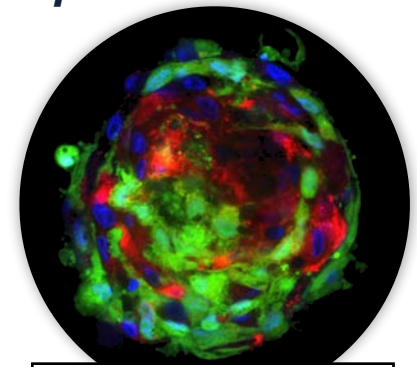
***“Neo-  
Islet”  
Therapy***

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**CEO, SymbioCellTech, LLC**  
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# SymbioCellTech's (SCT) MISSION in Regenerative Medicine

## 1° FOCUS: Provision of a Durable, Stem Cell-Enabled, Biologic Therapy for Diabetes in *Humans and Companion Animals*

- Delivered in a *simple, safe and cost-effective out-patient procedure*
- *Free from significant Adverse Effects*
- Capable of halting serious diabetes-associated
  - Complications (*blindness, amputations, kidney failure, strokes, abortions, early death*) &
  - the negative Lifestyle Impact of diabetes
- Scalable Technology for world-wide distribution



**“Neo-Islets”**

Type 2 Diabetes in Patients and in Companion Animals

NEXT: Treatment of Chronic Disorders: *Microvascular Disorders*

NEXT: Prevention and Treatment of *Acute and Chronic Renal Failure*.

# The Problem: DIABETES



**422,000,000**

Individuals living with Diabetes  
worldwide  
8.4% of the adult population

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**COSTS: \$ 1.31 TRILLION**

**1.8% of global GDP spent/year on DM**

*World Health Organization*

*THE LANCET Diabetes & Endocrinology 5(6):*

*423-430, 2017*

# Market Opportunity: T1DM and T2DM



## USA



**\$105 billion**  
spent yearly  
on diabetes in USA



**22.4 million**  
people have diabetes  
in USA  
(8.4% population)



**1.9 million**  
new diabetics per year  
diagnosed in USA



**30%**  
of US adults are  
pre-diabetic



*The Lancet*, Volume 387 (10027): 1513  
The WHO Global Report on Diabetes 2

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## World



**\$825 billion**  
spent yearly  
on diabetes

**422 million**  
people have  
diabetes

**10 million**  
New diabetics  
diagnosed/yr



**26%**  
of Type-2 diabetics  
require insulin



**10%**  
of diabetics are  
Type-1

**34%**  
of all diabetics  
require insulin

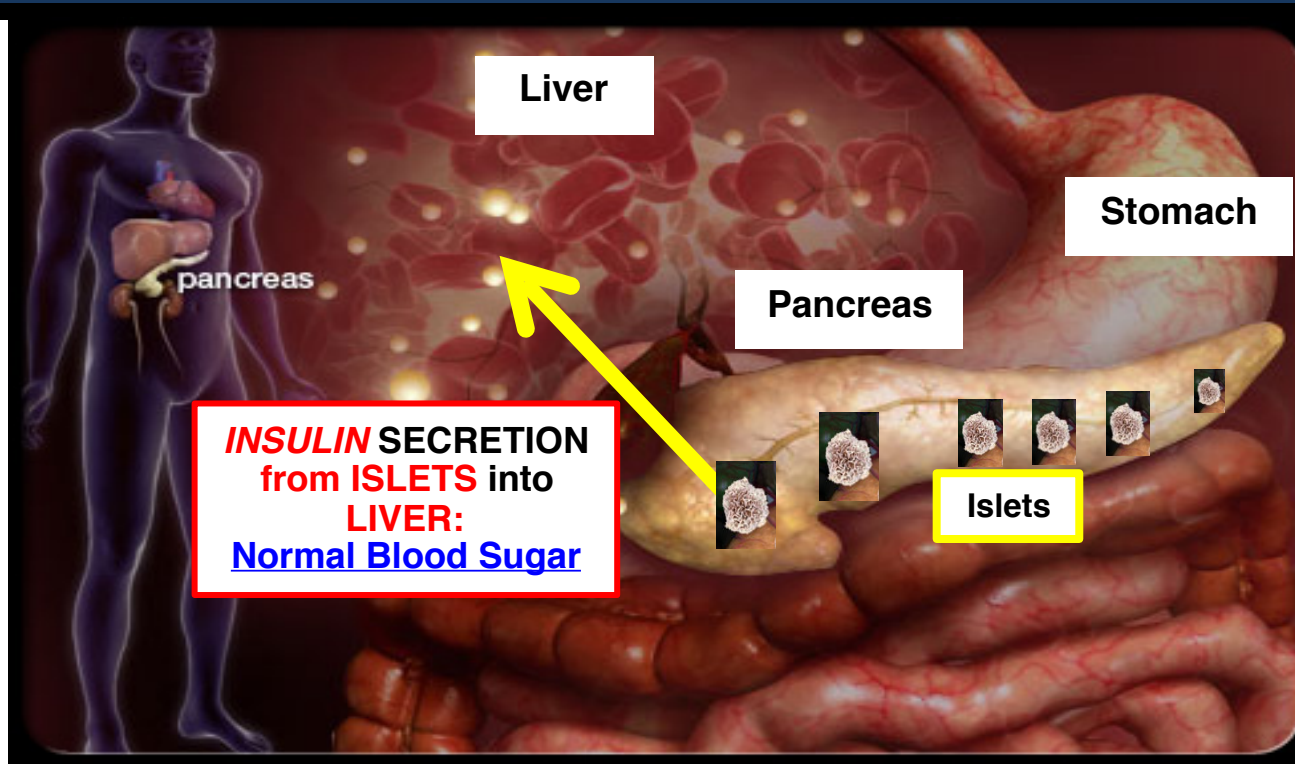


**SCT's EXPECTED  
MARKET SHARE**  
*Initially*

**USA:** ~30% Clinical  
~15% Veterinary

**WORLD:** ~15% Clinical  
~10% Veterinary

# Type 1 DM = The Problem: Insulin Deficiency causes “Juvenile” Diabetes mellitus

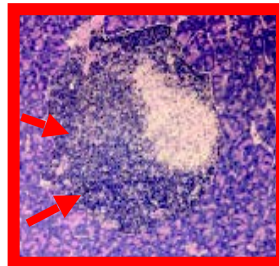


Islets in Pancreas make **Insulin** & other Hormones

Normal Islet → **Insulinitis: T1DM**

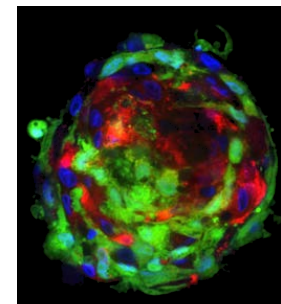


**Auto-immune Attack**  
on Insulin-Producing  $\beta$ -Cells:  
**DIABETES Type I**



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← **Neo-Islets CURE T1DM**

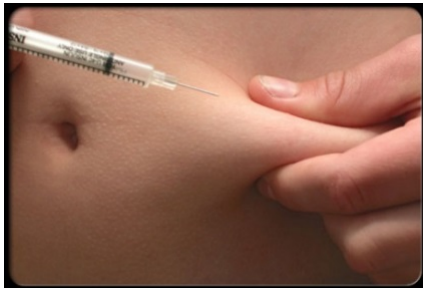
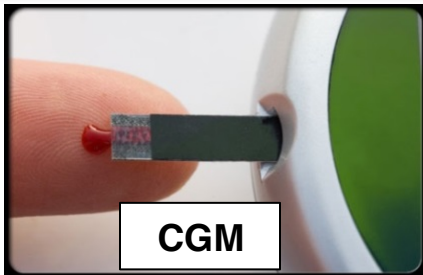


**ENABLED**  
by **ADULT STEM CELLS**

# Type 1DM: Current Therapies vs. SCT's Neo-Islets (NIs)



## Standard Current Insulin-Dependent



## Optimal Current Insulin-Independence

- **Pancreas transplants** (>60,000 to date) (1) donor scarcity, (2) need for anti-rejection drugs: **damage kidneys, cause infections, cancers**

**COST: up to \$ 300,000.-**

- **Islet transplants** (~2,000 to date); up to **5 donors needed**, often repeatedly, lifelong anti-rejection drugs

**COST: ~ \$ 270,000.- UCSF**

- Both Therapies and other Cell-based Technologies still face **Major Techn. Hurdles**

## "NEO-ISLET" Technology 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, **effectively addressing the scarcity of pancreas donors**

**COSTS projected: ~ 1/3<sup>rd</sup> of Optimal Current Therapies**

**"NEO-ISLET" Technology overcomes Major Hurdles**

# Type 1 DM: *Technical Hurdles* to achieving *Insulin Independence*



## I. Immune Attack

The use of *Anti-Rejection Drugs* has severe side-effects and should ideally be avoided

## II. Donor Scarcity

*Scarcity of donors* limits the ability to produce sufficient numbers of islets for worldwide Pancreas and Islet transplant therapy

## III. New Blood Vessel Formation

*Without New Blood Vessel Formation* transplanted islet cells die from inadequate blood supply, nutrients, oxygen, energy stores.

## IV. Physiologic Insulin Delivery

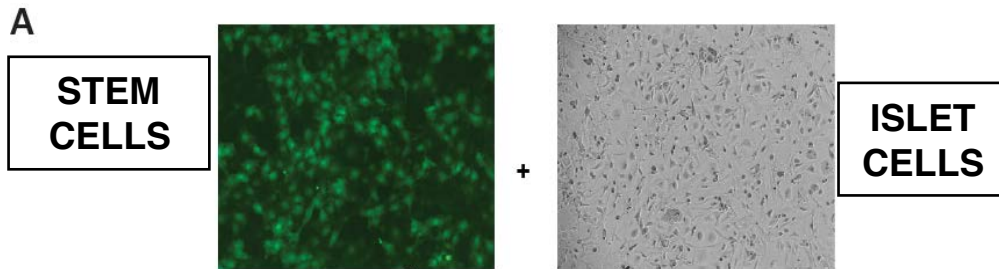
Suboptimal insulin delivery, dosing, and timing leads to organ failure and premature death (regularly seen with current injected Insulin)

**NOVEL NEO-ISLET TECHNOLOGY** overcomes these technical Hurdles and thereby successfully addresses this **MAJOR MEDICAL NEED for Diabetic Patients**

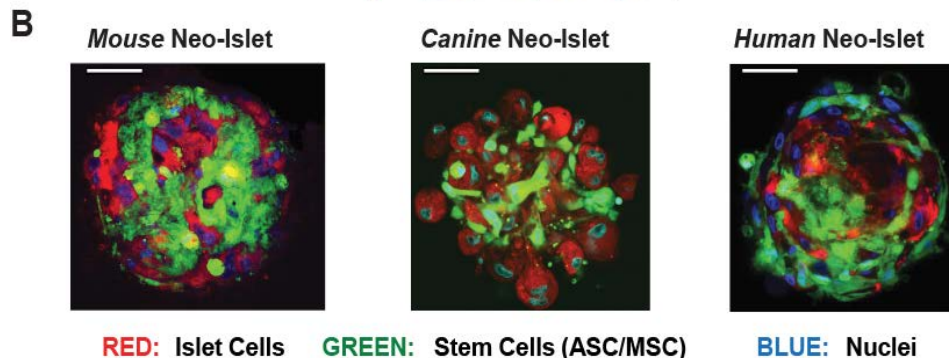
# SCT's Technology and Current Status



## Neo-Islets: Stem Cell-Enabled Therapy for Type I Diabetes



Coculture



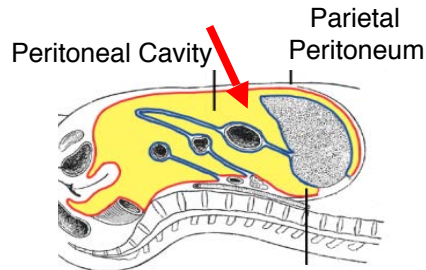
Scale Bar: 64  $\mu$ m

- **Diabetic Mice** treated with Neo-Islets were **cured of Type I diabetes**.
- **Diabetic Pet Dogs** treated with Neo-Islets under an FDA INAD have **better blood sugars and need much less insulin**. SCT is in talks to **License** this successful application.
- SCT had **successful Pre-IND meeting** with the **FDA** and is **preparing for first Clinical Trial**.

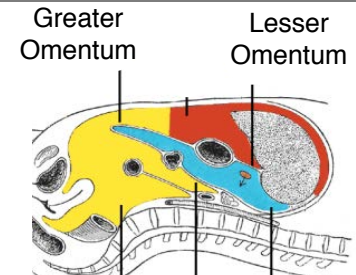
# Clinical Trial: Outpatient Procedure



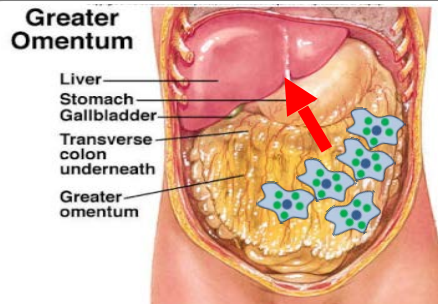
Under local anesthesia and  
Ultrasound guidance



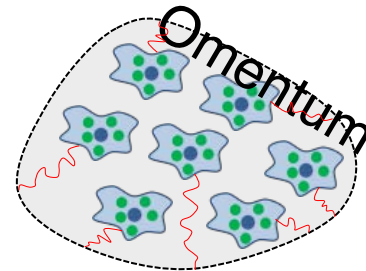
Suspended **Neo-Islets** are  
administered intraperitoneally



**Neo-Islets** home to and  
engraft in the omentum



**Insulin** is physiologically  
delivered into the liver



Omentum becomes site of  
**new Endocrine Pancreas**

# Ongoing Clinical Trial: FDA Approved & Guided

## Short and simple Outpatient Procedure



**NI Infusion to sedated Dog**

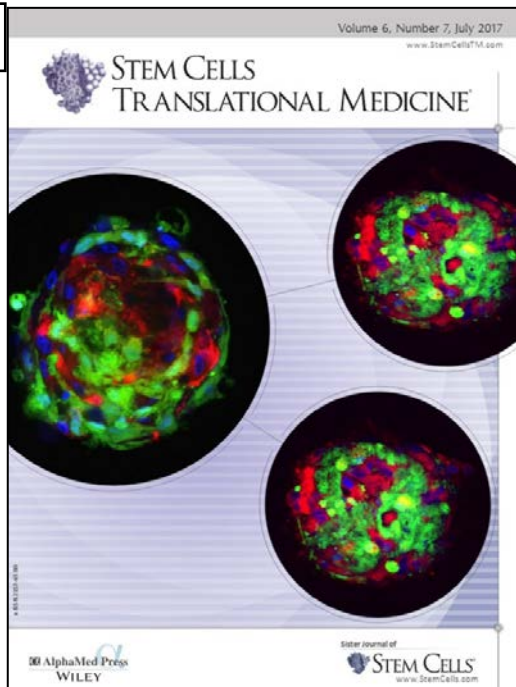
**15 min. post Infusion**



# Two SCT Landmark Publications



1



The details of SCT's Neo-Islet technology were first published in ***Stem Cells Translational Medicine*** and featured on the cover of the July 2017 issue. It was the “most downloaded/read paper in 2017-2018.”

***“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**

2

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>).

# SCT Intellectual Property



## **SCT Patents:** filed in US, Canada & Europe

- (1) **Filed Dec 2014:** - “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
- (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 are being 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.

# Funding Needs and Use of Capital



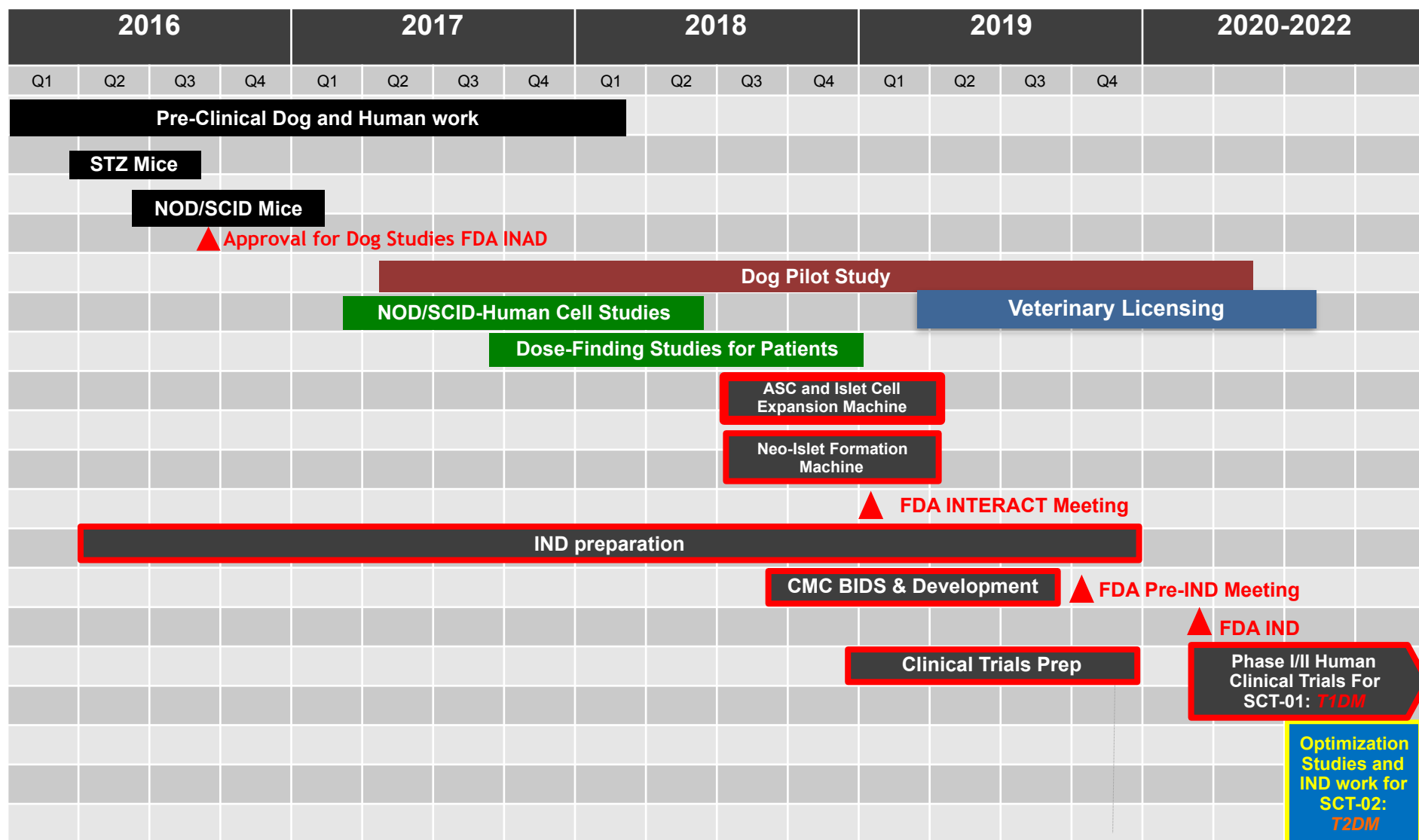
- **Series A:** \$20-30M: Completion of a successful IND application and FDA approval **to begin human clinical trials.**
- **Bridge Round:** up to \$3M is available as a **convertible note** to maintain operations through the Series A raise.
- **Series B:** Amount TBD (anticipated ~\$50M) to complete Phase I/IIb human clinical trials.
- **Potential Exit:** M&A opportunities likely upon favorable Phase I/IIb clinical trial results.

# Current Capital Structure



- **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 – 50,000 units**
- **Units not outstanding – 189,696**

# Current Estimated Timeline



\$10.5M  
Seed & Early Investors

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Bridge to Series A

# Thank you! Questions?



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## **Point of Contact**

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