
DiscGenics™
REVOLUTIONIZING CARE FOR CHRONIC BACK PAIN
Company Overview
November 2022

COMPANY OVERVIEW

DiscGenics is a clinical stage biopharma company developing cell-based regenerative therapies that alleviate pain and restore function in patients with degenerative diseases of the spine.

Our Vision: To create a cell therapy for disc degeneration that transforms patient lives.

IDCT is realizing this vision. Our injectable, allogeneic cell therapy utilizes proprietary Discogenic Cells to treat adult lumbar disc degeneration.

Phase I/II study demonstrates high dose IDCT is well tolerated, increases disc volume, and produces rapid, durable, statistically significant and clinically meaningful improvements in pain, function and quality of life.

COMPANY LEADERSHIP

Flagg Flanagan
CEO & Chairman

Mr. Flanagan has over 30 years of experience in the medical device field as an entrepreneur, executive and advisor. He founded Flanagan Instruments in 1981, which he built into a leading neurosurgical device distribution business before selling it to Itochu International in 2005.

Robert Wynalek
COO, Director

Mr. Wynalek is a skilled medical device and biologics executive with over 30 years of experience in the orthopedic, spinal and neurosurgical markets. As President of Osteotech (acquired by Medtronic in 2010) he oversaw development and commercialization of many biologic devices for bone healing.

Kevin T. Foley, M.D.
CMO, Director

Dr. Foley is a practicing neurosurgeon at Semmes-Murphy Neurologic & Spine Institute, tenured professor at the University of Tennessee, and active entrepreneur who invented many of the surgical devices and techniques that have revolutionized minimally invasive spine surgery.

Najeeb Thomas, M.D.
Director

Dr. Thomas is an internationally recognized neurosurgeon who practices at Southern Brain and Spine in New Orleans, where he focuses on treatment of degenerative diseases of the spine. He has vast experience in neurosurgery, reimbursement strategy and business success, having co-founded the Crescent City Surgical Centre where he currently serves as Medical Director.

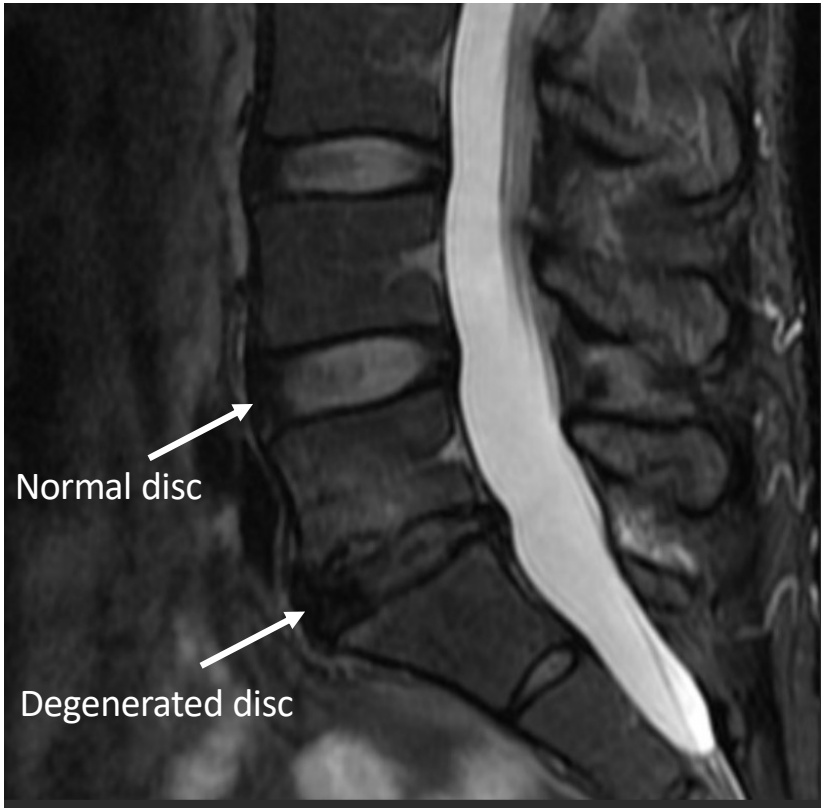
Colin Lee Novick
Director

Mr. Novick is a cofounder and managing director of CJ PARTNERS, one of Japan's leading regenerative medicine consulting firms. He is natively fluent in Japanese and has worked as a management consultant at Deloitte Tohmatsu Consulting within the Financial Services Industry Group and at SMBC Nikko Securities.

LOW BACK PAIN & DISC DEGENERATION

- Disc degeneration is a common cause of debilitating low back pain.
- This chronic and progressive condition is characterized by inflammation and breakdown of tissue within the intervertebral disc, resulting in pain and disability.

An ideal treatment for disc degeneration, such as IDCT, would ***reduce pain*** by modulating the local environment of the disc and possibly slowing or reversing the degenerative progression of the disease.



LUMBAR DISC DEGENERATION

Affects more than 250 million individuals worldwide every year [1]

Is a leading cause of disability worldwide [2]

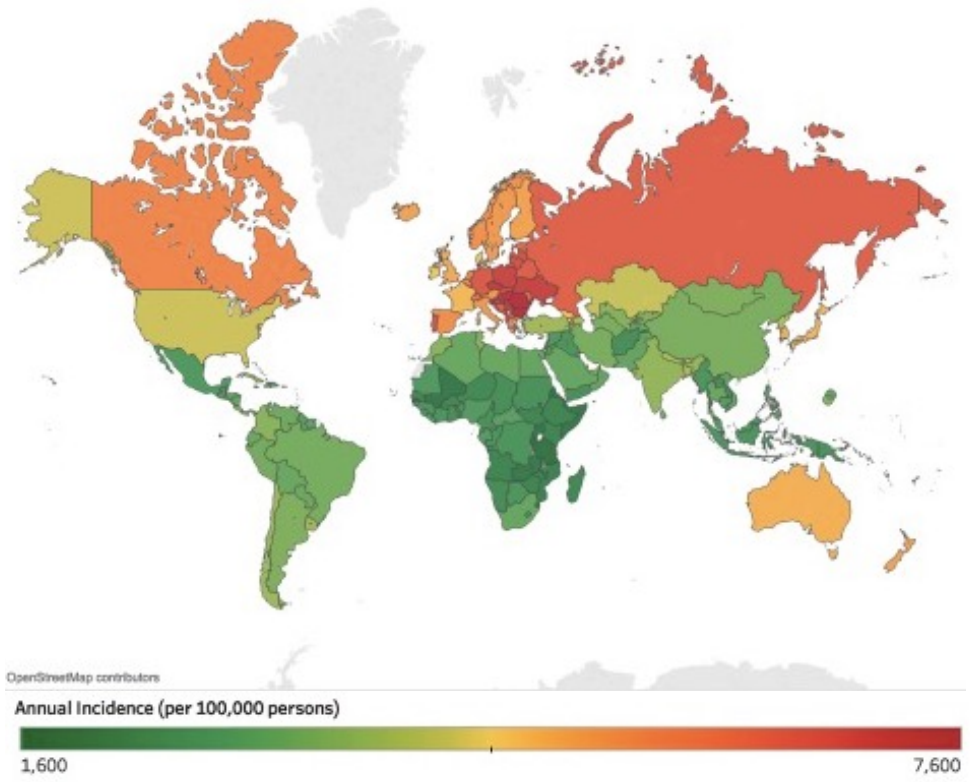
Costs more than $100B per year in the U.S. alone [3]

Is the primary reason for non-cancer opioid prescriptions [4]

1. Ravindra VM et al. "Degenerative lumbar spine disease: Estimating global incidence and worldwide volume." *Global Spine Journal* 2018.
2. Hoy D et al. “The global burden of low back pain." *Ann. Rheum Dis.* 2014.
3. Davis AD et al. “Where the United States spends its spine dollars.” *Spine* 2012.
4. Ringwalt et al. "Differential prescribing of opioid analgesics." *Pain Res Manag* 2014.

GLOBAL INCIDENCE OF DEGENERATIVE LUMBAR SPINE DISEASE [1]

Incidence of Degenerative Lumbar Spine Disease by Country



North America (US/Canada)

- Persons Affected per Annum: **16,079,267**

Western Pacific Region (Japan/China/Australia)

- Persons Affected per Annum: **65,163,498**

Worldwide

- Persons Affected per Annum: **265,726,606**

We estimate the global market opportunity to be greater than $100 billion.

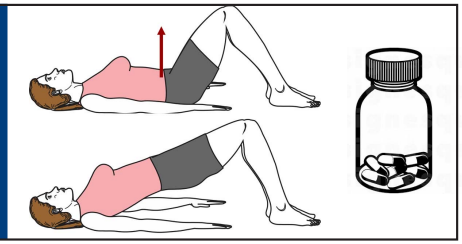
1. Ravindra VM et al. "Degenerative lumbar spine disease: Estimating global incidence and worldwide volume" *Global Spine Journal* 2018.

CURRENT THERAPIES & UNMET NEED

- Current treatment options include either palliative care or invasive surgery.
  - Palliative care only masks symptoms while doing nothing to fix the underlying pathology.
  - Invasive surgery becomes the only option when symptoms can no longer be managed.
    - Fusion surgery is costly, has notoriously mixed outcomes, can cause adjacent level disc disease and lead to long-term opioid abuse.

Palliative Care

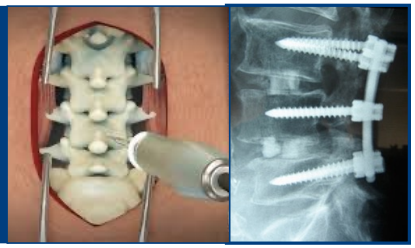
- Lifestyle modifications (posture, weight loss, smoking cessation)
- Rehabilitative care (physical therapy, yoga, chiropractic)
- Medications (anti-inflammatory, steroids, opioids)



Never-Ending Cycle of Degeneration

Invasive Surgery

- Discectomy
- Fusion surgery (>$100,000)



- Very few currently available treatments have shown robust clinical evidence in:
  - Reducing pain and disability
  - Increasing quality of life
  - Delaying subsequent surgical interventions
  - Restoring disc architecture **(NONE)**

DISC DEGENERATION & RISK OF OPIOID ADDICTION

- Patients suffering from chronic LBP, such as disc degeneration, account for nearly 60% of prescription opioid usage in the U.S. [1]
- Opioid addiction is contributing significantly to a rise in drug-related deaths.
- Pain physicians need novel therapeutic strategies that no longer involve a prescription to opioids.

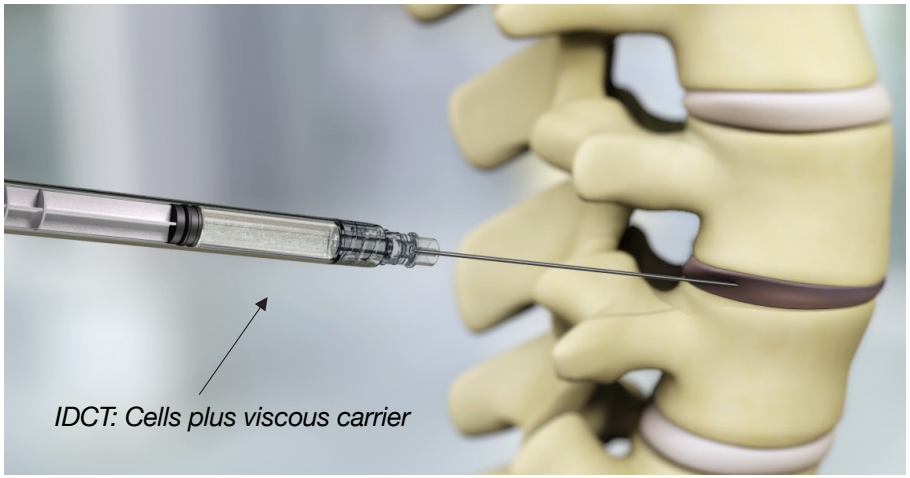
Cell therapies, like IDCT, have the potential to curb the opioid epidemic by reducing low back pain and disability due to disc degeneration. [2]

1. Hudson TJ et al. "Epidemiology of regular prescribed opioid use: results from a national, population-based survey" *J Pain Symptom Manage* 2008.
2. Silverman et al. “Perspectives on the Treatment of Lumbar Disc Degeneration: The Value Proposition for a Cell-Based Therapy, Immunomodulatory Properties of Discogenic Cells and the Associated Clinical Evaluation Strategy” *Frontiers in Surgery* 2020.

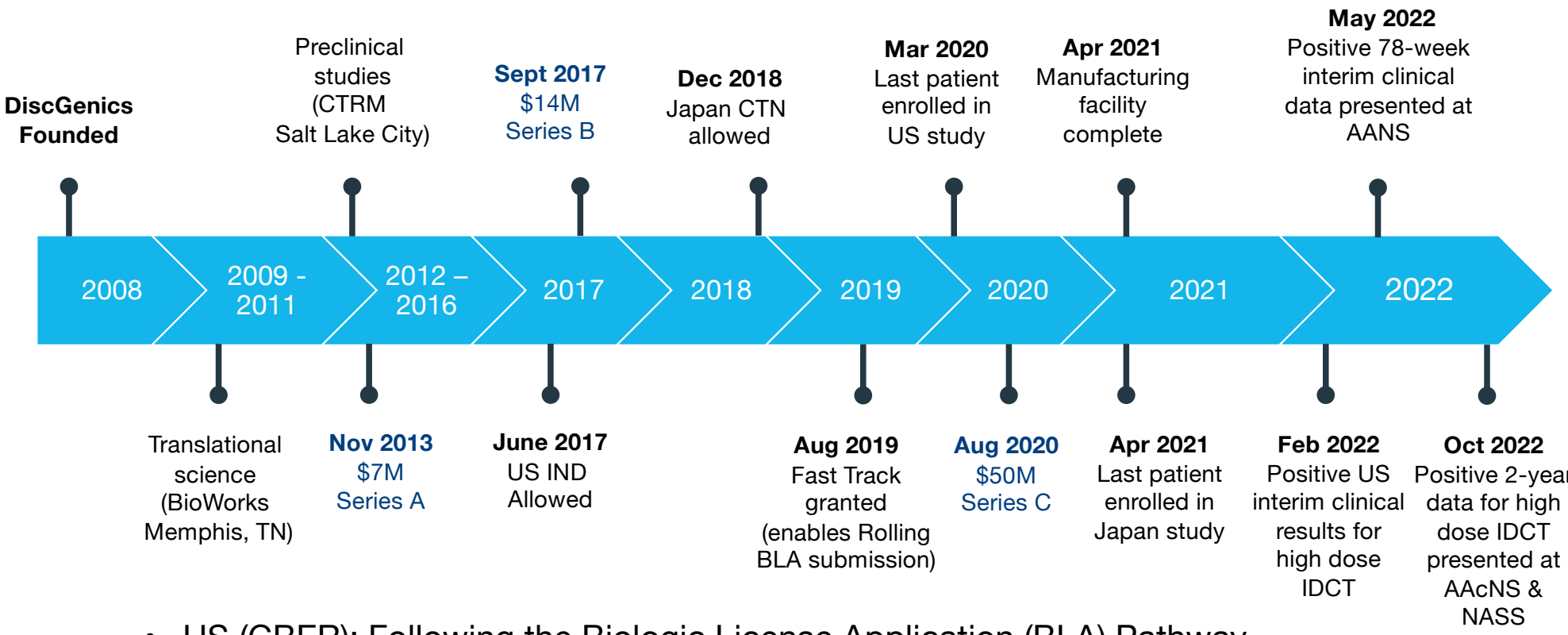
PRODUCT DESCRIPTION: IDCT

- IDCT (rebonuputemcel) is a mixture of live Discogenic Cells and a viscous carrier.
- Discogenic Cells are a unique progenitor cell population derived from donated adult human intervertebral disc tissue (allogeneic).
- IDCT is intended for adults experiencing pain caused by early to moderate lumbar disc degeneration.
- IDCT is injected into the center of the intervertebral disc using fluoroscopic guidance in outpatient procedures.
- IDCT is manufactured and cryopreserved in Salt Lake City and will be distributed worldwide through cold chain logistics.

Injection of IDCT (rebonuputemcel) into Painful, Degenerated Lumbar Discs



DISCGENICS HISTORY

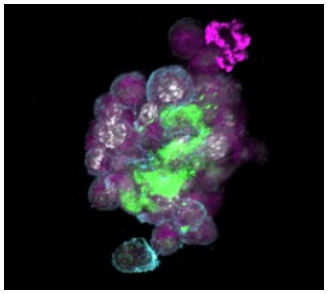


- US (CBER): Following the Biologic License Application (BLA) Pathway
- Japan (PMDA): Following the pathway for Regenerative Medical Products

CELL CHARACTERIZATION

- Intervertebral disc cells are converted into Discogenic Cells over 6-8 weeks through a scalable 2-step manufacturing process
- Stable, non-tumor phenotype
- Modes of action:
  - Anti-inflammatory effect
  - Regenerative effect

Confocal Imaging

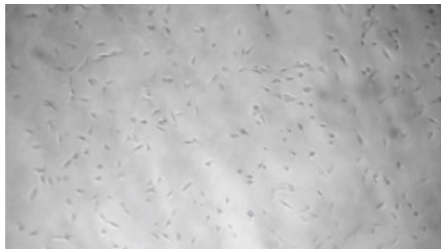


Nucleus

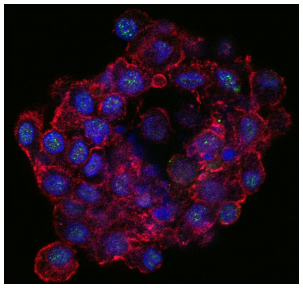
Actin Cytoskeleton

Aggrecan

Collagen 2 (Col2a)

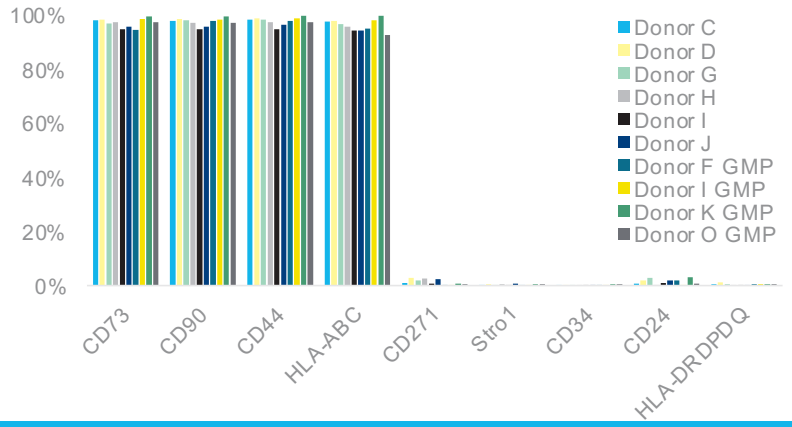


Intermediate Cells



Cluster of Discogenic Cells

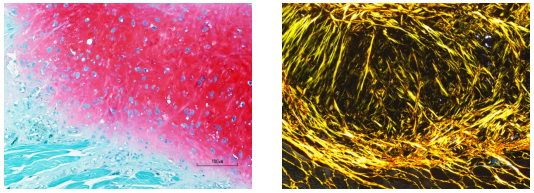
Flow Cytometry



PRECLINICAL DATA: SAFETY & REGENERATIVE EFFECTS

- 13 independent animal studies to evaluate dosing, delivery, safety, etc.
- GLP studies did not identify any toxicity or adverse immunogenic response after delivery of human IDCT into multiple animal species
- Formation of disc-like tissue in multiple models:
  - Subcutaneous pouch of nude mice
  - Injured intervertebral discs of rabbits, pigs and dogs

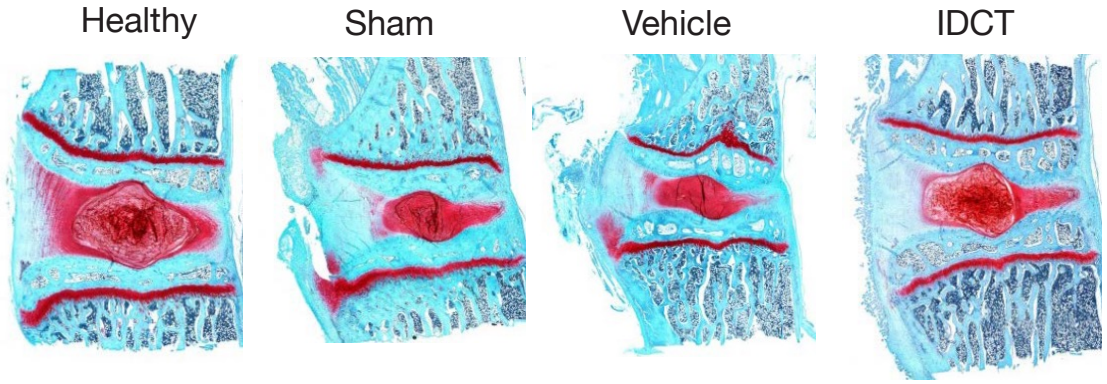
In Vivo Neo-Disc Formation
(Mouse Subcutaneous Pouch)



Proteoglycan (red)

Collagen fibers

Histology of Rabbit Discs
(Safranin O Stain)



CLINICAL EVALUATION: TWO COMPLETED STUDIES

DGX-A01 (US)

- Phase I/II prospective, randomized, double-blind, multicenter clinical studies to evaluate the safety and efficacy of IDCT (rebonuputemcel) in subjects with single-level, symptomatic lumbar intervertebral disc degeneration
- Subjects (n=60) were randomized to one of four treatment groups and received a single intradiscal injection of either a low or high dose of IDCT, vehicle alone, or a saline placebo
- Confidential one-year, eighteen-month, and final two-year (104-week) data analysis complete

DGX-J01 (Japan)

- Prospective, randomized, double-blind, multicenter safety study of IDCT
- Subjects (n=38) were randomized to one of three treatment groups, including low or high dose IDCT or sham control
- Final one-year data analysis in process (expected H2 2022)

INDEPENDENT DATA MONITORING COMMITTEE (IDMC)

- Reviewed unblinded interventions/therapies and adverse events data
- All IDMC reviews resulted in continuation of the studies without modifications

DGX-A01 STUDY DESIGN

- DGX-A01 was a Phase 1, first-in-human study to investigate the safety and tolerability of IDCT in subjects with symptomatic lumbar intervertebral disc degeneration.
- 60 subjects were enrolled at 13 centers in 12 states.
- Eligible subjects were randomized to one of 4 treatment groups: low dose IDCT (3,000,000 cells/mL; N=20), high dose IDCT (9,000,000 cells/mL; N=20), IDCT vehicle (N=10) or saline placebo (N=10).
- Each subject received a single intradiscal injection of 1 mL of their assigned treatment into a single symptomatic lumbar [L3-S1] intervertebral disc.
- Subjects were assessed at weeks 4, 12, 26, 52, 78 and 104 following treatment for various outcome measures.

SAFETY	PRIMARY EFFICACY	SECONDARY EFFICACY	EXPLORATORY
Incidence of grade 2 (moderate) or greater adverse event (AEs) and serious adverse events (SAEs) observed from Day 1 to Week 104	Change from Baseline in **lower-back pain** at 52 weeks as measured on a 100-mm visual analog scale (VAS)	Change from Baseline at various intervals (0-104 Weeks) in: • **Lower-back pain** as measured on a 100-mm VAS • **Disability** as measured by Oswestry Disability Index (ODI)	Change from Baseline at various intervals (0-104 Weeks) in: • EQ-5D Index Score & Overall Health VAS (**Quality of Life**) MRI-based evaluation of: • **Disc Volume**

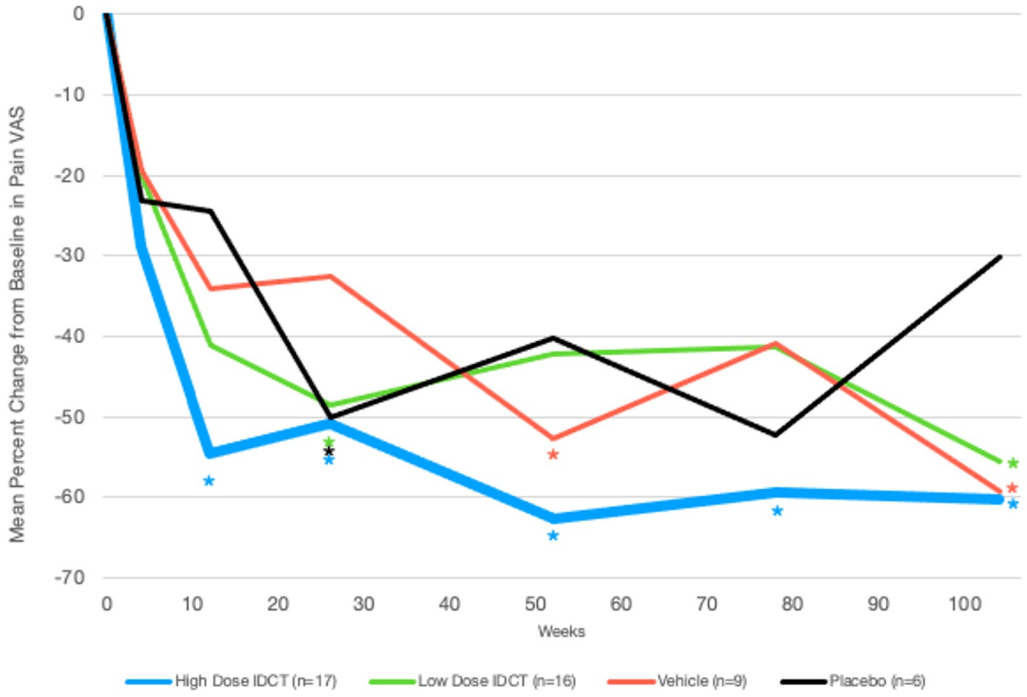
Additional analysis includes minimal clinically important difference (MCID) for patient-derived scores that reflect changes in a clinical intervention that are meaningful for the patient.

DGX-A01 EFFICACY CONCLUSIONS

- The data indicate that high dose IDCT appears to be a safe and effective treatment for degenerative disc disease.
- No serious treatment-emergent adverse events were experienced in either cell therapy group.
- The primary efficacy endpoint of the study was achieved, with statistically significant changes from Baseline to Week 52 in lower back pain >30% in the high dose IDCT group.
- By 12 weeks post-injection, high dose IDCT produced clinically meaningful, statistically significant improvements in low back pain, function and quality of life. Improvements were sustained at the final 104-week readout.
- Disc volume in the high dose IDCT group increased steadily from Baseline, reaching statistical significance at 52 weeks with increases continuing out to 104 weeks.
- Treatment with saline placebo, an agent believed to have analgesic benefits when injected into the disc, did not result in consistent, durable, statistically significant, or clinically meaningful outcomes throughout the study.

LOW BACK PAIN VAS: PRIMARY ENDPOINT

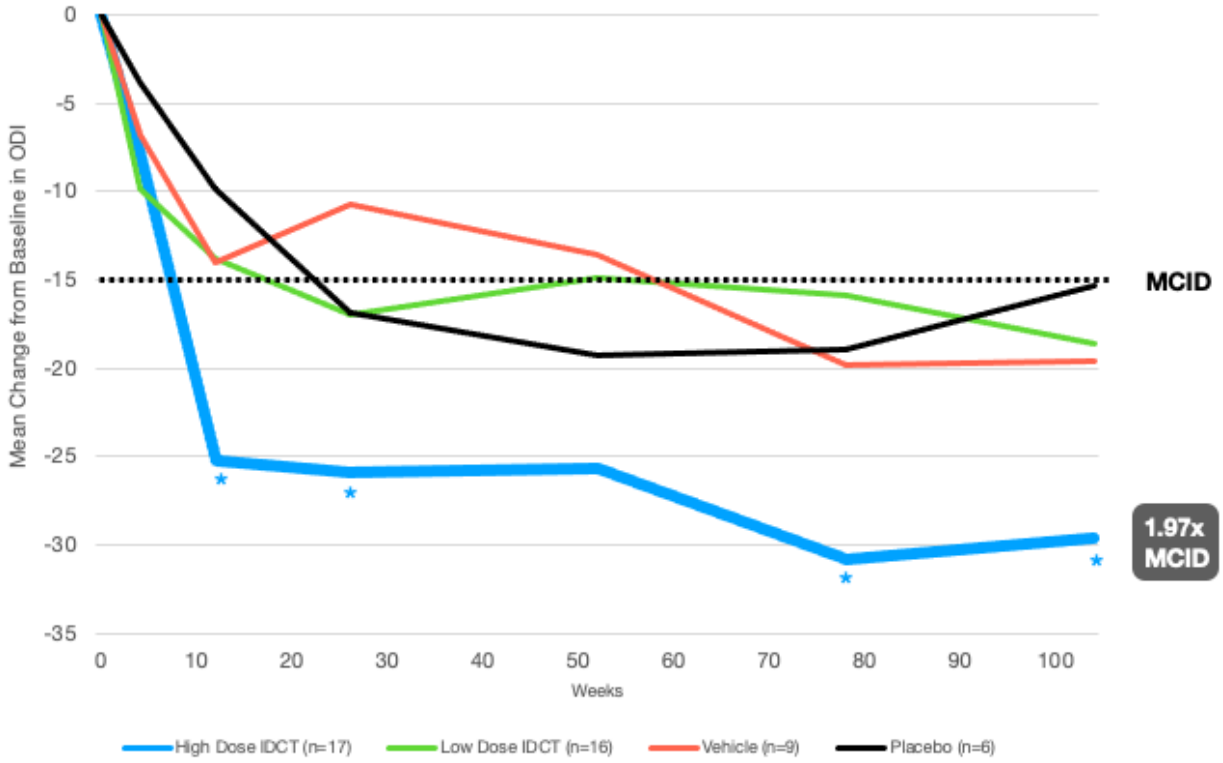
Mean % Change from Baseline in Low Back Pain 100-mm VAS (mITT Set)



*Asterisk indicates statistically significant for improvement >30%

FUNCTION

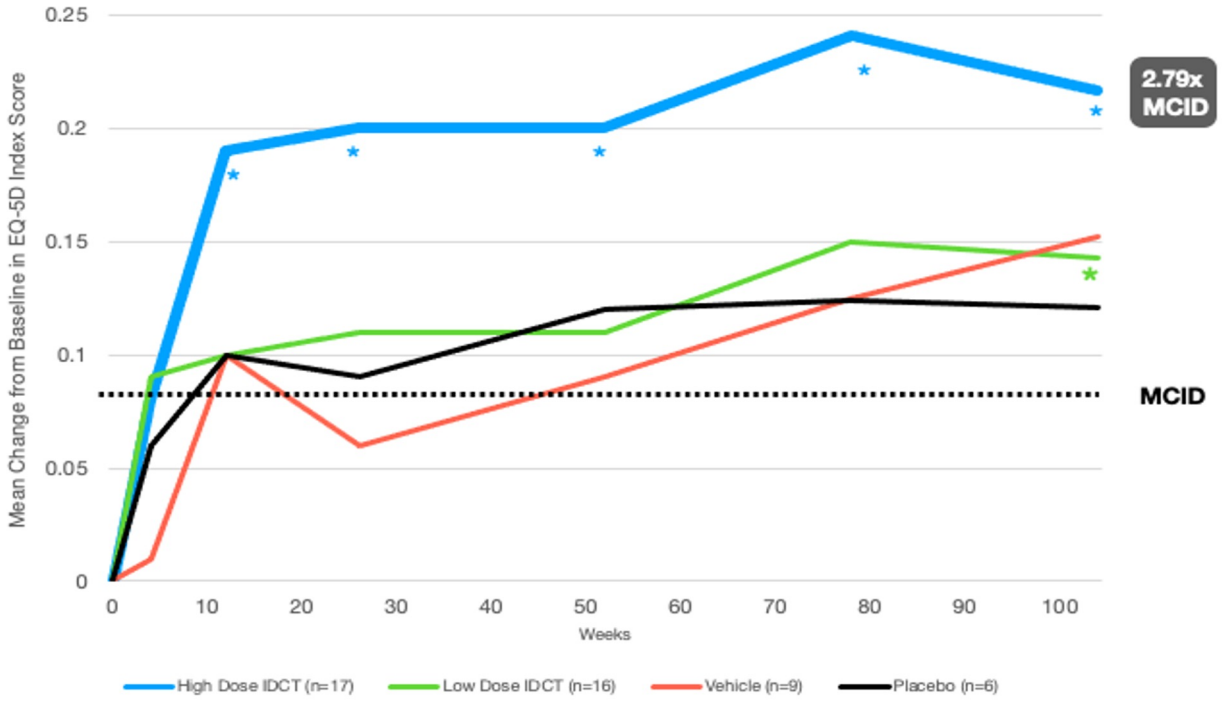
Mean Change from Baseline in ODI by Visit (mITT Set)



*Asterisk indicates statistically significant over MCID of -15

QUALITY OF LIFE

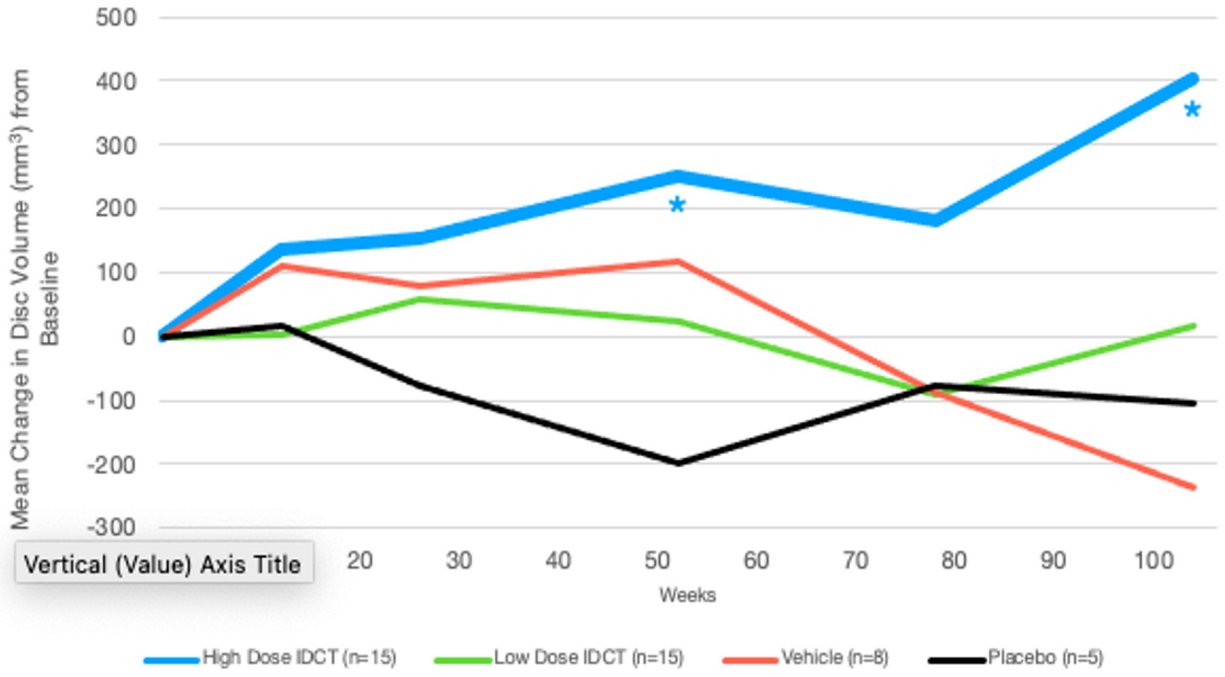
Mean Change from Baseline in EQ-5D by Visit (mITT Set)



*Asterisk indicates statistically significant over MCID of 0.08

DISC VOLUME

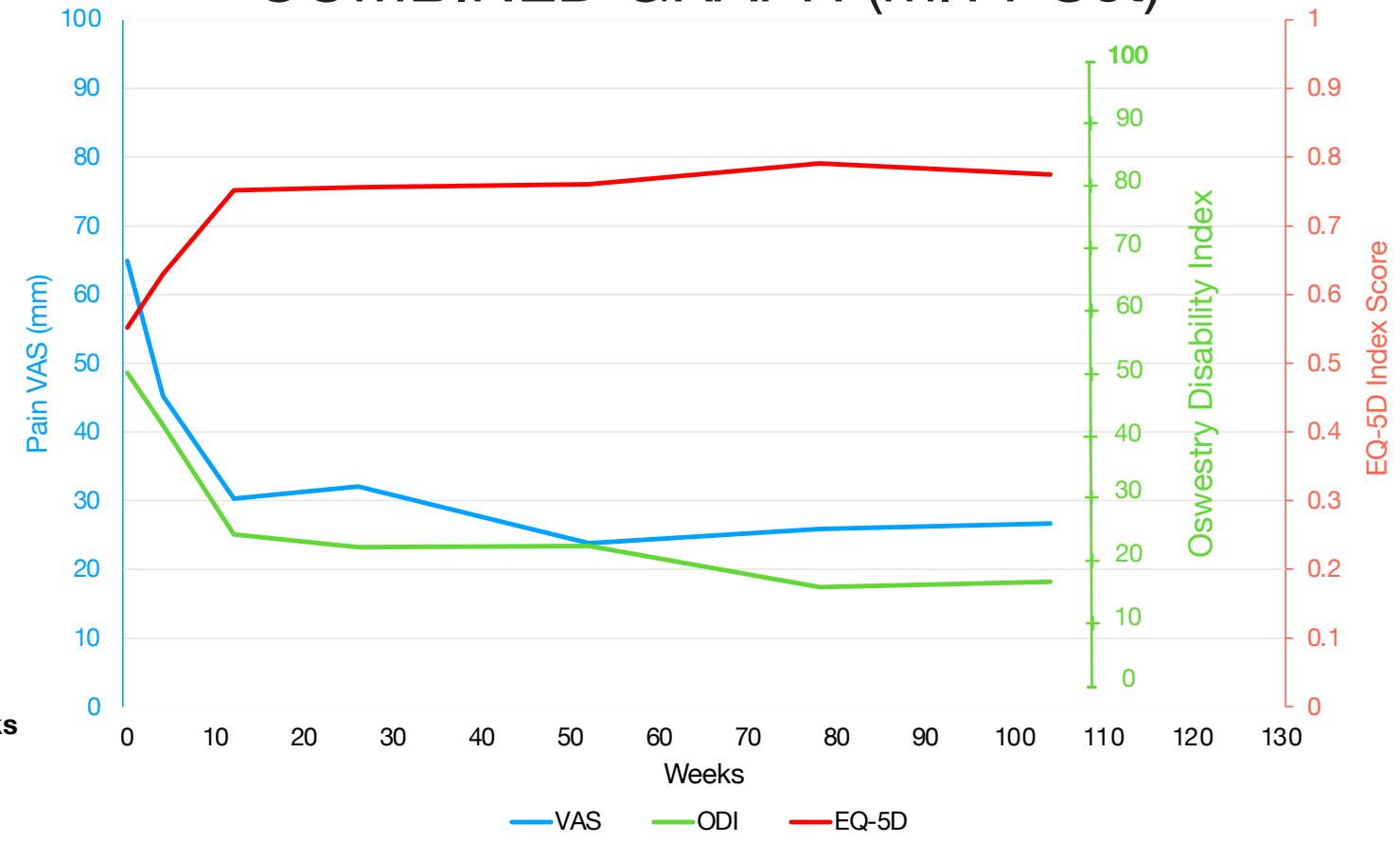
Mean Change from Baseline in MRI Measurement** of Disc Volume (mITT Set)



*Asterisk indicates statistically significant over baseline

** Based on validated, semi-automated analysis methodology

RELATIVE RESULTS OF HIGH DOSE IDCT IN A COMBINED GRAPH (mITT Set)



MCID at 104 Weeks
VAS = 1.91x
ODI = 1.97x
EQ-5D = 2.79x

IDCT MANUFACTURING PROCESS OPTIMIZATION

- Remove subjective steps
- Improve media
- Close systems

Step 1-2:
Primary Cell Isolation

Frozen Product Intermediate Bank

Step 3:
Cell Expansion

- Increase process scale
- Enhance process control
- Selected technology from Pall

- Utilize fully-closed systems
- Completely single use vessels
- Automated process control
- 50L pilot scale at Thermo
- 50L internal run successful (pilot scale)
- 250L demonstration in Q1 (full scale)

Step 4:
Suspension Culture

Step 5:
Fill & Finish
Labeling
Freezing

- High speed automated vial filling
- High speed automated labeling

Manufacturing process covered by 30 patents issued and 29 pending; trade secret protections.

DISCGENICS GMP MANUFACTURING FACILITY

- 25,000 SF (2,323 m2) built out in two stages
- Headquarter Manufacturing Space
  - Construction Complete!
    - Certificate of Occupancy issued by Salt Lake City
  - 16,600 SF
    - Manufacturing cleanrooms (Class B, C, & D)
    - QC Labs
    - Warehouse and Support Space
  - Facility commissioning ongoing
  - Additional utilities & manufacturing equipment to be installed Q2-2022
  - Facilities, utilities, and manufacturing equipment validation Q3-Q4 2022


Cell Culture Room

Today

DISCGENICS GMP MANUFACTURING FACILITY

Filling Cleanroom Suite

PRODUCT PIPELINE

Product Candidate	Indication	Discovery	Preclinical	Early-Stage Clinical	Late-Stage Clinical	Approval
IDCT	Lumbar Disc Degeneration (US)					
	Lumbar Disc Degeneration (Japan)					
IDCT	Multi-Level Lumbar Disc Degeneration					
c-IDCT	Cervical Disc Degeneration					
a-IDCT	Adjacent-Segment Degeneration After Spinal Fusion Surgery					
ICCT	Articular Cartilage Degeneration					
d-IDCT	Post-Discectomy & Annular Repair					
TBD	Facet Joint Degeneration					

FUNDRAISING

- Raised $71M in funding to-date
- Recognized by Goldman Sachs at 2021 Builders + Innovators Summit
- Presented in Private Track at 2022 JP Morgan Healthcare Conference
- Raising $30-$50M Convertible Note
- Current considerations:
  - Venture debt financing
  - Series D fundraising round of $70-$90M (including Convertible Note)
  - Potential crossover to an IPO (Q4 2023/Q1 2024)

CONCLUSIONS

- IDCT (rebonuputemcel) is a homologous, allogeneic, injectable cell therapy for treating discogenic low back pain.
- Clinical results from DGX-A01 indicate high dose IDCT appears to be a safe and effective treatment for degenerative disc disease.
- The primary safety and efficacy endpoints of the U.S. study were achieved with Japanese data to follow shortly.
- By 12 weeks post-injection, high dose IDCT produced consistent, durable, statistically significant, and clinically meaningful improvements in low back pain (VAS), function (ODI), and quality of life (EQ-5D).
- Pain and functional improvements in the high dose IDCT group were sustained at the one-year, eighteen-month, and two-year data readouts.
- Disc volume in the high dose IDCT group increased from Baseline and reached its maximum value at 104 Weeks. Statistical significance from baseline was achieved at 52 and 104 weeks.
- Commercial GMP manufacturing preparations underway to meet regulatory requirements and market opportunity.
- Convertible Note to Series D/Crossover raise in process.

DiscGenics™

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