UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

Current Report
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): June 19, 2018

HISTOGENICS CORPORATION
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-36751**	**04-3522315**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

830 Winter Street, 3rd Floor
Waltham, Massachusetts 02451
(781) 547-7900
(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

Histogenics Corporation ("Histogenics") will be hosting its first Investor Day and live webcast on Tuesday, June 19, 2018, in New York City. Members of Histogenics' management team will provide a corporate overview and discuss the commercialization plan for NeoCart®, Histogenics' lead investigational product, designed to rebuild a patient's own knee cartilage to treat pain at the source and potentially prevent a patient's progression to osteoarthritis. Histogenics' management will be joined by leading orthopedic surgeons who will provide their clinical perspectives on NeoCart, as well as market access insights into today's orthopedic marketplace. The program will also include perspectives from a patient that received NeoCart in the Phase 3 clinical trial as well as additional content related to Histogenics' technology platform including a discussion on tissue engineering and the biomechanics of cartilage tissue. The slides that will be used for such presentation are furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Various statements to be made during the Investor Day and webcast are "forward-looking statements" under the securities laws. Words such as, but not limited to, "anticipate," "believe," "can," "could," "expect," "estimate," "design," "goal," "intend," "may," "might," "objective," "plan," "predict," "project," "target," "likely," "should," "will," and "would," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties.

Important factors that could cause actual results to differ materially from those reflected in Histogenics' forward-looking statements include, among others: the timing and success of Histogenics' NeoCart Phase 3 clinical trial, including, without limitation, possible delays in generating the data from the clinical trial; the ability to obtain and maintain regulatory approval of NeoCart or any product candidates, and the labeling for any approved products; NeoCart's regulation as a Regenerative Medical Product in Japan; the market size and potential patient population in Japan; the scope, progress, expansion, and costs of developing and commercializing Histogenics' product candidates; the ability to obtain and maintain regulatory approval regarding the comparability of critical NeoCart raw materials following our technology transfer and manufacturing location transition; the size and growth of the potential markets for Histogenics' product candidates and the ability to serve those markets; Histogenics' expectations regarding its expenses and revenue; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Histogenics' Annual Report on Form 10-K for the year ended December 31, 2017 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, which are on file with the Securities and Exchange Commission ("SEC") and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Histogenics' annual report on Form 10-K and quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, other unknown or unpredictable factors also could affect Histogenics' results.

There can be no assurance that the actual results or developments anticipated by Histogenics will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Histogenics. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Histogenics or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Histogenics cautions investors not to rely too heavily on the forward-looking statements Histogenics makes or that are made on its behalf. The information conveyed on during the Investor Day and webcast will be provided only as of the date of the Investor Day, and Histogenics undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements made during the call after the date thereof, whether as a result of new information, future events or otherwise.

The information in Item 7.01 of this Current Report on Form 8-K and the Exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) ***Exhibits***

Exhibit No.	Description
99.1	Presentation Slides.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: June 19, 2018

HISTOGENICS CORPORATION

By: /s/ Adam Gridley
Adam Gridley
President and Chief Executive Officer

Histogenics

Investor Day

June 19, 2018

Agenda

Time	Topic	Speaker	Duration
8:15 am	Introductions and corporate overview	Adam Gridley	15 Minutes
8:30 am	Physician Panel – The Clinicians' Perspective	Dr. Deryk Jones Dr. Dean Taylor Moderator: Adam Gridley	40 Minutes
9:10 am	Care Pathway and Patient Impact – A Patient's Perspective	George Pierce Dr. Deryk Jones Moderator: Adam Gridley	25 Minutes
9:35 am	Break		10 – 15 Minutes
9:50 am	NeoCart Data Package	Adam Gridley	5 Minutes
9:55 am	NeoCart Biomechanics and Mechanism of Action	Steve Kennedy Larry Bonassar	30 Minutes
10:25 am	NeoCart Launch and Market Access Discussion	Don Haut	20 Minutes
10:45 am	Pipeline and Financials	Jon Lieber	15 Minutes
11:00 am	Closing Remarks	Adam Gridley	15 Minutes

A Leadership Team with a Track Record of Success

Adam Gridley, Chief Executive Officer

Multiple IPO's and transactions, global operating/R&D & commercial experience (Merz, BioForm, Gliatech) across devices, drugs & biologics

Don Haut, Chief Business Officer

Business development, strategic planning, line management and banking/consulting experience (Medicines Co, Smith & Nephew, JBS, 3M, McKinsey), with over $4 billion of transactions in biotechnology, and medical device businesses

Steve Kennedy, Chief Operating Officer

Global product development, manufacturing, technical operations experience leading global clinical and commercial launches (Genzyme, Mascoma, Genencor, MIT) across devices, drugs & biologics

Jonathan Lieber, Chief Financial Officer

Investment banking & CFO experience, multiple IPO's & financing & public market experience (Salomon, Cowen / Altus, Repligen, Xcellerex, Metamark) across drugs, diagnostics, tools & biologics

Disclaimer Regarding Forward-Looking Statements

This presentation includes statements that are, or may be deemed, "forward-looking statements." All statements, other than statements of historical facts, included in this presentation regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "opportunity," "proposition," "strategy," "potential," "ongoing," "plan" or the negative of these terms and similar expressions intended to identify forward-looking statements.

These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Actual results may be materially different. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements include, but are not limited to, statements about: the timing and success of preclinical studies and clinical trials; the ability to obtain and maintain regulatory approval of our product candidates in the United States, Japan or in other jurisdictions in which we or our partners may seek such approval; the scope, progress, expansion and costs of developing and commercializing our product candidates; our expectations regarding our expenses and revenue; the sufficiency of our cash resources and needs for additional financing; our ability to adequately manufacture our product candidates and the raw materials utilized therein; our ability to obtain and maintain intellectual property protection for our product candidates; our expectations regarding competition; the size and growth of the potential markets for our product candidates and the ability to serve those markets; the rate and degree of market acceptance of any of our product candidates; our anticipated growth strategies; the anticipated trends and challenges in our business and the market in which we operate; our ability to establish and maintain development partnerships; our ability to attract or retain key personnel; our expectations regarding federal, state and foreign regulatory requirements; and regulatory developments in the United States and foreign countries and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of our Annual Report on Form 10-K for the year ended December 31, 2017 and our Quarterly Report on Form 10-Q for the period ended March 31, 2018, which are on file with the SEC. All of our filings are available on the SEC's website at www.sec.gov. All written and verbal forward-looking statements attributable to Histogenics or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Histogenics cautions investors not to rely too heavily on the forward-looking statements Histogenics makes or that are made on its behalf.

The information in this presentation is provided only as of the date of this presentation, and Histogenics undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

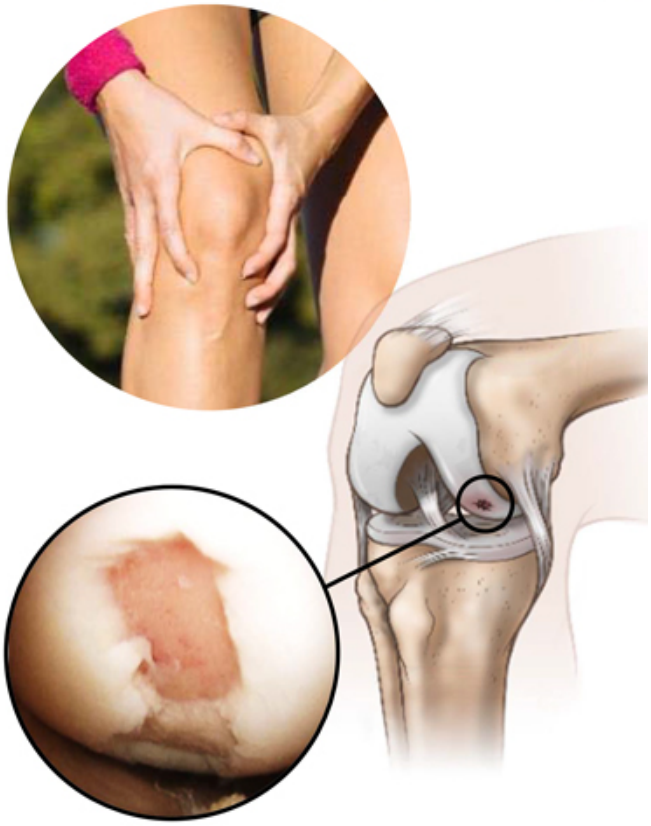
NeoCart is limited by Federal Law to investigational use only and not available for sale.

The Histogenics Value Proposition

- Powerful, proprietary platform that provides restorative cell therapies (RCTs) for active living
- Lead product candidate, NeoCart® is a proprietary RCT that potentially rebuilds patients' own knee cartilage, reducing pain at the source and potentially preventing progression to osteoarthritis (OA)
- Large market opportunity to treat knee cartilage damage
- Phase 3 enrollment complete; data in Q3:18. Near-term value creation opportunity with possible U.S. launch of NeoCart in 2019
- Planned expansion of NeoCart platform into additional markets and indications

Knee Cartilage Damage: A Complex Problem

- Cartilage is a complex tissue – shock absorber that must withstand significant pressure, and allow for rolling and sliding
- Damage due to acute injury or repetitive trauma
- Cartilage injury causes pain and loss of function
- Limited ability to regenerate due to lack of vascularity
- Strong correlation between knee cartilage damage and OA
- Current treatment options are sub-optimal with variable outcomes due to variable cellular response
- Patients and physicians seeking alternatives that may offer a more rapid and durable recovery



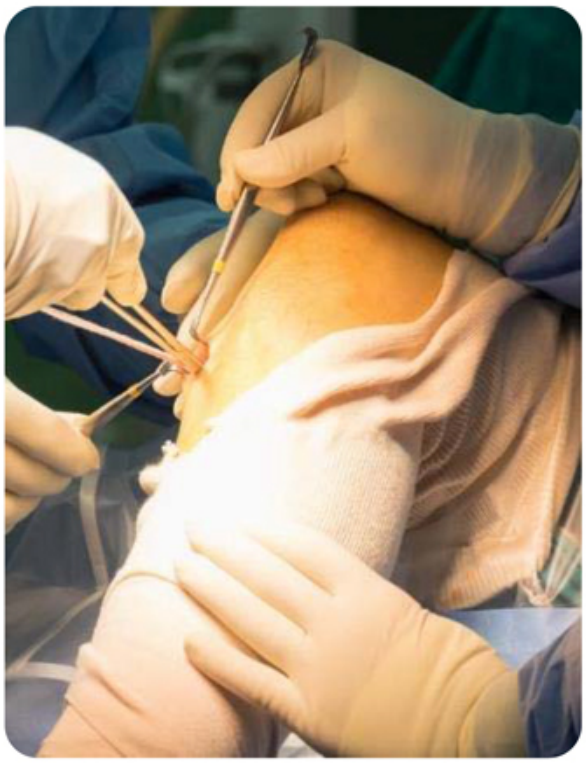
Cartilage Injury
Focal Chondral Defect

OA Causes Significant Health and Economic Burdens

- Knee injury increases the risk of developing OA by more than **fivefold**
- **~27 million** Americans diagnosed each year with knee OA – with a large portion due to cartilage damage
  - 1.2 million arthroscopies annually in U.S. associated with cartilage defects; 500,000 procedures including 150,000 microfractures
- **50%** of Americans expected to develop symptomatic knee OA
- Globally, more than **half** of patients with knee OA ultimately undergo total join replacement
- Global direct expenditures for knee OA treatment are **$185 billion** annually

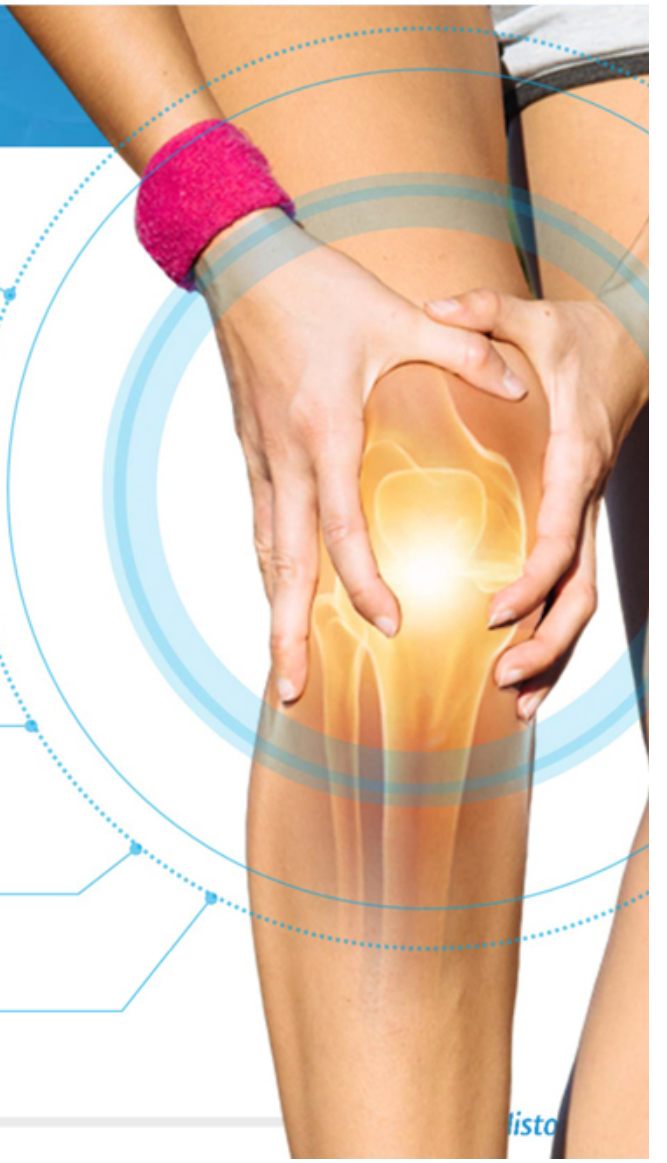
Limitations of Current Therapies

- Debridement may reduce pain but does not repair cartilage
- Microfracture yields variable outcomes
  - 30% of microfracture patients continue to have pain and reduced knee function and require additional procedures
- Current treatments require extensive recovery time and impede return to work and daily living
- Current treatments are often ineffective in the long term because they do not adequately address cartilage damage
  - May lead to additional surgeries
  - Failure to correct cartilage damage may lead to development of OA



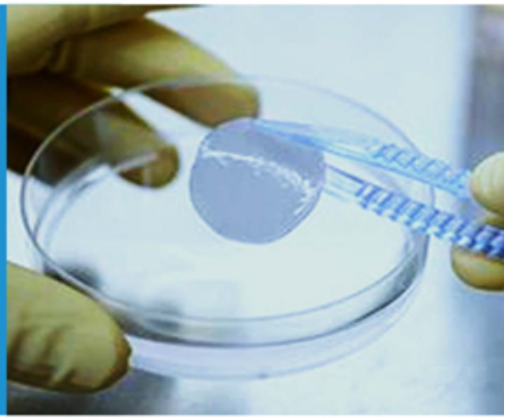
Attributes of an Optimal Treatment for Knee Cartilage Damage

- Reduces pain
- Improves function
- Promotes repair of damaged cartilage
- Short rehabilitation / more rapid return to daily activities
- Durable response
- No specialized surgical techniques and less operating room time
- Non-opioid approach

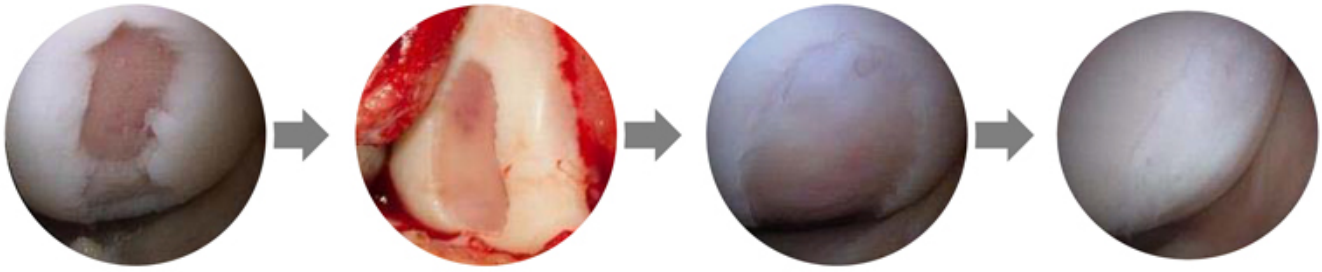


NeoCart: Restorative Cell Therapy with Novel Mechanism of Action

- NeoCart combines breakthroughs in bio-engineering and cell processing to enhance the autologous cartilage repair process
- NeoCart merges a patient's own cells with a fortified three-dimensional scaffold designed to accelerate healing and reduce pain
- Patients receive functional cartilage at the time of treatment



Follow-up Arthroscopy Demonstrates NeoCart Progression and Integration



Initial Lesion | Time Zero Implantation | 8 Weeks | 6 Months

Phase 3 patient follow-up arthroscopies unrelated to NeoCart implant.

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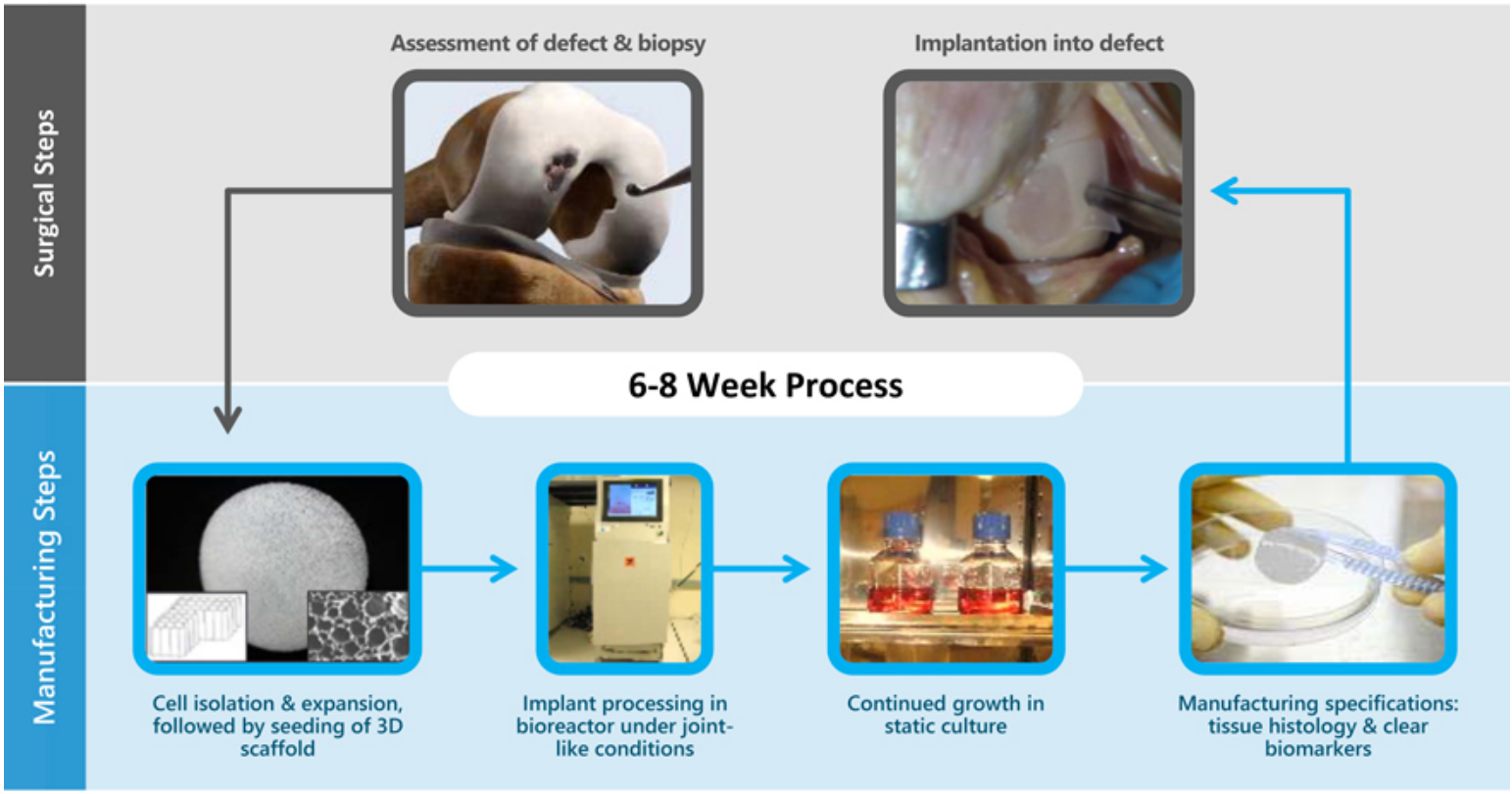
Commercially Scalable Manufacturing Process



Ex-vivo manufacture of living cartilage tissue with biomarkers & biomechanical data

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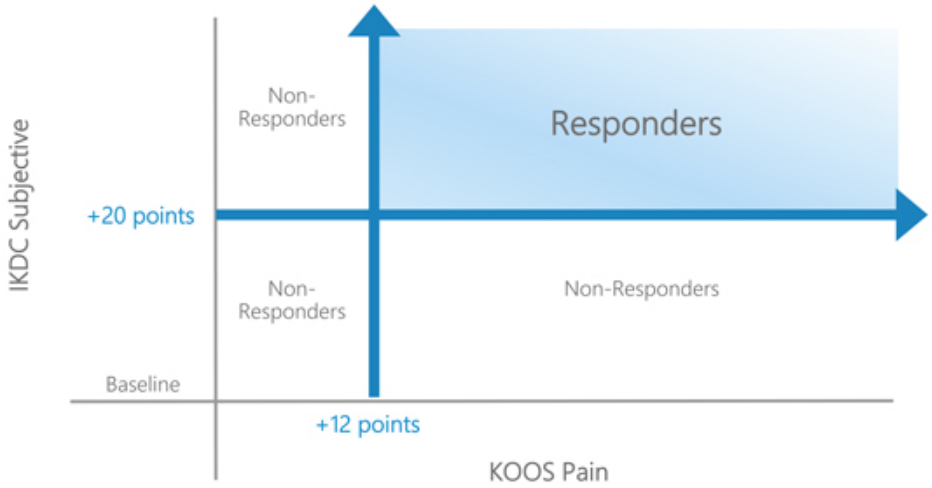
Positive Phase 2 Results Support Phase 3 Trial Design

Dual-Threshold Responder Rate Analysis Sets High Efficacy Threshold

- 30 patients at 6 U.S. centers; 2:1 randomization (NeoCart v. Microfracture)
- 2011 FDA and 2016 PMDA guidance – subjective Pain & Function endpoints, with high hurdle "clinically meaningful" improvement thresholds:
  - >12 pts KOOS Pain vs. Y1 Baseline, and
  - >20 pts IKDC Subjective vs. Y1 Baseline
- 5-year MRI and outcomes data published in Q1:17



Superiority Endpoint:

% of NeoCart "Responders" vs Mfx "Responders"

Source: Roos E, Lohmander SL. The knee injury and osteoarthritis outcome score (KOOS): from joint injury to osteoarthritis. Health Quality Life outcomes. 2003; 1: 64.

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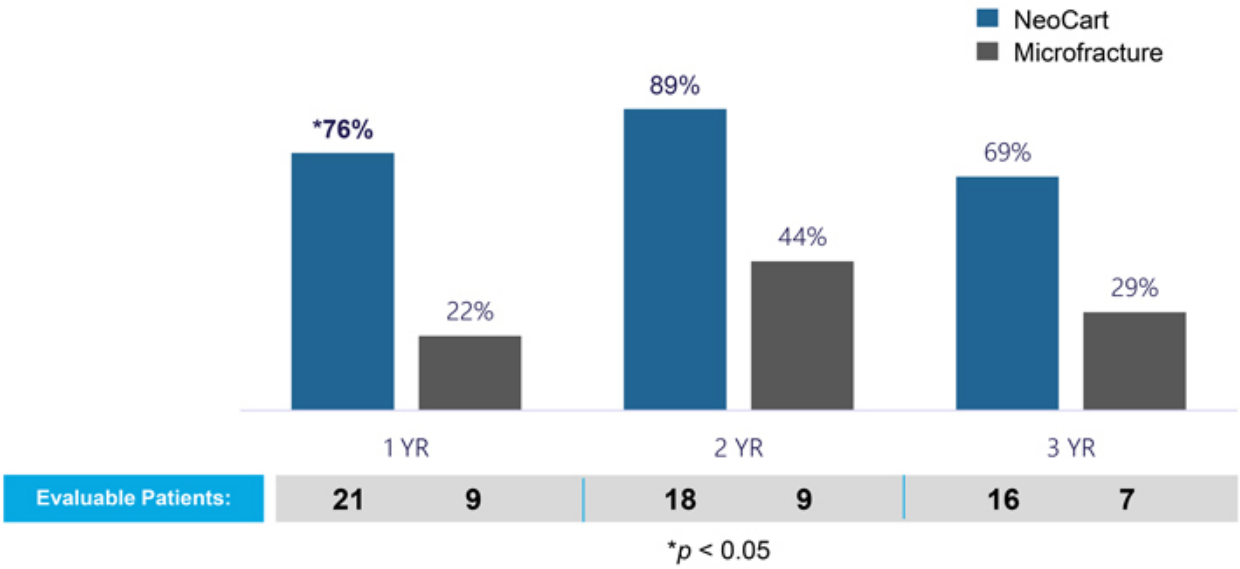
NeoCart Phase 3 Clinical Trial Based on Successful Phase 2 Trial

1 year primary superiority endpoint

Phase 3 requires only ~15-20% difference between NeoCart and microfracture



*$p < 0.05$

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Consistent Improvement in Pain and Function

Early (3 mo) yet Sustained Improvement in Pain
Median Phase I & II Scores All Highly Statistically Significant

TABLE 2
Change in Patient-Reported Outcomes From Baseline to Each Time Point[a]

	Score						
Parameter	3 mo	6 mo	12 mo	24 mo	36 mo	48 mo	60 mo
IKDC subjective (n = 29)	6.7 ± 19.0	15.7 ± 19.0[b]	27.3 ± 18.4[b]	31.8 ± 19.5[b]	31.4 ± 21.9[b]	28.5 ± 27.0[b]	27.4 ± 20.2[b]
VAS mean (n = 29)	−13.5 ± 23.9[c]	−20.8 ± 21.2[b]	−22.5 ± 21.2[b]	−27.9 ± 18.8[b]	−24.2 ± 21.8[b]	−26.2 ± 21.2[b]	−19.0 ± 27.4[c]
VAS highest (n = 21)	−23.2 ± 31.2[c]	−30.2 ± 32.7[b]	−39.8 ± 24.6[b]	−46.6 ± 24.3[b]	−36.8 ± 29.8[b]	−51.5 ± 28.5[b]	−36.4 ± 32.2[b]
KOOS-Pain (n = 21)	11.6 ± 11.1[b]	19.6 ± 14.1[b]	21.4 ± 10.4[b]	22.4 ± 9.4[b]	22.0 ± 10.0[b]	23.3 ± 10.8[b]	21.0 ± 11.2[b]
KOOS-ADL (n = 21)	10.6 ± 15.6[c]	15.1 ± 13.6[b]	16.7 ± 10.7[b]	18.9 ± 11.5[b]	15.9 ± 11.1[b]	16.7 ± 11.4[b]	16.0 ± 12.4[b]
KOOS-QoL (n = 21)	15.6 ± 18.0[b]	22.9 ± 16.8[b]	30.7 ± 17.2[b]	43.4 ± 23.3[b]	42.2 ± 26.8[b]	46.7 ± 32.3[b]	45.4 ± 23.9[b]
KOOS-Symptoms (n = 21)	8.4 ± 15.9[d]	17.0 ± 10.8[b]	18.2 ± 13.2[b]	20.5 ± 15.3[b]	20.1 ± 19.9[c]	21.4 ± 20.8[c]	22.1 ± 15.1[b]
KOOS-Sports (n = 21)	3.8 ± 29.8	16.4 ± 33.9[d]	27.7 ± 22.7[b]	35.8 ± 22.5[b]	35.6 ± 25.4[b]	36.3 ± 24.1[b]	31.7 ± 28.5[b]
Active ROM (n = 29), deg	1.6 ± 8.6	3.6 ± 8.8[d]	5.0 ± 8.6[c]	5.7 ± 9.5[c]	8.2 ± 9.0[b]	8.6 ± 8.0[b]	10.7 ± 9.6[b]
Loss to follow-up,[e] n	2	0	0	2-3	4-6	6-8	7

[a]Data are reported as mean ± SD unless otherwise indicated. ADL, Activities of Daily Living; IKDC, International Knee Documentation Committee; KOOS, Knee injury and Osteoarthritis Outcome Score; QoL, Quality of Life; ROM, range of motion; SF-36, Short Form–36; VAS, visual analog scale.
[b]Statistically significant difference from baseline: $P < .001$.
[c]Statistically significant difference from baseline: $P < .01$.
[d]Statistically significant difference from baseline: $P < .05$.
[e]Loss to follow-up values (n) are variable because of patients omitting 1 patient-reported outcome at the visit indicated.

> 9 point KOOS Pain = clinically meaningful

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NeoCart Phase 3 Clinical Trial

Screening

Key Inclusion Criteria

- Age: 18-59
- Severe and symptomatic cartilage lesions (0.5-6cm^2)
- Femoral condyle and/or trochlear lesions

Key Exclusion Criteria

- Prior lesion treatment
- High BMI
- Significant arthritis
- Concomitant surgeries

n = 249

Randomization

- Arm 1: NeoCart (n = 169)
- Arm 2: Microfracture (n = 80)

Endpoints at 1 Year

Primary

- Knee pain/function improvement:
  - ≥12 pts KOOS pain
  - ≥20 pts IKDC Subjective

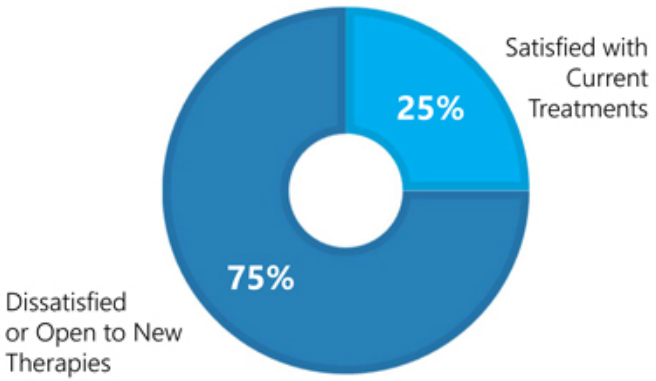
Secondary

- Time to full weight-bearing
- Failure: Reop or deterioration
- Collagen layering via MRI

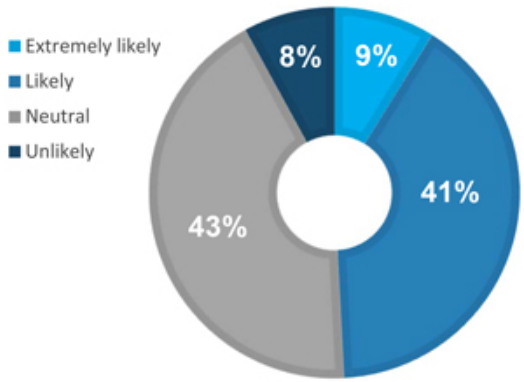
- Enrollment completed Q2:17
- Topline one-year superiority data anticipated in Q3:18; potential FDA approval by end of 2019
- Trial being conducted under a SPA; may minimize risk of regulatory delays

Well-Defined Target Market Seeks Alternative Treatment Options

LOW LEVELS OF PHYSICIAN SATISFACTION
(N=170)



WILLINGNESS TO PRESCRIBE NEOCART (PRODUCT X);
(N=79)



- Target: Sports medicine physicians seeing patients with knee pain & function loss, regularly performing debridement & microfracture
- Surgeons see 10 to 20 patients with cartilage damage each month but treat only 30-40% of these patients due to low satisfaction with the current treatment options
- Novel products with 1-year clinical superiority to microfracture and minimal training/procedure time may grow the market

** Source: Histogenics primary market research with U.S. orthopedic surgeons.*

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Physician Panel
Clinician's Perspective

Deryk Jones, MD – Section Head of Sports Medicine and Cartilage Restoration at the Ochsner Sports Medicine Institute

Dean Taylor, MD – Director of the Duke Sports Medicine Fellowship Program, Director of the Duke School of Medicine Leadership Education and Development (LEAD) Curriculum, Team Physician, and Chairman of the Feagin Leadership Program

Investigator Panel

- Introduction & your clinical history with NeoCart?
- Microfracture surgeons & patient profile?
- How does NeoCart serve an unmet need? What are the potential benefits? Ease of application, adhesive?
- Unique features?
- Your anecdotal experience with NeoCart – short-term rehab/recovery and long-term durability?
- Future applications – what is possible with this restorative cell therapy platform vs other products?

A Patient's Perspective

George Pierce

Patient Experience – George Pierce

- Introduction: your lifestyle – work and play?
- Your microfracture experience & current pain/function for that knee?
- When did you have NeoCart? Compare your experiences – rehabilitation, time to work, sitting, squatting?
- Why did you choose NeoCart, and had you considered Microfracture again?
- How do you feel today, quality of life, ability to work and play with your NeoCart knee?
- Final thoughts – appeals of NeoCart vs current alternate therapies

Clinical Data

Our Commitment: Growing Body of Clinical Evidence

An Autologous Cartilage Tissue Implant NeoCart for Treatment of Grade III Chondral Injury to the Distal Femur

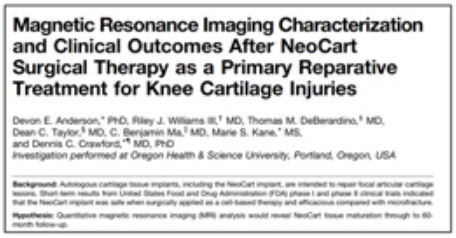
Prospective Clinical Safety Trial at 2 Years

Dennis C. Crawford,*† MD, PhD, Chelsea M. Heveran,† W. Dilworth Cannon Jr,‡ MD, Li Foong Foo,§ MD, and Hollis G. Potter,‖ MD

From the †Department of Orthopaedics, Oregon Health and Science University, Portland, Oregon, the ‡Department of Orthopaedic Surgery, University of California San Francisco Medical School, San Francisco, California, and the §Magnetic Resonance Imaging Division, Department of Radiology and Imaging, Hospital for Special Surgery, New York, New York

Background: The healing potential of damaged articular cartilage is limited. The NeoCart is a tissue-engineered collagen matrix seeded with autogenous chondrocytes designed for the repair of hyaline articular cartilage.

Hypothesis: The NeoCart implant is well tolerated in the human knee.



Magnetic Resonance Imaging Characterization and Clinical Outcomes After NeoCart Surgical Therapy as a Primary Reparative Treatment for Knee Cartilage Injuries

Devon E. Anderson,* PhD, Riley J. Williams III,† MD, Thomas M. DeBerardino,‡ MD, Dean C. Taylor,§ MD, C. Benjamin Ma,‖ MD, Marie S. Kane,* MS, and Dennis C. Crawford,*¶ MD, PhD

Investigation performed at Oregon Health & Science University, Portland, Oregon, USA

Background: Autologous cartilage tissue implants, including the NeoCart implant, are intended to repair focal articular cartilage lesions. Short-term results from United States Food and Drug Administration (FDA) phase I and phase II clinical trials indicated that the NeoCart implant was safe when surgically applied as a cell-based therapy and efficacious compared with microfracture.

Hypothesis: Quantitative magnetic resonance imaging (MRI) analysis would reveal NeoCart tissue maturation through to 60-month follow-up.

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NeoCart, an Autologous Cartilage Tissue Implant, Compared with Microfracture for Treatment of Distal Femoral Cartilage Lesions

An FDA Phase-II Prospective, Randomized Clinical Trial After Two Years

Dennis C. Crawford, MD, PhD, Thomas M. DeBerardino, MD, and Riley J. Williams III, MD

Investigation performed at Oregon Health and Science Center, Portland, Oregon; Keller Army Community Hospital, West Point, New York; Duke Sports Medicine Center, Durham North Carolina; University of California, San Francisco California; TRIA Orthopaedic Center, Bloomington, Minnesota; and the Hospital for Special Surgery, New York, NY

Background: Despite introduction of autologous chondrocyte therapy for repair of hyaline articular cartilage injury in 1994, microfracture remains a primary standard of care. NeoCart, an autologous cartilage tissue implant, was compared with microfracture in a multisite prospective, randomized trial of a tissue-engineered bioimplant for treating articular cartilage injuries in the knee.

Robust Clinical Data Package:

- One of the most rigorously studied RCTs for orthopedic use – Phase 1 (n=9), Phase 2 (n=30), and Phase 3 (n=249), clear level 1 published evidence
- Only rapid-onset RCT with a one-year primary superiority endpoint under SPA in a Phase 3 trial, high hurdle dual threshold pain/function endpoints
- Rapid Recovery as measured by HEOR endpoints + Long-term Durability (3-year data in many patients already). Expect up to 7-year data via registry

We collect cartilage biomarkers for every NeoCart

Further MOA data via biomechanical testing with Cornell

- Developing further evidence of how NeoCart works, and the importance of providing tissue, structure and ECM
- Based on FDA request initially, now broadening collaboration to further characterize our unique RCT platform and identify future product oppties

NeoCart Biomechanics and Mechanism of Action

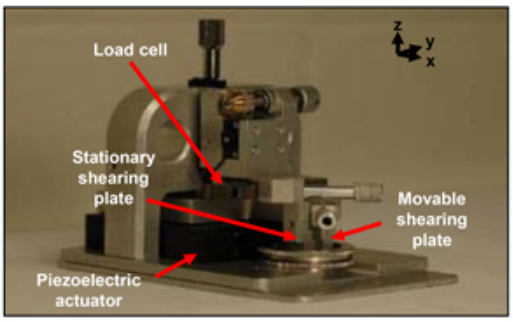
Lawrence Bonassar, PhD - Scientific Advisory Board, Histogenics Corporation, Professor in the Meinig School, of Biomedical Engineering and the Sibley School of Mechanical and Aerospace Engineering at Cornell University

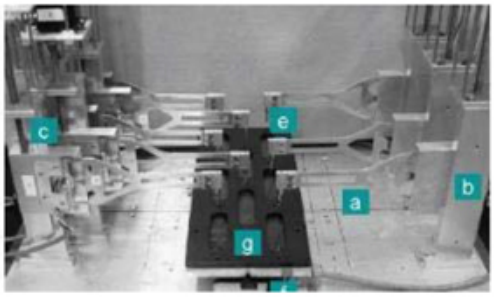
Histogenics/Cornell Sponsored Research Agreement

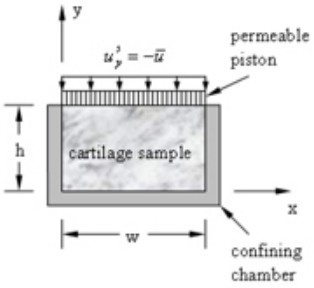
- Sponsored Research Agreement (SRA) initiated in 2014
  - Bonassar Lab, Meinig School of Biomedical Engineering/Sibley School of Mechanical and Aerospace Engineering, Cornell University
  - Original Aims
    1. Develop 3D printing methods for cartilage manufacturing
    2. Biomechanical test methods for NeoCart
  - Current Aims
    1. Use of non-invasive optical techniques to measure structure and composition of NeoCart constructs
    2. Examine the relationship between measurement of local structure, composition, and mechanical properties of NeoCart constructs
    3. Apply techniques for process control and validation of NeoCart constructs
- 2011 FDA guidance regarding biomechanical testing of cartilage constructs
  - Histogenics/Cornell SRA is most comprehensive effort to date, setting the standard for the industry

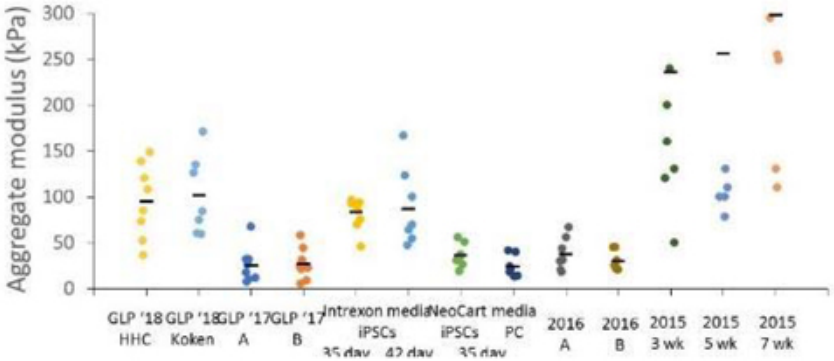
New Paradigm for Mechanical Analysis

- Multi-modal analysis of NeoCart performance
  - Customized devices to measure performance in compression, shear, friction
  - Implant-scale performance and micromechanical analysis
- Longitudinal analysis of batches over 3 years
  - Analysis of the effects of cell source, patient batch, material source
  - Largest data set on assessment of performance of a cartilage repair product (336 independent combination of sample/test)









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Initial NeoCart Biomechanical Test Data Presented in February 2016 at ORS

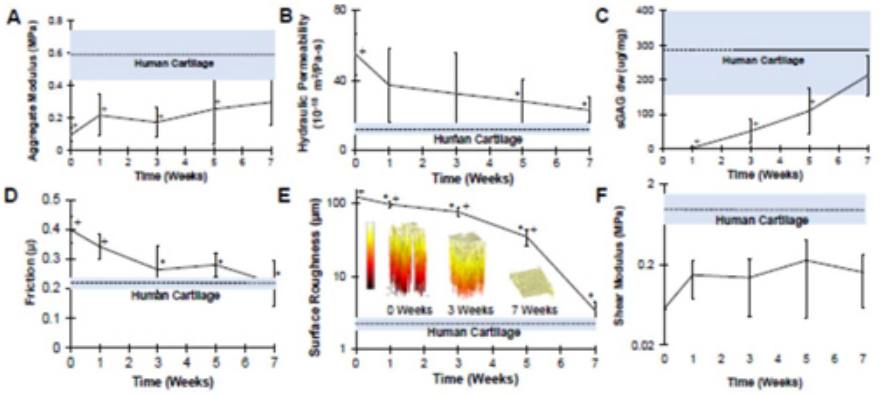
NeoCart macro-scale biochemical and biomechanical properties approach those of native cartilage prior to implantation
No other tissue-engineered product on the market with these characteristics

Mechanical Characterization of Autologous Chondrocyte-Seeded Matrix Grafts After In Vitro Growth

Jill Middendorf[1]; Darvin Griffin[2]; Stephen Kennedy[3]; Sonya Shortkroff[3]; Caroline Dugopolski[3]; Joseph Siemiatkoski[3]; Lena Bartell[4]; Itai Cohen[5]; Lawrence Bonassar[1,2]
[1]Sibley School of Mechanical and Aerospace Engineering; [2]Meinig School of Biomedical Engineering; [4]School of Applied and Engineering Physics; [5]Department of Physics; Cornell University; [3]Histogenics Corporation, Waltham, Massachusetts

Results

Macroscale Mechanical Characteristics of Constructs Improve Over Culture Time



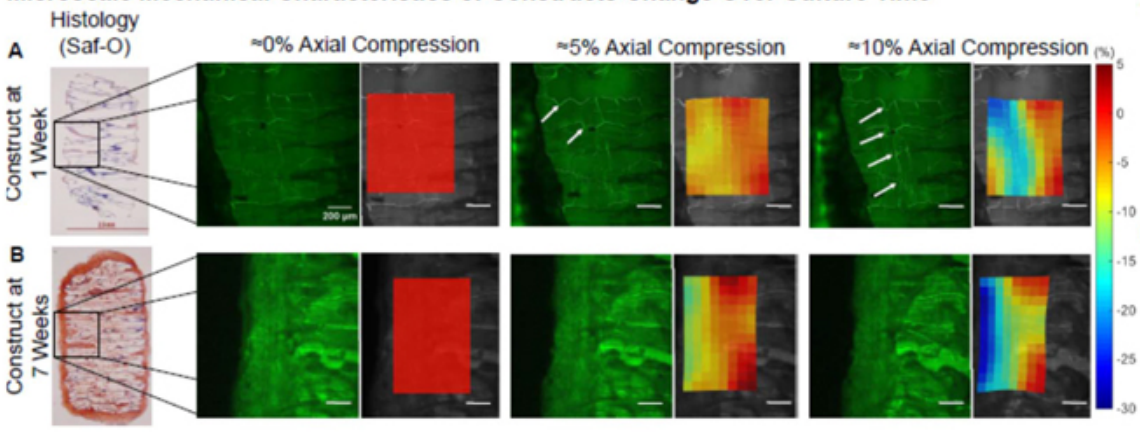
A) Aggregate modulus increased over time to a value half that of human cartilage.
B) Hydraulic permeability decreased over time to twice that of human cartilage.
C) sGAG content increased to values similar to human cartilage.
D) Friction coefficient plateaued at values similar to human cartilage.
E) Surface roughness values decreased over time to values similar to human cartilage.
F) Global shear modulus of samples remained an order of magnitude less than human cartilage.

(*p<0.05 compared to 0 week value, *p<0.05 compared to human cartilage; n=7-8 constructs, n = 3 human cartilage)

NeoCart Micro-scale Properties Presented in February 2016 at ORS

Mechanical properties are controlled by extracellular matrix in developed tissue
Cells and scaffold only results in scaffold buckling under strain

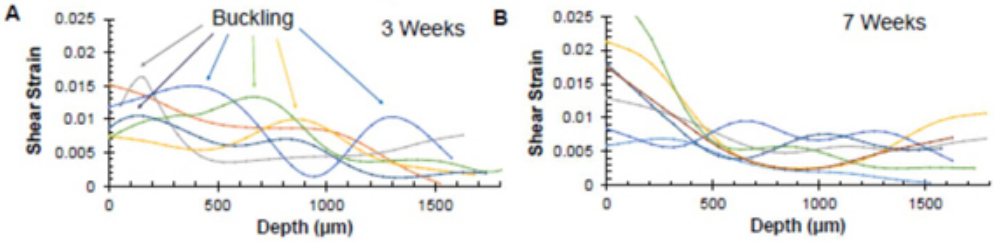
Microscale Mechanical Characteristics of Constructs Change Over Culture Time



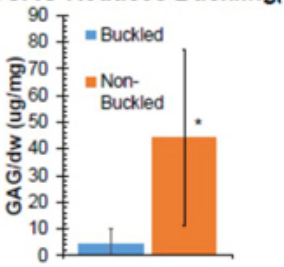
A) Axial compression videos show scaffold buckling in less developed tissue resulting in areas of high axial strain. Arrows indicate buckled scaffolds.
B) More developed constructs resist scaffold buckling and results in areas of high axial strain at or near construct surface.

Scan for Videos

High Shear Strain Occurs at Buckling Locations or Construct Surface



sGAG Reduces Buckling



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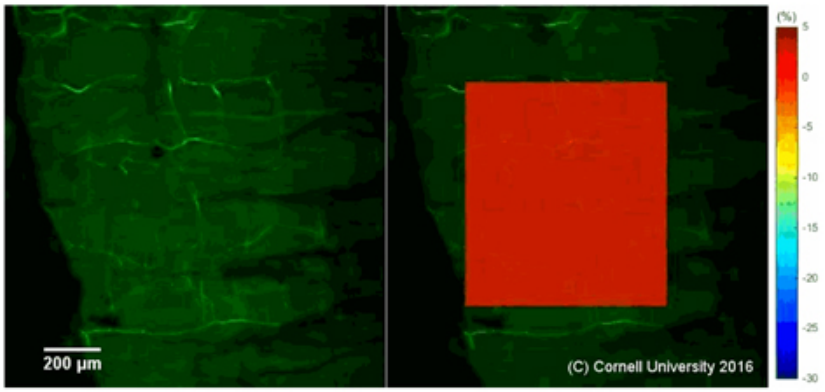
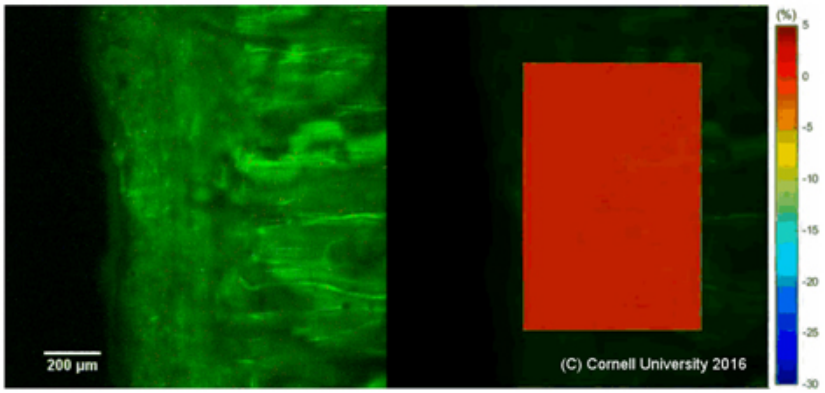
NeoCart Micromechanics

- Confocal elastography provides key insights into the maturation mechanism of NeoCart
  - Compression of early stage constructs with minimal fill causes buckling in scaffold pores
  - After in vitro cultivation new matrix deposition reinforces pores and prevents buckling
- Novel mechanical analysis technique provides new framework for QA/QC
  - Replaces arbitrary target with observation with clear transition in mechanical behavior
  - Amenable to correlation with non-destructive, in-line imaging

1 Week



7 Weeks



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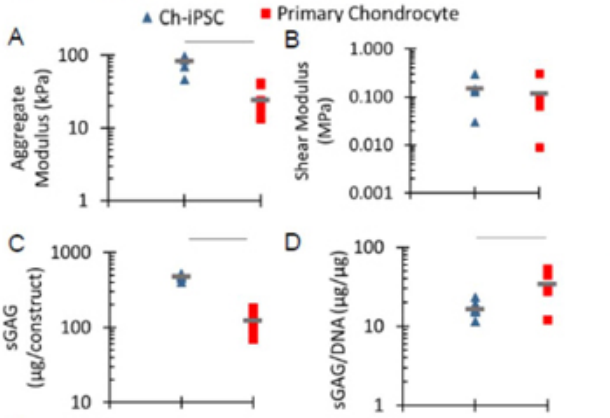
Mechanical Characteristics of Cartilage Produced from Induced Pluripotent Stem Cells (iPSC's)

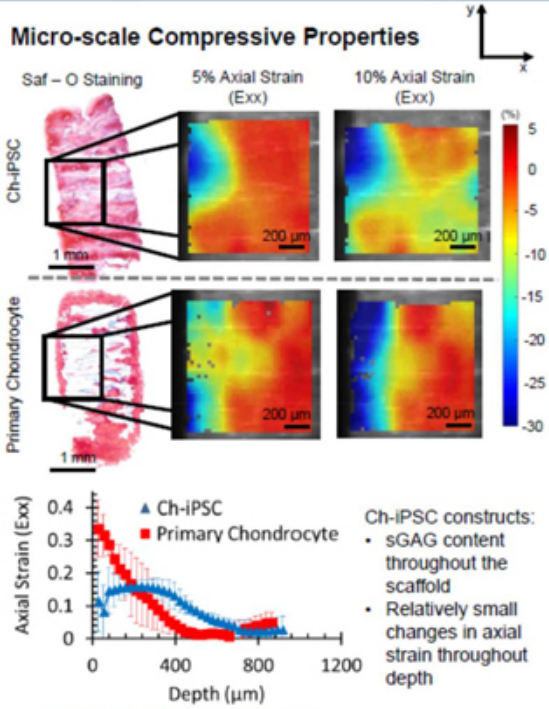
Cartilage tissue generated using iPS cells with similar mechanical properties as that of tissue produced using native chondrocytes

Macro-scale Properties of iPSC form Chondrocytes and Primary Chondrocyte Constructs



A) Aggregate Modulus was not affected by cell type
B) Shear modulus was not affected by cell type
C)Total sGAG content was influenced by cell type
D) sGAG per DNA was affected by the cell type
E) Friction did not change based on cell type
(N = 8, bars indicate $p < 0.05$)

Micro-scale Compressive Properties



Ch-iPSC constructs:
- sGAG content throughout the scaffold
- Relatively small changes in axial strain throughout depth

Primary chondrocyte constructs:
- sGAG content concentrated on the edges of the scaffold with less sGAG content near middle of constructs
- High axial strain at construct surface (N = 4)

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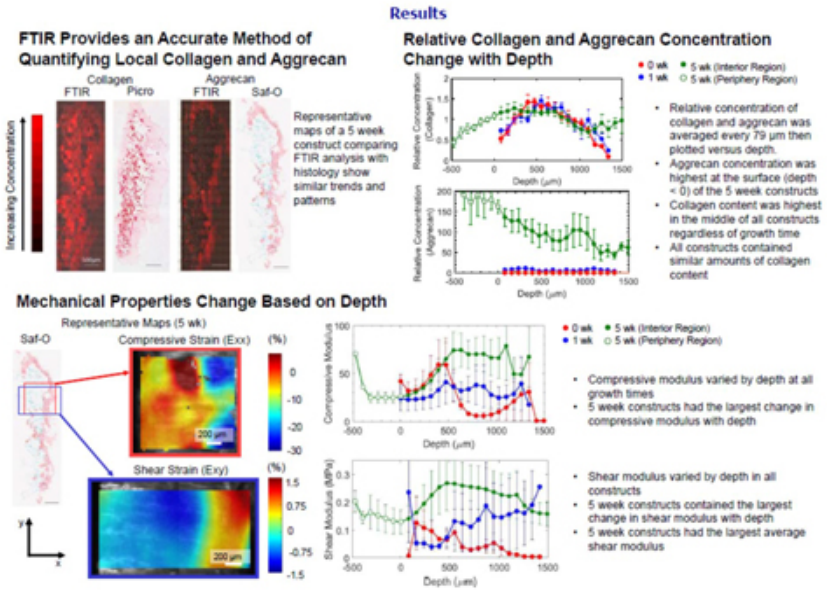
Next Steps

Utilizing biochemical and biomechanical test methods for NeoCart characterization in BLA filing, per FDA Guidance

- Developing non-invasive methods for in-process monitoring
- Applying techniques in Advanced Regenerative Manufacturing Institute (ARMI) partnership to ligament, bone and nerve tissues, with partners



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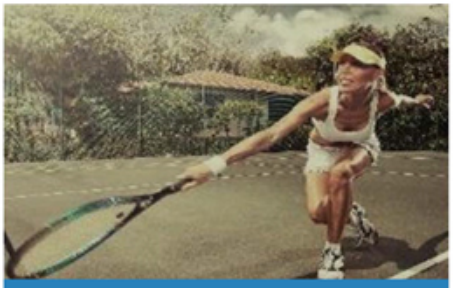
Potential NeoCart Launch and Market Access Discussion

NeoCart – The New Standard of Care vs. Microfracture

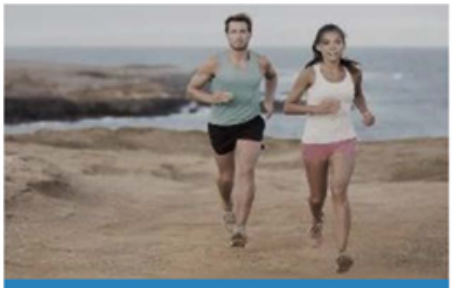


Potential Patient Benefits and Outcomes

- Pain relief and return to function in typically ½ the time
- Better QOL, improved productivity
- Fewer rehab and recovery days
- Excellent safety profile
- Early pain relief may result in less use of pain medication

Potential Physician Benefits

- Robust clinical data - 1-year superiority endpoint
- Functional tissue at the time of implantation
- Uncomplicated 30-minute procedure
- No special surgical training required
- Happy patients build practices



Potential Payer Cost Effectiveness

- Lower overall total cost of care
- Less costly rehab
- Less use of opioids and faster return to work
- Delay and prevent OA progression and total knee replacement
- Fewer re-ops (30% failure rate of microfracture)

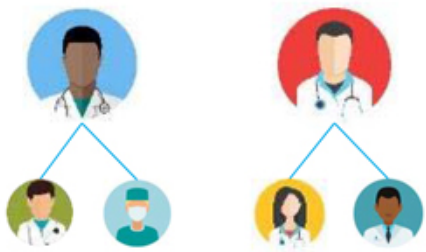
"Get Your Life Back!"

A Focused Launch Plan

Year One Objectives

- Establish a core of high-volume customers with deep knowledge of NeoCart
- Develop a core body of knowledge around product use in the market
- Institute strong training, and certification program
- Establish a solid platform for logistics, and service
- Build a foundation with payers
- Lay the groundwork for significant growth in years 2 and 3

Focused Launch



Clinical Partners and associated surgeons (<90)

Surgeons, staff and institutions already have experience with NeoCart

Minimal training requirement

Commercial Execution Priorities

Surgeon Selection

- High volume per surgeon
- Experienced with product
- Institutional experience with process

Market Access

- Carve-out code
- Benefit decisions with key insurers
- Limited requirements for prior treatment

Customer Service

- Easy
- Reliable
- Focused on supporting practice operations

Medical Affairs Team Built Strong Relationships in Clinical Trials

Surgeons Value the NeoCart Partnership

- Grow their practice with innovative products
- Help them differentiate against their peers and attract more patients
- Happy patients bring additional patients to their practice – "everyone has or knows someone with knee pain!"

Joseph Guettler, MD

Deryk Jones, MD

Scott Hacker, MD

Robert Grumet, MD

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Initial U.S. Commercialization Targets

- Phase 3 clinical sites amongst the highest volume sites
- Initial focus of sales force: physicians already experienced with NeoCart patient benefits and ease of use
- Total of 87 physicians at these sites seeing approximately 1,300 patients per month

We Can Potentially Use Existing Codes for ACI

Existing codes are applicable to NeoCart (partial list)

Code System	Code	Description[3]
HCPCS	J7330	Autologous cultured chondrocytes, implant
CPT	S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)
CPT	27412	Autologous chondrocyte implantation, knee

- Focus on small number of surgeons enables laser focus on only the most impactful payers in the first year
- Orderly progression for following years
- Helps to build the foundation for strong growth in years two and beyond

Most Insurers Already Cover ACI (representative list)

Coverage Requirements Generally Not Restrictive

Age:	Generally adults under the age of 55
Size:	Varies, most have minimum of 1.5 cm2 – 2 cm2
Location:	Most include femoral condyle only (medial, lateral, trochlea)
Grade:	Full-thickness (grade III or IV)
Prior Treatment:	Varies • All require failure of conservative treatment • Many require failure of prior surgical treatment (including debridement) • Some require failure of microfracture or other procedure
Common Exclusions:	• Osteoarthritis • Lesions of the patella • Kissing lesions • Total meniscectomy

Customer Service Will Largely Be Outsourced To Tier 1 Partners

Multiple Well Established Vendors for Customer Service

Pre-authorization

Patient Support

Reimbursement & Appeals Support

Scheduling & Process Transparency

Logistics & Distribution

Practice Management Will Be Run In-house

Practice Management

- Local specialized clinical recruiting/marketing was a critical component of our trial enrollment success
- Become a business partner to help grow practices
- Drive interested patients to certified NeoCart providers

Working Together To Build A Platform For Growth

Medical Affairs

MSL's

- Inform, create interest
- Train
- Certify
- Some case coverage initially

- No ownership of accounts

Commercial

Account Execs

- Institutional bureaucracy
- Contracting
- Occasional case coverage
- Coordination of service elements
- Practice management

- Ownership of accounts

3rd Party Service

- Pre-authorization
- Logistics and scheduling
- Appeal assistance
- Patient support

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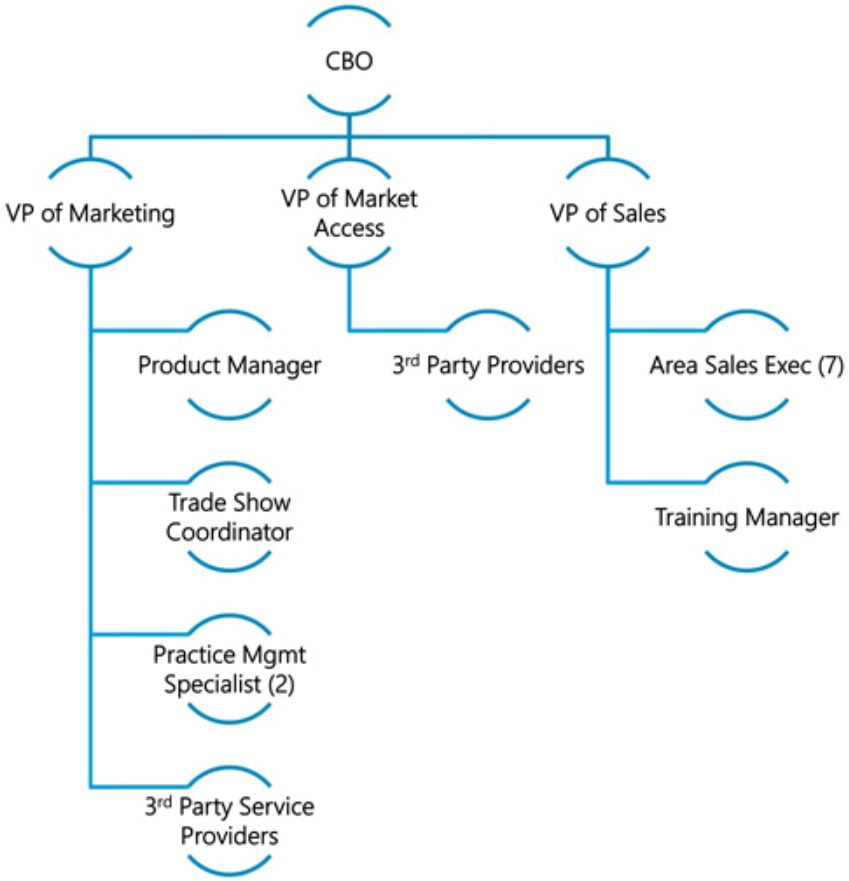
Anticipated Year 1 Commercial Organization



Years 2 and 3 Expect:

- Additional sales reps
- Additional sales management
- National accounts
- Additional marketing

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Our Commercial Plan

- The New Standard of Care for Cartilage Lesions
- Real Tissue to Get Your Life Back
- Partner with Medical Affairs in a Focused Launch Year 1
- Customer Selection, Market Access, Customer Service

Pipeline and Financials

Technology Platform Supports Long Term Strategy to Build Value

- Maximize U.S. NeoCart Opportunity
- Leverage Histogenics' Technology Platform
- Continue to Develop Manufacturing Capabilities and Build Out Manufacturing Capacity

Strong Competitive Position

Regulatory pathway creates complex barrier to competition

- BLA pathway and SPA
- Phase 2 demonstrated 1-year superiority leading to Phase 3 trial design

Robust intellectual property

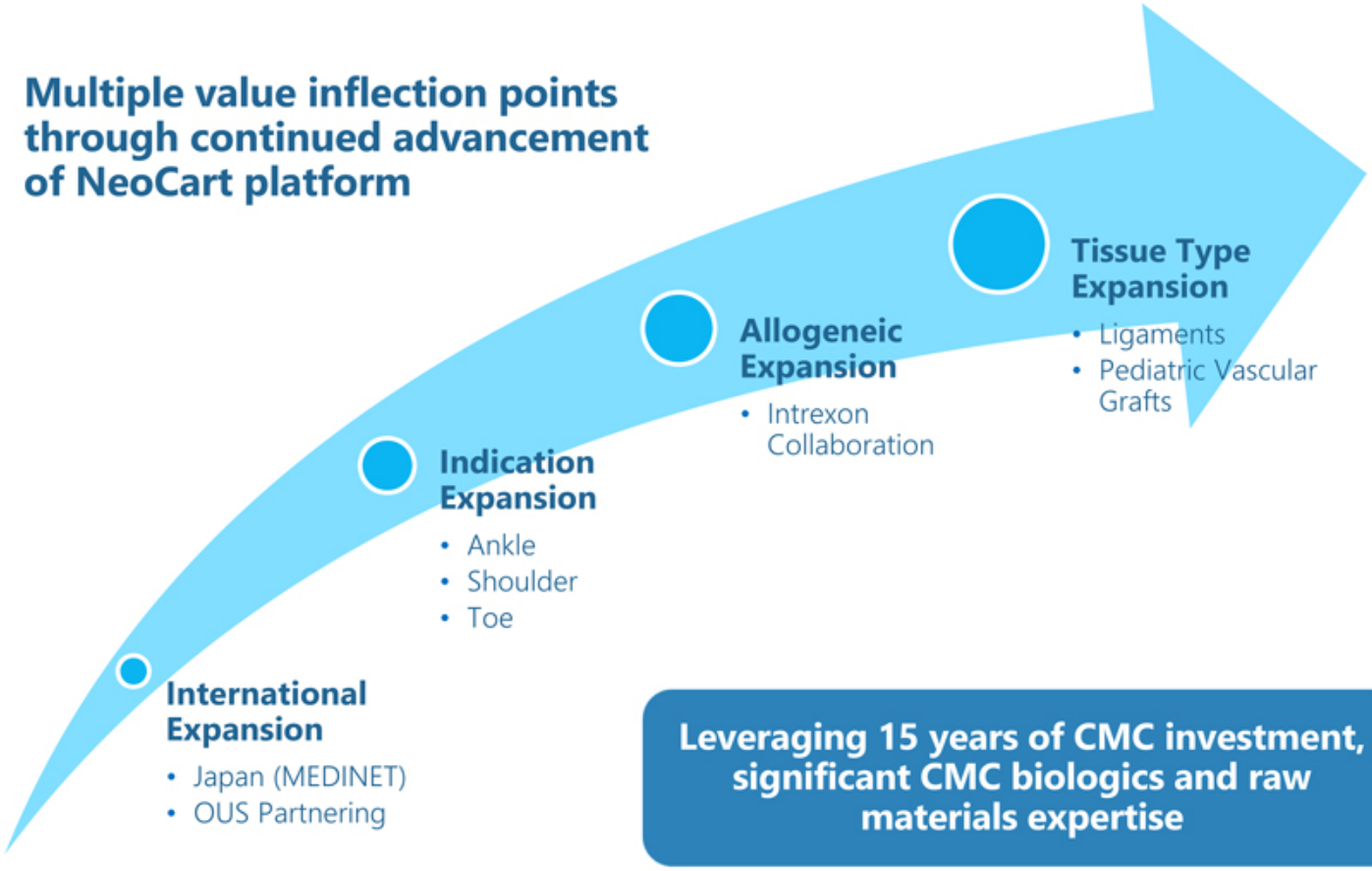
- More than 85 global and 45 U.S. owned and licensed patents covering cell culture, bioreactors and materials; provide broad coverage for methods in cartilage production and tissue sciences
- Coverage through 2031

cGMP manufacturing process and facility

- Autologous process; no generic substitute
- In-house manufacturing of raw materials results in greater control and enables potential improvements in gross margin

Multiple Opportunities for Value Creation

Multiple value inflection points through continued advancement of NeoCart platform



Leveraging 15 years of CMC investment, significant CMC biologics and raw materials expertise

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Leveraging the RCT Platform

$87M partnership for Japan commercialization and development rights completed in December 2017

- $10M up-front payment; up to ~$77M in additional milestones
- 30 Patient Ph3 bridging study begins in H2:18 leading to potential launch in 2021
- Large market with reimbursement in place at ~$20,000 USD
- Tiered royalties rising to low double digits with increasing annual sales

MEDI NET

Exploring additional International partnerships (e.g. China, Korea)

Research collaborations with leading universities and institutions

- NeoCart BLA support
- Manufacturing initiatives to reduce COGs including 3-D tissue printing and optical testing
- Additional product opportunities in soft tissues, bones and nerves

* Source: Histogenics primary market research with Japanese orthopedic surgeons (n=80)

World-Class Advisory Board and Academic Collaborations

Dr. Shuichi Mizuno: Assistant Professor, Orthopedic Surgery, Harvard University /Brigham Women's (Histogenics Technical Founder), ongoing collaborations for HA / Col Gel Formulations

Dr. Lane Smith: Department of Orthopedic Surgery, Stanford University. Decades of cartilage research experience, Licensed Patents

Dr. Kerry Athanasiou: UC Irvine, Distinguished Professor BioMedical Engineering, Orthopedic Surgery

Dr. Charles Cooney: MIT Professor of Chemical Engineering (Emeritus). Board of Directors at Genzyme, Focus on Biopharmaceutical Manufacturing, Carticel experience, Biologics including original process engineering work with Genentech

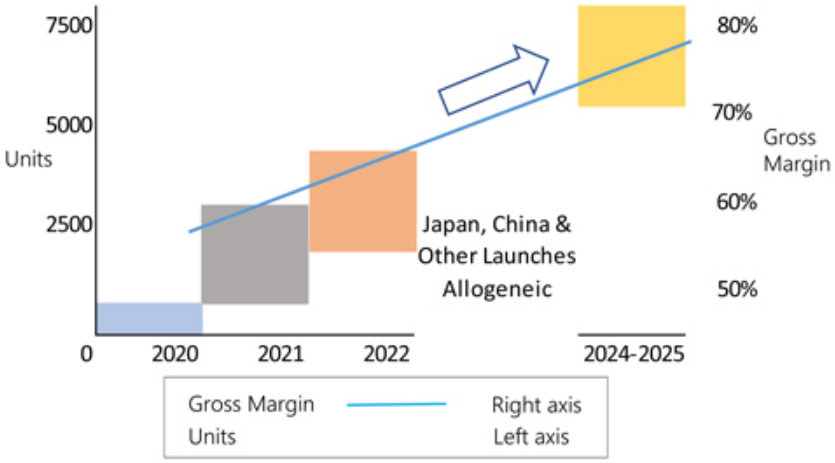
Dr. Lonnie Shea: University of Michigan Department of BioMedical Engineering. Department Chair. Working at intersection of scaffolds and biologics, including regeneration of axons, donor islet cells.

Dr. Jennifer Elisseeff: Johns Hopkins Department of Biomedical Engineering – Cartilage regeneration, hydrogels, stem cells, Industry friendly, founder of several companies

Dr. Lawrence Bonassar: Cornell University Meinig School of Biomedical Engineering and Sibley School of Mechanical and Aerospace Engineering, leader in cartilage biomechanics and tissue engineering, ongoing collaborations for biomechanical testing of NeoCart

Academic Collaborations

NeoCart Growth Opportunity & Key Financial Metrics



	Oppty for Cost Reduction
Rent and Volume	Manufacture in lower cost env; significant reduction in COGs
Automation	Reduction in labor and testing costs
New Mfg. Technologies	Multi-unit Tep (lower COGs and ability to scale); optical QC testing
Raw Materials	Bringing remaining raw materials in-house
Allogeneic Product	Likely necessary to get to more than 10k NeoCarts/year and to increase margins > 80%

- Key Market Metrics
  - >1M patients with cartilage defects WW
  - Multi-billion dollar market opportunity
  - ~$40K price point (based on publicly available competitor information)

- Key Financial Metrics
  - Cash runway into Q4:18
  - ~28.7M primary shares o/s; ~45.5M FD
  - Cash and mktbl securities @ 3/31/18: ~$15.5M

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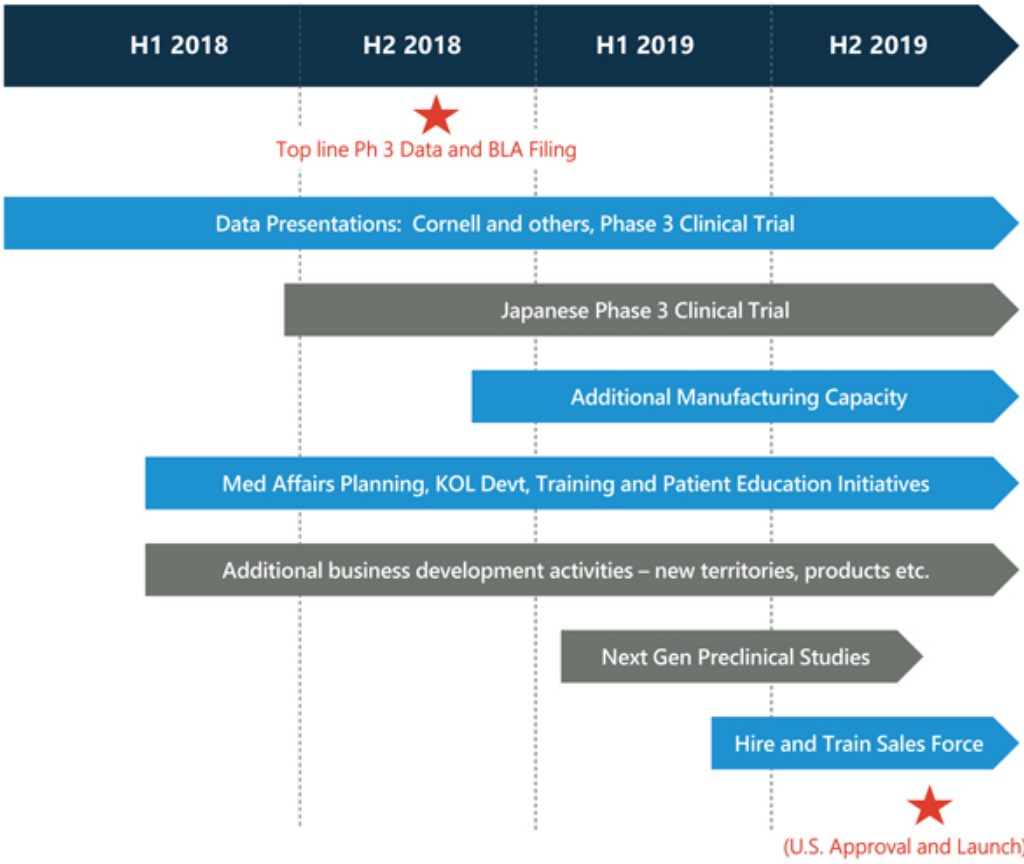
Conclusion

Progress on the Path to Commercialization and Launch

Completed:

- ✓ FDA raw materials approved – collagen and scaffold
- ✓ Acquisition of Japanese NeoCart product rights
- ✓ Publication of Phase 2 MRI and clinical outcomes data
- ✓ Publication of NeoCart mechanical data
- ✓ Japanese regulatory pathway established
- ✓ NeoCart Phase 3 trial fully enrolled
- ✓ NeoCart Japanese licensing agreement



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The Histogenics Value Proposition

- Powerful, proprietary platform that provides restorative cell therapies (RCTs) for active living
- Lead product candidate, NeoCart® is a proprietary RCT that potentially rebuilds patients' own knee cartilage, reducing pain at the source and potentially preventing progression to osteoarthritis (OA)
- Large market opportunity to treat knee cartilage damage
- Phase 3 enrollment complete; data in Q3:18. Near-term value creation opportunity with possible U.S. launch of NeoCart in 2019
- Planned expansion of NeoCart platform into additional markets and indications

Thank you for participating today. A copy of this presentation will be added to our website shortly.

If you have additional questions, please email investorrelations@histogenics.com

References & Supporting Information

1. D Crawford MD, PhD, RJ Williams III, MD, TM DeBerardino MD – *NeoCart, an Autologous Cartilage Tissue Implant, Compared to Microfracture for Treatment of Distal Femoral Cartilage Lesions. An FDA Phase 2 Prospective, Randomized Clinical Trial after two Years.* J Bone Joint Surg Am. 012;94:979-89.

2. D Crawford MD, PhD, DE Anderson, PhD, RJ. Williams III, MD, TM DeBerardino, MD, DC Taylor, MD, CB Ma, MD, and M Kane, MS - *Magnetic Resonance Imaging Characterization and Clinical Outcomes After NeoCart Surgical Therapy as a Primary Reparative Treatment for Knee Cartilage Injuries,* American Journal of Sports Medicine AJSM Vol. 45, No. 4, p 875-883

3. DC Crawford MD, PhD, CM Heveran, WD Cannon Jr, MD, LF Foo, MD, and HG P, MD – *An Autologous Cartilage Tissue Implant NeoCart for Treatment of Grade III Chondral Injury to the Distal Femur Prospective Clinical Safety Trial at 2 Years*

4. *Maturation of Human Tissue Engineered Constructs Improves GAG Content and Fibrous Matrix Stability* - JM Middendorf, S Shortkroff, C Dugopolski, S Kennedy, J Siemiatkoski, L Bartell, I Cohen, LJ Bonassar.

5. *Mechanical Characterization of Autologous Chondrocyte Seeded Matrix Grafts After In Vitro Growth* – JM Middendorf, D Griffin, S Kennedy, S Shortkroff, C Dugopolski, J Siemiatkoski, L Bartell, I Cohen, LJ Bonassar