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): September 5, 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.

On September 5, 2018, management of Histogenics Corporation ("Histogenics") will hold a conference call and webcast at 8:30 a.m. ET to discuss the top-line results from its NeoCart Phase 3 clinical trial. A copy of the presentation being used in connection with this conference call is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

The information included in this Current Report on Form 8-K pursuant to Item 7.01, including Exhibit 99.1 attached hereto, is intended to be furnished and 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 filing.

Item 8.01. Other Events.

On September 5, 2018, Histogenics issued a press release announcing top-line results from the Phase 3 clinical trial of NeoCart.

A copy of Histogenics' press release is attached hereto as Exhibit 99.2 and is hereby incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Presentation of Histogenics Corporation dated September 5, 2018.
99.2	Press Release of Histogenics Corporation dated September 5, 2018.

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: September 5, 2018

HISTOGENICS CORPORATION

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

Exhibit 99.1

Histogenics

NeoCart Phase 3 Clinical Trial Results Call

September 5, 2018

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: NeoCart's potential as a treatment for knee cartilage damage; expectations regarding the timing and success of discussions with the FDA regarding the submission of a biologics license application for NeoCart; the timing, associated expenses and ability to obtain and maintain regulatory approval of NeoCart or any product candidates, and the labeling for any approved products; the market size and potential patient population in markets where we and our partners expect to compete; updated or refined data based on our continuing review and quality control analysis of clinical data; the scope, progress, timing, expansion, and costs of developing and commercializing our product candidates; the ability to obtain and maintain regulatory approval regarding the comparability of critical NeoCart raw materials following its technology transfer and manufacturing location transition; our expectations regarding its expenses and revenue; our ability to obtain additional debt or equity capital; 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 June 30, 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.

Agenda

1. Executive Summary
2. History – Regulatory Guidance and Clinical Trial Design, Comparators & Current Standards
3. Phase 3 Clinical Trial Design & Demographics
4. Overview of Dual Threshold Responder Analysis
5. Dual Threshold Data Review
6. Current FDA Guidelines for Clinical Trials
7. Current Guidelines Data Review
8. Conclusion & Next Steps

Summary of NeoCart Phase 3 Clinical Trial Results

1. NeoCart demonstrated clinically meaningful improvement at 1 year vs. microfracture on highest hurdle, dual-threshold endpoint. The trial narrowly missed statistical significance and did not meet the primary endpoint by 2 microfracture responders in the mITT population (one sided test: *p=0.025).
   - 62% of NeoCart patients were responders at 6 months vs 46% of microfracture (*p=0.0188).
   - 74% of NeoCart patients were responders at 1 year vs 62% of microfracture (p=0.0714).
   - Based on current MCID on IKDC for example, NeoCart demonstrated statistically significantly superiority.
2. NeoCart demonstrated statistically significant results compared to microfracture at 1 year on KOOS and IKDC endpoints, as established in FDA Guidance & used in ongoing clinical trials conducted by third parties. It also demonstrated superiority at 2 years based on only ~120 patients (visits pending for rest).
3. NeoCart performed better than expected, demonstrating early and sustained clinically meaningful improvements at 1 year and 2 years.
   - However, microfracture did better than expected in what we believe is the most robust study conducted to date under current FDA guidance in a population intended to maximize its performance (low BMI, most appropriate lesion size and strict rehabilitation program).
4. Risk / benefit believed to be established, safety between arms was comparable.
5. Based on totality of data and published FDA guidelines, we believe NeoCart should be acceptable for review and potential approval. We intend to confirm this with the FDA via a Type A Meeting.

History of Cartilage Repair Trials & Microfracture

Perspective – Regulatory History & Approved / Cleared Products:

- 1997 Carticel (Genzyme) approved – initially "361 Product" regulated, changed to BLA
- 1997 to 2011 – physicians, industry & FDA (CBER/CDRH) work to define endpoints, comparators, I/E criteria
- December 2011 guidance issued by FDA (superiority, pain/function endpoints, microfracture control)
- 2016 MACI (Vericel) approved – 2 year endpoints, 144 patient study done in EU

Microfracture History - Variable and Challenging Standard of Care:

- The procedure was developed in the early 1990s by Dr. Steadman of the Steadman-Hawkins Clinic/Vail
- Initial excitement, now less so due to variability of results & poor durability
- Microfracture results are highly dependent on lesion size, BMI, age, and rehabilitation protocol
- Surgeons have lobbied to eliminate microfracture as surgical control, but few other options available

NeoCart Phase 3 Background - Robust Dual Threshold Analysis Prior to Issuance of Current FDA Guidance:

- Phase 2 (2006 to 2008) informed Phase 3 design, SPA secured in 2009 due to lack of clarity on trials endpoints, other than microfracture control and superiority design using pain/function
- 2009 to 2010 – Initiated the largest prospectively enrolled trial to date, using highest hurdle endpoints

Other Third-Party Cartilage Therapies - Current Trial Designs:

- Since 2014, four products entered into knee cartilage trials in the U.S. (BLA & PMA's)
- KOOS Pain, Function and / or IKDC Scales used to show superiority (no dual threshold)
- One historical microfracture control arm allowed

NeoCart Phase 3 Clinical Trial Design & Demographics

Screening

Key Inclusion Criteria

- Age: 18-59
- Severe and symptomatic cartilage lesions (0.5-6cm^2)

Key Exclusion Criteria

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

n = 249

Randomization

Arm 1: NeoCart (n = 170)

Arm 2: Microfracture (n = 79)

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

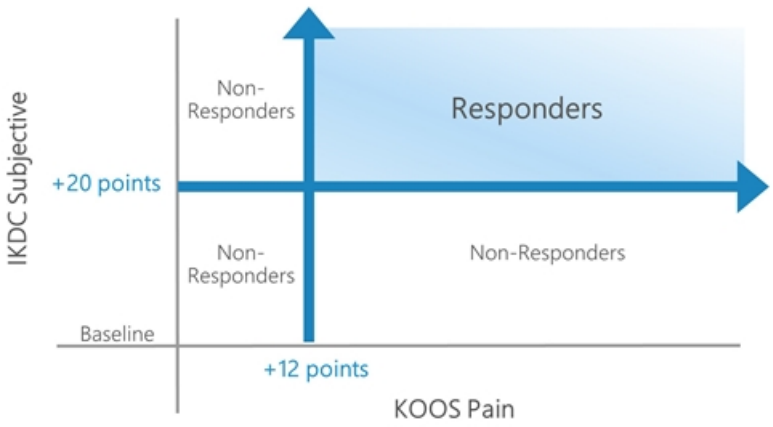
Key Demographics	NeoCart	Microfracture
Sex (Female/Male)	35% F / 65% M	39% F/ 61% M
Age	38.7	38.8
BMI	27.3	26.7
# of Lesions (1/2)	83%	89%
Lesion Size (Min/Max cm^2)	0.5 / 6	0.5 / 5.3
Lesion Size (Mean cm^2)	2.1	1.8
Mean KOOS Pain Score:	54.0	52.4
Mean IKDC Function Score:	40.3	40.0

Dual Threshold : Reasons for Its Use, Design & Impact

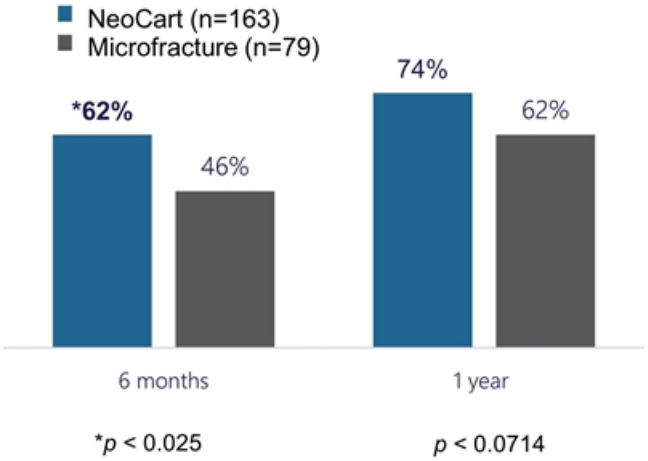
- Dual Threshold Responders typically used in Oncology or Cardiology to further demonstrate magnitudes of clinically relevant effects.
- When our trial was designed in 2009 (prior to FDA guidance released in 2011), it had been rarely used in Orthopedics, particularly with patient reported outcome endpoints.
- Initial thesis: true leveler design to modulate the tendency for patients to accommodate pain or loss of function. Goal is to show that each patient gets better on both scores vs. mean differences on individual scores.
- Minimum clinically important/meaningful differences or cut-off's have greater impact than in other designs – balance of specificity and sensitivity.

NeoCart Phase 3 Clinical Trial Preliminary Data (mITT Population)

Responder Analysis: Responses required on both Pain & Function (~15% delta needed)



Responder Analysis Results: 6 month data significant (early improvement) with 1 year data narrowly missing significance



- 1-year endpoint would have been statistically significant if two microfracture patients had not been responders
- Microfracture patients performed significantly better than expected, and better than in most previous published studies (62% response vs. 50% projected in statistical plan) and real world experience
- Clinicians in this trial requested current MCID analysis, which demonstrated superiority at 1 year

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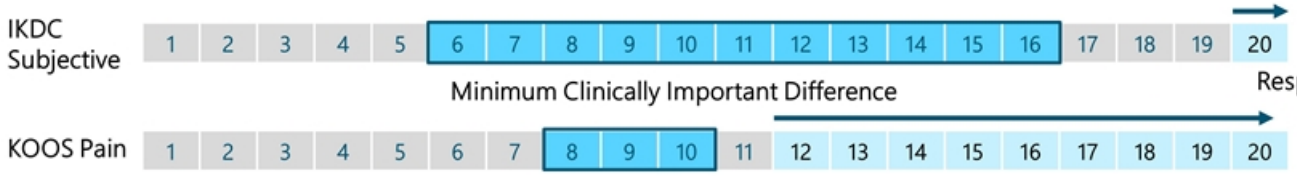
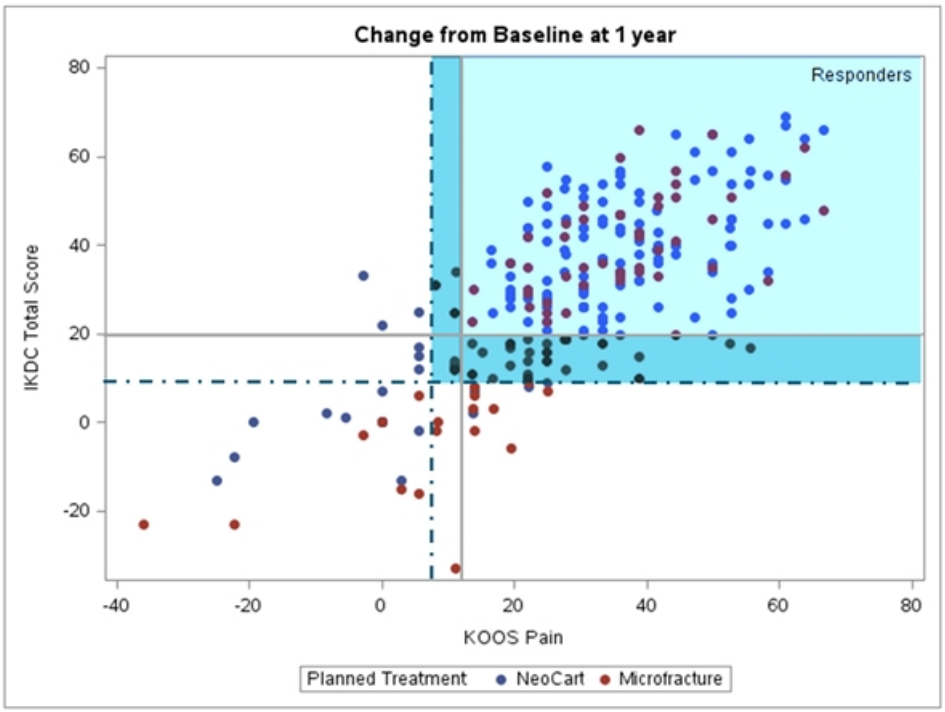
Phase 3 Clinical Trial Results Would Be Statistically Significant at 1 Year Using Current Clinical Guidelines for MCID





Existing Responder Analysis p=0.0714

MCID Sensitivity Analysis
**p=0.0082 to 0.0200*

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1-Year Dual Threshold Endpoint: Patient Populations & Observations

Patient Populations (all analyses on mITT):

	NeoCart (N=170)		Microfracture (N=79)		Change	
	Positive Responders	Responder Rate	Positive Responders	Responder Rate	Difference	p value:
Intent to Treat (ITT)	121/170	71.2%	49/79	62.0%	9.2	p=0.1877
Modified ITT (mITT)	121/163	74.2%	49/79	62.0%	12.2	P=0.0714
As Treated (AT)	120/162	74.1%	50/80	62.5%	11.6	p=0.0735
Per Protocol (PP)	118/155	76.1%	43/65	66.2%	10.0	p=0.1362

Other Important Responder Observations:

- In BMI >28: NeoCart 78% response rate vs 48% for microfracture (*p= 0.0168)
- In > 2.2 cm lesions: NeoCart 76% response rate vs 52% for microfracture (*p= 0.0145)
- In two lesions: NeoCart 85% response rate vs 43% for microfracture (p=0.0418)

Failure Observations (% of patients at 1 year with scores below baseline)

- IKDC: 2.5% for NeoCart; 12.7% for microfracture
- KOOS: 3.7% for NeoCart; 3.7% for microfracture
- BOTH: 1.2% for NeoCart; 3.8% for microfracture

Current Study Designs: What Endpoints are FDA Requiring Today?

- If we were designing a knee cartilage trial today?
  - KOOS Pain and/or IKDC function scales vs baseline, superiority vs microfracture
  - Statistically significant mean improvements required on one or both scales (individually)
  - Dual threshold responder not required
  - 2 year endpoints employed, 3 year follow up (1 year being unique and difficult to achieve)
  - Same inclusion / exclusion criteria – more balanced evaluation of microfracture in a more limited population

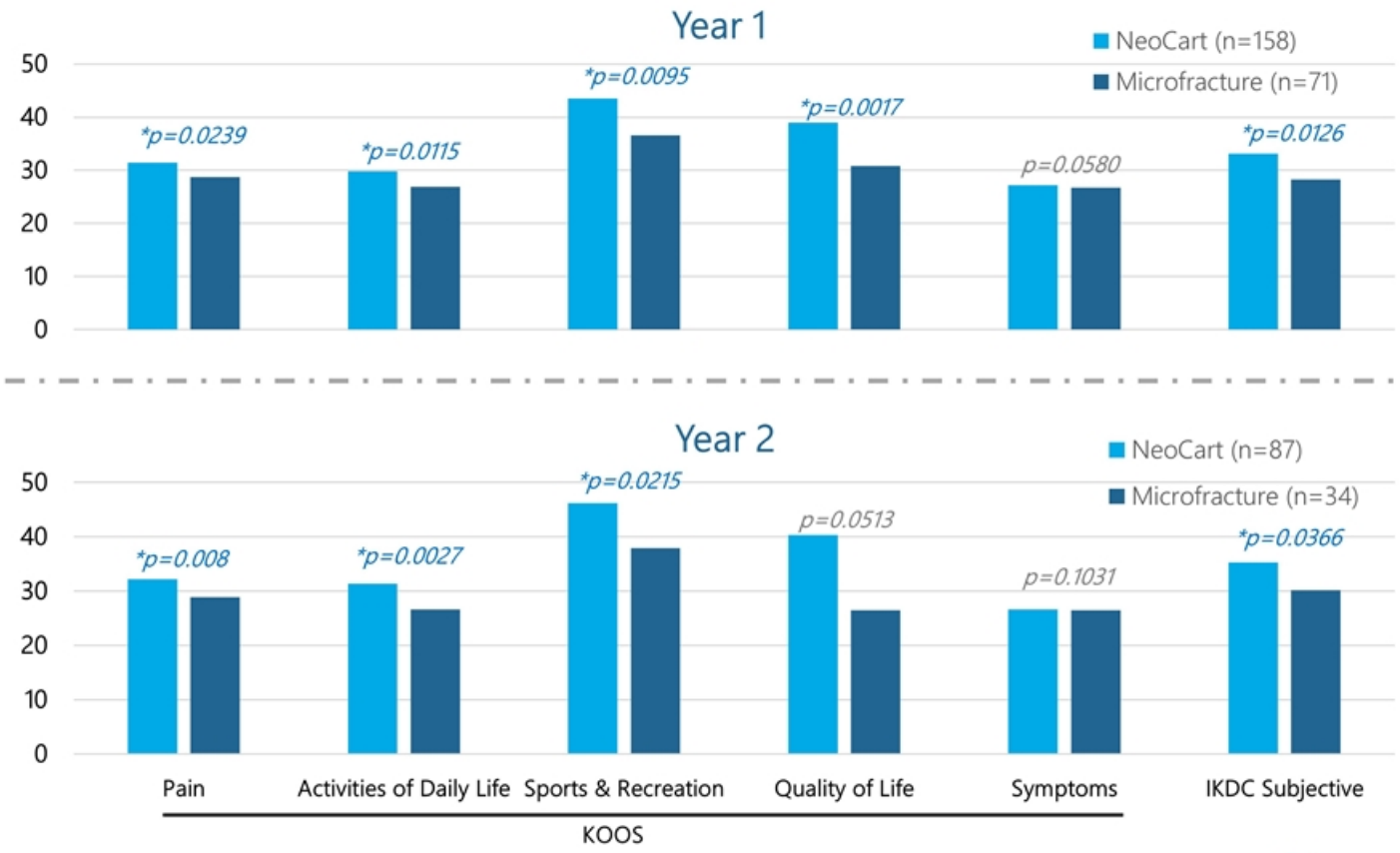
- Using current criteria, how would Phase 3 NeoCart trial have done?

- NeoCart would have demonstrated statistically significant results vs microfracture on relevant IKDC & KOOS scales/endpoints at 1 year & 2 years
  - KOOS Pain – 1 year & 2 years (p=.024 and .008)
  - IKDC Subjective (Pain/Function) – 1 year & 2 years (p=.013 and .037)
  - Note 2 year data only includes ~120 patients (remainder of visits outstanding)

Note: The discussion in this presentation of how NeoCart hypothetically would have performed against endpoints other than those included in its Phase 3 clinical trial are for illustrative purposes only and do not impact or change the outcome of the Phase 3 clinical trial and NeoCart's performance against its endpoints

Clinically Relevant and Statistically Significant Improvement on Most Subscales at 1 and 2 Years

Pain & Function Patient Reported Outcomes (KOOS & IKDC) – Change from Baseline



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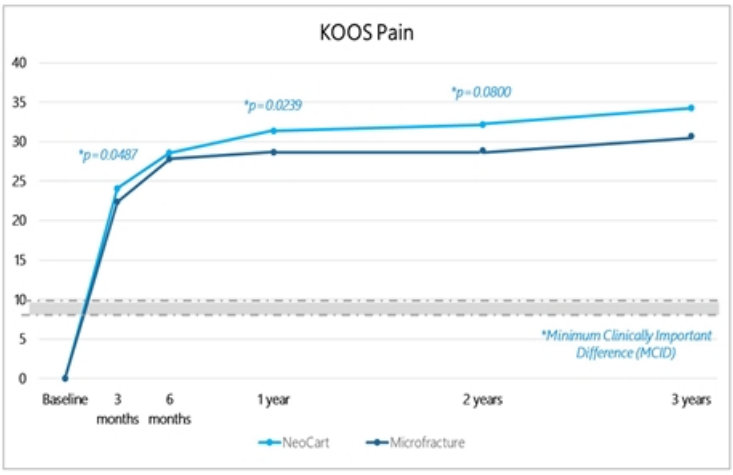
Current FDA Endpoints: KOOS Pain

KOOS pain score (mITT Population)
Change from Baseline
(NeoCart Baseline = 54.0; Microfracture Baseline = 52.4)

	NeoCart		Microfracture		
Visit	N	Mean Improvement	N	Mean Improvement	P-Value
3-months	160	24.1	75	22.4	0.0487
6-months	157	28.6	75	27.0	0.0819
1-year	158	31.4	72	28.7	0.0239
2-years	87	32.2	34	28.9	0.0080
3-years	39	34.3	16	30.7	0.1071



- KOOS Pain is one of several measures used to demonstrate superiority vs baseline, and control arm in ongoing clinical trials for cartilage knee repair

- NeoCart would have demonstrated clinically meaningful improvements in KOOS pain as early as 3 months and sustained through two years with statistical significance

Note: The discussion in this presentation of how NeoCart hypothetically would have performed against endpoints other than those included in its Phase 3 clinical trial are for illustrative purposes only and do not impact or change the outcome of the Phase 3 clinical trial and NeoCart's performance against its endpoints

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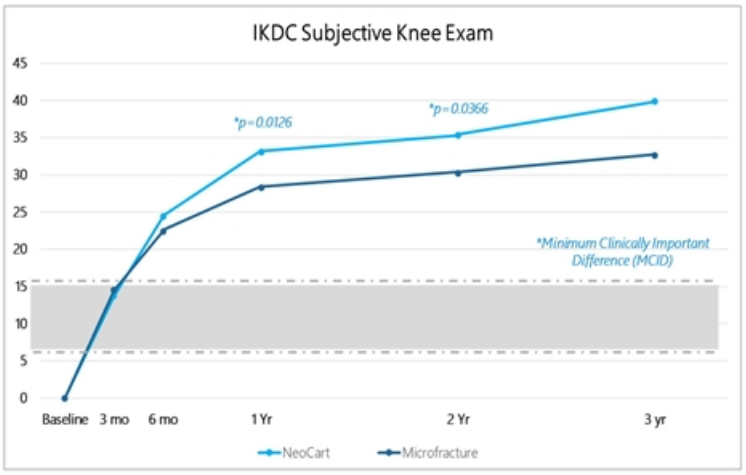
Current FDA Endpoints: IKDC Function/Pain

IKDC subjective knee exam score (mITT Population)
Change from Baseline
(NeoCart Baseline = 40.3; Microfracture Baseline = 40.0)

	NeoCart		Microfracture		
Visit	N	Mean Improvement	N	Mean Improvement	P-Value
3-months	159	13.7	76	14.5	0.9686
6-months	156	24.4	74	22.4	0.1572
1-year	158	33.1	71	28.3	0.0126
2-years	87	35.3	34	30.2	0.0366
3-years	38	39.9	16	32.6	0.2691



- IKDC Pain / Function is used to demonstrate superiority vs baseline, and control arm in ongoing clinical trials for cartilage knee repair
- NeoCart would have demonstrated clinically meaningful improvement in IKDC Subjective Pain / Function as early as 6 months and sustained through two years (statistically significant at one and two years)

Note: The discussion in this presentation of how NeoCart hypothetically would have performed against endpoints other than those included in its Phase 3 clinical trial are for illustrative purposes only and do not impact or change the outcome of the Phase 3 clinical trial and NeoCart's performance against its endpoints

Key Conclusions & Next Steps

- Based on the totality of the data at 6 months, 1 year, and 2 years, we believe NeoCart has demonstrated superior clinically meaningful results.
- Risk / Benefits: Safety profile of NeoCart was comparable, with data that were superior to standard of care.
- Clinicians who have used NeoCart believe this product could be a market leading therapy, if approved.
- We are requesting meeting with FDA to discuss our BLA filing strategy, and if granted, would expect feedback in October 2018.
- Based on expert feedback, we believe the data supports FDA review & potential FDA approval, without considerable impact to timelines.
- Assuming BLA filed & accepted, targeting early 2020 NeoCart launch, if approved.

References & Supporting Information

Select Publications

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

Current U.S. Clinical Trials (www.clinicaltrials.gov)

NOVOCART® 3D for Treatment of Articular Cartilage of the Knee (N3D) https://clinicaltrials.gov/ct2/show/NCT01957722
HyaloFAST Trial for Repair of Articular Cartilage in the Knee (FastTRACK) https://clinicaltrials.gov/ct2/show/NCT02659215
Pivotal Study to Evaluate the Safety & Efficacy of GelrinC for Treatment of Cartilage Defects (SAGE)
https://clinicaltrials.gov/ct2/show/NCT03262909
Agili-C™ Implant Performance Evaluation https://clinicaltrials.gov/ct2/show/NCT02423629

Definitions: *Knee injury and osteoarthritis outcome score (KOOS): International Knee Documentation Committee (IKDC), Minimum Clinically Important Difference (MCID); Body Mass Index (BMI); Premarket Approval (PMA); Biologics License Application (BLA); U.S. Food & Drug Administration (FDA)*

HISTOGENICS ANNOUNCES TOP-LINE RESULTS FROM PHASE 3 CLINICAL TRIAL OF NEOCART® IN PATIENTS WITH KNEE CARTILAGE DAMAGE

– Phase 3 Clinical Trial of NeoCart Did Not Meet Primary Endpoint of a Statistically Significant Improvement in Pain and Function in a Dual Threshold Responder Analysis One Year After Treatment as Compared to Microfracture –
– NeoCart Demonstrated Statistically Significant and Clinically Meaningful Improvements on Dual Threshold Responder Analysis Six Months After Treatment and Nearly All Pain and Function Measures Compared to Microfracture One and Two Years After Treatment –
– Data Compared Favorably to Other Products on the Market or in Development Per Guidance from the U. S. Food and Drug Administration –
– Company to Discuss Plans for Submission of Biologics License Application with U.S. Food and Drug Administration –
– Company to Host Conference Call and Webcast Today at 8:30 a.m. ET –

WALTHAM, Mass., September 5, 2018 /GLOBE NEWSWIRE/ – Histogenics Corporation (Histogenics) (Nasdaq: HSGX), a leader in the development of restorative cell therapies that may offer rapid-onset pain relief and restored function, today announced that its Phase 3 clinical trial of NeoCart did not meet the primary endpoint of a statistically significant improvement in pain and function in a dual threshold responder analysis one year after treatment as compared to microfracture. In the modified Intent to Treat (mITT) population (which excludes those patients who were randomized but not treated with NeoCart), 74.2% of the NeoCart patients exhibited clinically meaningful improvements in pain and function compared to 62.0% of microfracture patients at one year (p=0.071). However, in this mITT population, patients treated with NeoCart achieved a statistically significant improvement in pain and function (p=0.018) six months after treatment as compared to patients treated with microfracture. Both NeoCart and microfracture were well tolerated and exhibited strong safety profiles.

“Based on the totality of the data generated in the Phase 3 clinical trial, we continue to believe in NeoCart’s potential as a treatment for knee cartilage damage. When we designed our Phase 3 clinical trial in 2009, we set a very high clinical bar for NeoCart and narrowly missed hitting the trial’s primary endpoint with statistical significance by only two microfracture responders out of the 249 patients that participated in the trial. While the NeoCart treatment group exhibited a response as early as three months after treatment that continued through two years, the microfracture response rate was better than expected, which impacted the statistics. We are encouraged by the results and believe we have a meaningfully differentiated product that, if approved, can compete effectively and provide physicians and patients with a beneficial treatment option that may grow the market,” said Adam Gridley, President and Chief Executive Officer of Histogenics. “We continue to analyze the data and are in the process of scheduling a meeting with the FDA to discuss the results and prepare for a potential submission of a biologics license application for NeoCart. We wish to acknowledge and thank the patients and investigators who participated in the trial and shared their positive experiences with NeoCart,” stated Mr. Gridley.

The NeoCart Phase 3 clinical trial is believed to be the largest and first prospectively designed, randomized clinical trial in North America evaluating the safety and efficacy of a restorative cell therapy to treat knee cartilage damage. It is also believed to be the only trial with a dual threshold responder analysis endpoint.

As part of the prospective data analysis, Histogenics collected a variety of patient reported outcome endpoints, including all measures of the Knee Injury and Osteoarthritis Outcomes Score (KOOS) and the International Knee Documentation Committee (IKDC) score, which are validated, patient-centered assessments of pain and function that are commonly used in current clinical trials of cartilage therapies. On all but one of these measures, two of which are being utilized as primary endpoints in ongoing clinical trials by third parties in the U.S. for other therapies, NeoCart demonstrated statistically significant superiority versus microfracture at one and two years.

The Phase 3 clinical trial is the first study prospectively enrolled consistent with current U.S. Food and Drug Administration (FDA) guidance, which provides for the use of microfracture as a comparator treatment in trials to repair knee cartilage damage. The published FDA guidance also specifically calls for a study population that, given the clinical limitations and variable results of microfracture, we believe provides more favorable results than what is typically seen in microfracture in both the literature and a real-world setting.

“We are pleased with the overall performance of NeoCart in this Phase 3 clinical trial and the data confirm the feedback we have received from several of the investigators who participated in the trial. Most importantly, patients treated with NeoCart displayed an early and sustained recovery from pain and return to function that was clinically meaningful. The data from this trial are also consistent with results seen in prior clinical trials of NeoCart as well as the biomechanical data generated as part of our collaboration with Cornell University,” said Lynne Kelley, M.D., Chief Medical Officer of Histogenics. “While we are continuing to analyze the data, we have already seen a number of important results, including a statistically significant improvement of NeoCart compared to microfracture in lesion sizes of greater than 2 cm and patients with higher body mass index. We think that results such as these will be an important part of our planned discussions with the FDA, as well as with clinicians if NeoCart is approved,” continued Dr. Kelley.

There are approximately 1.2 million arthroscopic procedures conducted each year to treat knee cartilage defects in the U.S., with less than half of eligible patients currently electing to receive treatment. Based on the data generated to date, NeoCart may offer many of these patients a safe and effective alternative, subject to FDA approval.

“As a physician who treats patients with knee cartilage damage, I am keenly aware of the limitations of current treatment approaches for this common and underserved condition,” said David C. Flanigan, MD Associate Professor, Department of Orthopedics, Director, Cartilage Restoration Program at The Ohio State University Wexner Medical Center, and a high-enrolling investigator in the Phase 3 clinical trial. “The pain and loss of function associated with uncorrected knee cartilage lesions can significantly limit these patients’ ability to maintain their daily routines and often leads to other more serious comorbidities over time. The rapid recovery for patients who received this cartilage tissue implant compared to those who underwent microfracture indicates that implants, such as NeoCart, may be an attractive alternative for patients seeking a better quality of life and faster return to function,” continued Dr. Flanigan.

The primary endpoint for the Phase 3 clinical trial was a dual-threshold responder analysis measuring the improvement in KOOS pain and IKDC function scores for each patient treated with NeoCart compared to those treated with microfracture one year after the time of treatment. Dual-threshold responders were defined as patients who, relative to their baseline measurements, had at least a 12-point improvement in the

KOOS pain sub-score assessment and a 20-point improvement in the IKDC subjective assessment. The trial also evaluated additional pain, quality of life, and function outcomes using all five measures of KOOS subscales, including Sports and Recreation. The change from baseline and the relative change between the NeoCart and microfracture arms was also measured at one year which contrasts with clinical trials of other products, either on the market or in development, that measured these changes at two years. Efficacy and safety will continue to be followed out to three years, and Histogenics expects to further track patients for future planned analyses, including patients from prior clinical trials who received a NeoCart treatment.

Demographics for both study arms were similar and represent a patient population that was intended to ensure that microfracture would respond favorably, including patients with an average age of approximately 39 years old and a Body Mass Index (BMI) of approximately 27. Furthermore, the mean lesion size was 2.1 cm in the NeoCart arm and 1.8 cm in the microfracture arm. There were no other significant differences between the treatment arms.

The results with respect to the primary endpoint (dual threshold responder analysis one year after treatment) are summarized below:

	NeoCart		Microfracture			
	Positive Responders	Responder Rate	Positive Responders	Responder Rate	Difference	
ITT	121/170	71.2%	49/79	62.0%	9.2	p=0.1877
mITT	121/163	74.2%	49/79	62.0%	12.2	P=0.0714
As Treated	120/162	74.1%	50/80	62.5%	11.6	p=0.0735
Per Protocol	118/155	76.1%	43/65	66.2%	10.0	p=0.1362

Key additional findings from the clinical trial include:

NeoCart demonstrated statistically significant improvements in pain and function at both one and two years after treatment as measured by changes in the KOOS and IKDC scores.

KOOS pain score (mITT Population)
Change from Baseline
(NeoCart Baseline = 54.0; Microfracture Baseline = 52.4)

	NeoCart		Microfracture		
Visit	N	Mean	N	Mean	P-Value
3-months	160	24.1	75	22.4	0.0487*
6-months	157	28.6	75	27.0	0.0819
1-year	158	31.4	72	28.7	0.0239*
2-years	87	32.2	34	28.9	0.0080*
3-years	39	34.3	16	30.7	0.1071

* *Statistically significant*

IKDC subjective knee exam score (mITT Population)
Change from Baseline
(NeoCart Baseline = 40.3; Microfracture Baseline = 40.0)

Visit	NeoCart		Microfracture		
	N	Mean	N	Mean	P-Value
3-months	159	13.7	76	14.5	0.9686
6-months	156	24.4	74	22.4	0.1572
1-year	158	33.1	71	28.3	0.0126*
2-years	87	35.3	34	30.2	0.0366*
3-years	38	39.9	16	32.6	0.2691

* *Statistically significant*

NeoCart, the most advanced therapy from Histogenics restorative cell therapy platform, is functional cartilage that combines breakthroughs in bio-engineering, biomaterials and cell processing to enhance the autologous cartilage repair process. NeoCart, which is one of the most rigorously studied restorative cell therapies for orthopedic use, merges a patient's own cells with a fortified three-dimensional scaffold designed to accelerate healing and reduce pain. NeoCart's ability to function like cartilage at the time of treatment may enable patients to return to work and daily activities more rapidly than currently available treatment options such as microfracture.

Histogenics is in the process of requesting a meeting with the FDA to discuss the data and a potential BLA submission. In addition, Histogenics intends to present the complete study results at upcoming medical conferences and will seek to have the data published in one or more peer reviewed journals.

Conference Call and Webcast Information

Histogenics management will host a conference call on Wednesday, September 5, 2018 at 8:30am EDT. A question-and-answer session will follow Histogenics' remarks. To participate on the live call, please dial (877) 930-8064 (domestic) or (253) 336-8040 (international) and provide the conference ID 8764946 five to ten minutes before the start of the call.

To access a live audio webcast of the presentation on the "Investor Relations" page of the Histogenics website, please click here. A replay of the webcast will be archived on Histogenics' website for approximately 60 days following the presentation.

About Histogenics Corporation

Histogenics (Nasdaq: HSGX) is a leader in the development of restorative cell therapies that may offer rapid-onset pain relief and restored function. Histogenics' lead investigational product, NeoCart, is designed to rebuild a patient's own knee cartilage to treat pain at the source and potentially prevent a patient's progression to osteoarthritis. NeoCart is one of the most rigorously studied restorative cell therapies for orthopedic use. NeoCart is designed to perform like articular hyaline cartilage at the time of treatment, and as a result, may provide patients with more rapid pain relief and accelerated recovery as compared to the current standard of care. Histogenics' technology platform has the potential to be used for a broad range of additional restorative cell therapy indications. For more information on Histogenics and NeoCart, please visit www.histogenics.com.

Forward-Looking Statements

Various statements in this release 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: NeoCart’s potential as a treatment for knee cartilage damage; expectations regarding the timing and success of discussions with the FDA regarding the submission of a biologics license application for NeoCart; the timing, associated expenses and ability to obtain and maintain regulatory approval of NeoCart or any product candidates, and the labeling for any approved products; the market size and potential patient population in markets where Histogenics’ and its partners expect to compete; updated or refined data based on Histogenics’ continuing review and quality control analysis of clinical data; the scope, progress, timing, 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 its technology transfer and manufacturing location transition; Histogenics’ expectations regarding its expenses and revenue; Histogenics’ ability to obtain additional debt or equity capital 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 June 30, 2018, which are on file with the 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 in this release is provided only as of the date of this release, 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.

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Contacts:

Investor Relations:
Tel: +1 (781) 547-7909
InvestorRelations@histogenics.com

Media Relations:

Glenn Silver, Lazar Partners Ltd.
Tel: + 1 (646) 871-8485
gsilver@lazarpartners.com