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: May 31, 2018
(Date of earliest event reported)

BIORESTORATIVE THERAPIES, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	000-54402	91-1835664
(State or Other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification Number)

40 Marcus Drive, Melville, NY	11747
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (631) 760-8100

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:

____ 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))

Item 7.01 Regulation FD Disclosure.

BioRestorative Therapies, Inc. (the "Company") intends to use and discuss, from time to time, on and after May 31, 2018, in presentations about the Company's business, a report prepared by Defined Health with regard to the Company's lead cell therapy candidate, BRTX-100, together with a product profile prepared by Defined Health with regard to BRTX-100 (the "Presentation Materials"). Defined Health was engaged by the Company to review BRTX-100 clinical material and to facilitate discussions with relevant key opinion leaders (KOLs) (i.e., orthopedic surgeons specializing in back and spine surgery, with experience in stem cell therapy) to better understand the future therapeutic potential of BRTX-100. Defined Health is a business development strategy consulting firm with clients in the pharmaceutical, biotech and healthcare industries. The Company may use the Presentation Materials in presentations to current and potential investors, lenders, creditors, insurers, vendors, customers, employees and others with an interest in the Company and its business.

The information contained in the Presentation Materials is summary information that should be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements that the Company may make by press release or otherwise from time to time. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While the Company may elect to update the Presentation Materials in the future to reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, the Company specifically disclaims any obligation to do so. The Presentation Materials are furnished as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and are incorporated herein by reference. The presentation materials will also be posted in the Investor Relations section of the Company's website, www.biorestorative.com, for 90 days.

The information referenced under Item 7.01 (including Exhibits 99.1 and 99.2 referenced in Item 9.01 below) of this Current Report on Form 8-K is being "furnished" under "Item 7.01. Regulation FD Disclosure" and, as such, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information set forth in this Current Report on Form 8-K (including Exhibits 99.1 and 99.2 referenced in Item 9.01 below) shall not be incorporated by reference into any registration statement, report or other document filed by the Company pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1	Defined Health Report
99.2	Defined Health Product Profile

SIGNATURES

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

BIORESTORATIVE THERAPIES, INC.

Dated: May 31, 2018

By: /s/ Mark Weinreb
Mark Weinreb
Chief Executive Officer

DefinedHealth
a CELLO HEALTH business

Objectives

BioRestorative Therapies (BRTX) is developing BRTX-100, a next generation autologous cell therapy for the treatment of chronic lumbar disc disease (cLDD). BRTX engaged with Defined Health (DH) to review existing BRTX-100 clinical material, and to facilitate discussions with relevant KOLs (i.e., orthopedic surgeons specializing in back and spine surgery, with experience in stem cell therapy) to better understand the future therapeutic potential of BRTX-100. The findings of this study aim to provide an informed, independent review of the BRTX-100 program and are intended to help BRTX refine future strategic initiatives and support ongoing investor relation activities.

Methodology

DH reviewed data provided by BRTX and assembled a blinded data pack such that BRTX-100 was referred to as "Product X." KOL physicians were then recruited for 60-minute telephone interviews conducted by DH research team's trained consultants, all of whom have PhD, MD, or MS degrees, and/or relevant experience including a combination of commercial, scientific and clinical knowledge. DH successfully scheduled and interviewed four (4) KOLs, each of whom confirmed that they: (a) diagnose and treat disorders of the spine using minimally invasive, needle-based techniques, (b) are comfortable with imaging of the spine and in particular the lumbar disc, (c) are familiar with the diagnosis and treatments for degenerative disc disease, and (d) published and/or have been involved in clinical studies of cell therapy to treat lumbar degenerative disc disease. Broadly, KOLs were asked to discuss the current diagnosis and treatment paradigms for cLDD, comment on their current opinion of stem cell therapies for cLDD and to react to the blinded data pack highlighting key data related to BRTX-100.

Summary of KOL Discussions

- Diagnosis and Treatment of cLDD Radiographic analysis (e.g., MRI) is required for clinicians to make a definitive diagnosis of cLDD. Once a patient is confirmed to have cLDD, the first line therapy is often physical therapy and core strengthening. Second line therapy will introduce pharmacotherapy including oral/systemic anti-inflammatory treatment initially, and locally injected anti-inflammatories if patients do not adequately respond. KOLs note that there are regional/geographic variations in the standard of care for patients with cLDD and some centers will introduce radio frequency ablation (RFA), before proceeding with surgical options. For patients having failed non-operative interventions, a surgical procedure is typically advised. Failure of conservative, non-operative treatment is defined as continued complaints of pain, discomfort, lack of mobility, potentially with a follow-up MRI that remains suggestive of cLDD. Spinal fusion is the most common option, with disc replacement said to be used less frequently. Additionally, the decision to proceed from medical therapy to surgical intervention must be coupled with a patient's stated desire to undergo an invasive procedure in order to alleviate their discomfort. KOLs note that aside from cash-pay patients in select centers, there is minimal use of stem cell therapy presently in the US. Experts contend that stem cell therapies are used more frequently in European geographies, but attribute that to very different regulatory procedures outside of the US.

- On the Broad Therapeutic Potential of Stem Cell Therapies KOLs agreed that stem cell therapy have great potential across a variety of therapeutic areas, including cLDD. Specifically, experts state that while allogeneic stem cell products have the convenient benefit of being off-the-shelf and ready for administration, they run the risk of host rejection, stimulating a clinically significant immunogenic response and concomitant concerns of low therapeutic durability. Some KOLs further noted that allogeneic cells may confer additional risk of infection or disease, to which the recipient would not have had prior exposure. Autologous therapies are thought to hold a large advantage over allogeneic cells because they are likely to avoid the risks associated allogeneic cells and would be inherently more durable. However, autologous therapies do require an additional invasive procedure to harvest host cells and additional time in which the patient is in discomfort while waiting to be treated. Both approaches are said to be relatively nascent and as of yet unproven in both orthopedic and non-orthopedic settings, but KOLs stated a general preference for autologous products and view this approach as the future of cell-based therapies.

- Expert Opinion on cLDD Patient Eligibility for a Stem Cell Therapy KOLs agreed that cLDD patients with single disc degeneration classified as stage 1, 2, or 3 who have failed conservative non-operative management for 6-12 months would be the target candidates for an autologous stem cell therapy. Ideally, clinicians would like to see stem cell therapy as suitably safe, efficacious and durable such that it would eliminate the need for surgical intervention in most patients. However, stem cell therapy could also be used as to delay need for surgical intervention.

- Reaction to BRTX-100 Non-Clinical/Preclinical Data The rabbit annular puncture model is seen as a well-established model and the best available preclinical representation of degenerative disc disease. Preclinical data for BRTX-100 seems to indicate that cell culture conditions generally recapitulate the chondrogenic phenotype. The preclinical *in vivo* studies were seen as interesting, including the assessment of change in disc height (i.e., increase), and histological improvements, but KOLs caution that these observations are not assessments that are likely to directly translate to clinical studies because these evaluations not performed in humans. However, experts note that this preclinical data is important, lends support to the hypothesis that an autologous stem cell therapy can improve the degenerative disc disease condition, and supports a decision for further clinical investigation.

- Reaction to BRTX-100 Clinical Data KOLs were largely enthusiastic about the clinical signals generated to date, but universally cautioned that it is critical to separate subjects with true radicular pain stemming from an acute problem with the disc from those with broader, less well-defined axial pain. Based on the diagnostic and enrollment criteria presented, experts agreed that the cohort is indeed likely enriched with subjects who have truly discreet radicular pain, but were emphatic in stressing the importance of maintaining this distinction for future clinical investigations. The clinical trials conducted to date were not randomized placebo-controlled studies and experts note that the reversal of disease phenotype observed in treated patients could occur spontaneously in patients with axial back pain.

  Experts were intrigued with the results from the 2017 Centeno study of 33 patients where no SAEs were reported and 90% of patients self-reported an improvement in their condition at the 3-year

follow-up. One KOL noted: *"...this is an appropriate metric to look at* (i.e., a patient-reported improvement*) – what's really most important is: How does the patient feel and what's their quality of life assessment?"* Similarly, KOLs were optimistic that the observation of patients self-reporting an overall improvement in strength that may increase with the number of cells injected is suggestive of a meaningful clinical signal and again stressed that a patient-reported outcome (PRO) is the best assessment of therapeutic efficacy in cLDD.

This Centeno study also showed that 85% of patients demonstrated some degree of reduction in disc bulge size, as assessed by MRI pre- and post- treatment with the autologous stem cell therapy. Experts found this to be an "*interesting observation*", but state they don't look to treat the disc, *per se*, rather they focus on improving the function and QOL of the patient.

- KOL Reaction to Outcome Measures The Oswestry Low Back Pain Disability Questionnaire (ODI) and Visual Analog Scale (VAS) are viewed by experts as the most appropriate efficacy measures for the evaluation of treatment efficacy in patients with cLDD. Specifically, it was noted that both ODI and VAS should be used in conjunction with one another, as one is an evaluation of function & disability, whereas the other is an assessment of the patient's pain. Radiographic validation (i.e., MRI) of the above outcome measures is thought to be a useful follow-up assessment for clinical investigation to further support therapeutic efficacy with an anatomic benefit. However, KOLs note that MRI is not likely to be used in real-world clinical assessment post-approval.

  The degree of durability observed in the retrospective analysis of 5 patients from Elabd 2016 study was seen by KOLs as encouraging and exactly the extent of high durability they expect and would like to see from an autologous stem cell therapy. KOLs expect a stem cell therapy to be highly durable. However they caution that it is difficult to attribute this effect directly to the autologous cell therapy as these were not placebo-controlled trials, but they did encourage and fully support further clinical development of BRTX-100 in larger RCTs with the aim of recapitulating these observations. Experts also noted that some patients will exhibit this degree of improvement from standard of care non-surgical approaches, but only to a very small degree in cLDD patients with radicular back pain.

- Expert Reaction to the FDA Authorized Phase 2 Study KOLs indicate the degree of effect they would need to see in order to be convinced of the efficacy of BRTX-100 compared with placebo is at least 30% increase in function assessed by ODI questionnaire, and at least 30% decrease in pain assessed by VAS. Experts further stated they want to see a duration of effect of at minimum 2 years (preferably longer). Minor injection site pain at the time of treatment would be an acceptable adverse event, but KOLs note that any immunogenic response would be unacceptable, as it would compromise therapeutic durability and add undue medical burden to the patient.

- KOL Concluding Impression Overall, KOLs reacted positively to the value proposition of BRTX-100 and were optimistic that the clinical data presented to date is likely to be mirrored in future clinical investigations. Given the opportunity, KOLs indicated that they would likely participate in a clinical trial should it be offered at their center and that they'd recommend the study to appropriately eligible patients. If BRTX-100 were to be granted FDA approval, KOLs anticipate that it would be integrated into the standard of care for eligible cLDD patients.

Product X is an Autologous HC-BMMSC with a Dual-Mechanism of Action

- Product X is an autologous, hypoxic-cultured, bone marrow-derived mesenchymal stem cell (HC-BMMSC) therapy in development for the treatment of patients with lumbar degenerative disc disease that have failed non-surgical options.
  - By utilizing hypoxic culture conditions, HC-BMMSCs experience improved chondrocyte differentiation, increased gene expression of notochord markers (data not shown), increased cell proliferation and survival, and greater plasticity leading to a more robust effect when compared to normoxia.
- Preclinical data suggests Product X works via a dual mechanism involving production of anti-inflammatory, pro-angiogenic factors as well as via tissue remodeling and the conversion of HC-BMMSCs into disc specific cell types suitable for the disc microenvironment.

Product X decreases inflammation and increases tissue regeneration

- BMMSCs cultured under hypoxic conditions demonstrated an increase in anti-inflammatory factors through the expression of high levels of genes such as SFN and TNFAIP6
  - Angiogenic growth factors expressed by the HC-BMMSCs (VEGFs, FGFs) promote neovascularization via progenitor cell activity

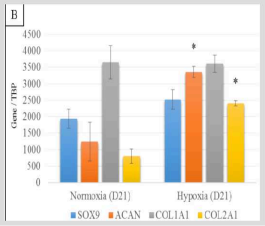
Anti-Inflammatory Factors	Hypoxia (H) Value (FPKM)	Normoxia (N) Value (FPKM)	Fold Difference H versus N
SFN	11.55	1.97	5.88
TNFAIP6	2.12	2.58	0.82

Angiogenic Growth Factors			
VEGFA	97.95	90.91	1.08
VEGFB	173.67	72.17	2.41
VEGFC	72.61	64.07	1.13
FGF1	43.35	16.24	2.67
FGF2	1.35	2.37	-1.76

Product X differentiates to chondrocytes and may replace lost/damaged resident disc cells; Product X increases nucleus pulposus (NP) ECM integrity

- Product X cells are highly chondrogenic and efficiently differentiate into chondrocytes in vitro, with increased differentiation in hypoxic culture
  - In the rabbit annular puncture model, Product X improved cellularity of the NP as well as increased extracellular matrix integrity of the NP

Human Notochord Markers	Hypoxia (H) Value (FPKM)	Normoxia (N) Value (FPKM)	Fold Difference H versus N
KRT19	57.12	14.18	4.03
KRT18	40.21	14.57	2.76
LGALS3 (GLA3/Galectin-3)	105.20	88.64	1.19
CD55	3.47	4.67	-1.35
BASP1	109.85	111.65	-1.02
CTGF	262.25	260.07	1.01
CA12	100.51	88.61	1.13
ANXA2	2619.54	2616.84	1.00
Growth Factors Involved in Chondrogenesis			
TGFB3	2.01	3.09	-1.53
FGF-2	1.35	2.37	-1.76
BMP-4	5.68	8.00	-1.41
GDF-5	42.63	38.47	1.11
PTHLH (PTHrP)	2.19	0.92	2.38
VEGF	97.95	90.91	1.08



Gene expression data by RNA sequencing. FPKM (Fragments Per Kilobase of Exon Per Million Fragments Mapped). HC-BMMSCs represented in the hypoxia column compared to cells cultured under normoxia conditions.

Product X Preclinical Safety and Efficacy Data

- Preclinical safety and efficacy studies were conducted involving the intradiscal injection of Product X using the rabbit annular puncture model

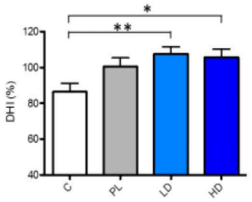
Efficacy Data:

- Rabbit lumbar degeneration was generated via annular puncture at day 0; at day 28, degenerating intervertebral discs were injected with HC-BMMSCs
- Product X demonstrated improvement in disc height, NP cellularity and improved disc extracellular matrix compared to the control group
- Product X cells were undetectable ~2 months after treatment, supporting the previously described mechanism of action of HC-BMMSCs

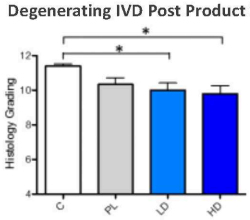
Safety Data:

- In the rabbit model, there were no gross toxicity issues or unusual histology findings; as well as no safety issues following radiographic image review
  - These safety results were true for both LD (target dose) and HD (5 times target dose)
- In a human cadaver intradiscal pressure study, Product X injection did not exceed 100 psi at 2.5mL (target volume of Product X 1.5mL)

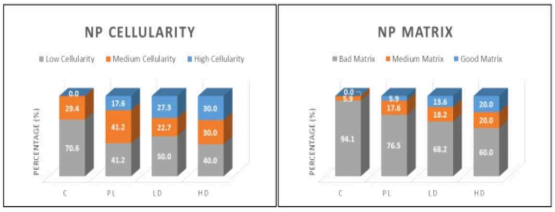
Disc Height Index of Degenerating IVD Post Product X



Histopathological Evaluation of Degenerating IVD Post Product X



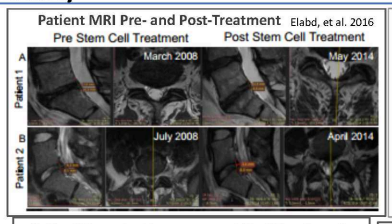
C: Contrast Agent (Control); PL: Platelet Lysate (Cell carrier); LD: Low Dose Product X (target dose); HD: High Dose Product X (5 times target dose)

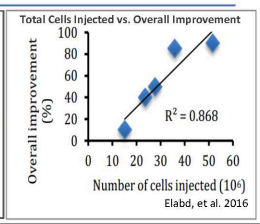


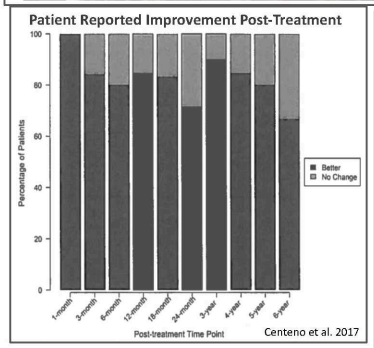
Previous In-Human Data Supports Product X Viability

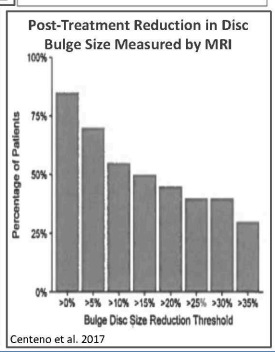
- In an in-human clinical safety and efficacy study, 33 patients diagnosed with degenerative disc disease who had exhausted conservative treatment options received intradiscal autologous, HC-BMMSCs
  - No serious AEs were reported; 3 patients reported pain related to injection procedure
  - At 3 years post-treatment, 90% of patients self-reported improvement (bottom left)
  - Numeric pain score compared to baseline were significant at 3, 36, 48, 60, and 72 months post treatment
  - Of patients who underwent MRIs, 85% demonstrated a >0% reduction in disc bulge size; as determined by pre-/post-treatment MRI scans of posterior disc bulge dimensions (bottom right)
- A long-term in-human safety study with HC-BMMSCs previously demonstrated an acceptable safety profile
  - 5 patients, treated in the above study, were part of a retrospective study for safety and efficacy
  - Patient lower back MRI data has shown an absence of abnormalities surrounding the treatment region 4-6 years post HC-BMMSCs intradiscal injection (top left)
  - Additionally, patients self-reported overall improvement in strength post-treatment (top right)

Sources: Elabd, et al. 2016; Centeno et al. 2017









P2 Study (cleared to proceed by FDA) : Product X in Patients with Lumbar Disc Disease

Study Design and Patient Population:

- 72 patient (48 Product X, 24 control) randomized, double blinded, placebo controlled trial with a primary efficacy endpoint at 6 months and follow-ups at 12 and 24 months post-treatment.
- Study to include subjects with a current diagnosis of chronic lumbar disc disease as defined as back and/or radicular pain with degeneration of a single disc confirmed by patient history, physical exam, radiographic measures, or other acceptable means.
- Study will enroll subjects who have exhausted previous conservative non-operative therapies.

Procedure:

- Treatment will take place in an outpatient setting with simple 60ml bone marrow harvest.
- Following bone marrow harvest, BMMSCs will be isolated, plated, and cultured in vitro in hypoxic conditions; BMMSCs harvested, prepared to be co-administered with patient's platelet lysate as a biomaterial carrier, then cryopreserved.
- ~40 million cells will be administered with fluoroscopic guidance via a single intradiscal injection directly into the damaged intervertebral disc in a 30 minute outpatient procedure

Primary Endpoints (Week 26):

- Improvement in function: at least 30% increase in function based on Oswestry Disability Index questionnaires (ODI)
- Reduction of pain: at least 30% decrease in pain as measured using visual analogue scale (VAS)

Secondary and Exploratory Endpoints:

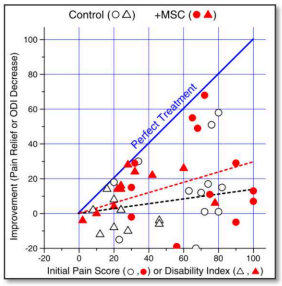
- Changes from baseline in pain (VAS) and function (ODI) at Weeks: 2, 12, 26, 52, 104
- Changes from baseline function as assessed by Roland Morris Disability Questionnaire at Weeks: 26, 52, 104
- Changes from baseline function as assessed by Functional Rating Index at Weeks: 12, 52, 104
- Changes from baseline quality of life assessment at Weeks: 2, 12, 26, 52, 104

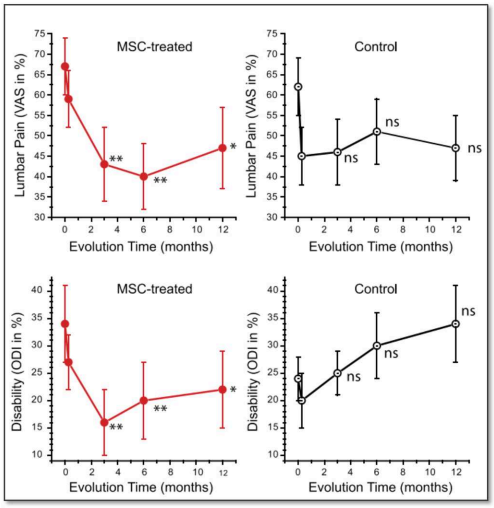
Recent Clinical Stage Studies Using Cell-Based Therapy in CLDD

Study	Year Published	n	Cell Type	Cell Dose	Route	Phase	Location	Allogeneic vs. Autologous	Placebo Controlled
Yoshikawa, et al.	2010	2	BMMSC	$2x10^6$ cells	Intradiscal	Clinical	Japan	Autologous	No
Orozco, et al.	2011	10	BMMSC	$10x10^6$ cells	Intradiscal	1	Spain	Autologous	No
Kumar, et al.	2017	10	ADMSC	$20\text{-}40x10^6$ cells	Intradiscal	1	South Korea	Autologous	No
Noriega, et al.	2017	24	BMMSC	$25x10^6$ cells	Intradiscal	1/2	Spain	Allogeneic	Yes
Elabd, et al.	2016	5	BMMSC	$15\text{-}35x10^6$ cells	Intradiscal	1	US	Autologous	No
Centeno, et al.	2017	33	BMMSC	Single dose cells	Intradiscal	1	US	Autologous	No

Autologous MSC Treatment have shown Safety and Feasibility, and Strong Indications of Clinical Efficacy in Patients with Lumbar Disc Degeneration

- Both lumbar pain and disability were significantly reduced at 3 months after MSC transplantation, and the improvement was maintained at 6 and 12 months. Compared with the basal level of pain and disability, improvement was statistically significant at all time points except at 8 days. (right).
- MSC-treated patients additionally displayed a quick and significant improvement in algofunctional indices versus the controls. (below)





Sources: Transplantation. 2017 Aug;101(8):1945-1951