UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): February 10, 2025

BioRestorative Therapies, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**001-37603**	**30-1341024**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

40 Marcus Drive Melville, New York	**11747**
(Address of principal executive offices)	(Zip code)

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

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	BRTX	NASDAQ Capital Market

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 February 10, 2025, BioRestorative Therapies, Inc. (the "Company") issued a press release (the "Press Release") announcing that, on February 8, 2025, Francisco Silva, the Company's Vice President of Research and Development, presented at the Orthopaedic Research Society (ORS) 2025 Annual Meeting (the "ORS Annual Meeting") in Phoenix, Arizona. A copy of the Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

At the ORS Annual Meeting certain presentation materials (the "Presentation Materials") were utilized by Mr. Silva. The Company intends to use the Presentation Materials from time to time on and after the date of this Current Report on Form 8-K in presentations about the Company's business. As indicated above, the Company used the Presentation Materials at the ORS Annual Meeting on February 8, 2025 and may use the Presentation Materials, possibly with modification, in other 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 or 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 Exhibit 99.2 to this Current Report on Form 8-K and are incorporated herein by reference. The Presentation Materials will also be posted on the Company's website, www.biorestorative.com, under "Scientific Publications" in the Product Candidate section, for 90 days.

The information referenced under this 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.

Number	Description
99.1	Press release, dated February 10, 2025, issued by BioRestorative Therapies, Inc.
99.2	Presentation Materials
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: February 10, 2025

By: /s/ Robert Kristal
Robert Kristal
Chief Financial Officer

Exhibit 99.1

BRTX-100 Front and Center at ORS 2025

– New blinded preliminary BRTX-100 data described this past Saturday at prestigious "2025 Winners in Industry Innovations in MSK Health" presentation –

– Among other positive preliminary data analyses, comparison of MRI images to baseline potentially demonstrate disc microenvironment remodeling –

MELVILLE, N.Y., February 10, 2025 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative", "BRTX" or the "Company") (NASDAQ:BRTX), a clinical stage regenerative medicine innovator focused on stem cell-based therapies and products, today announced that its Vice President of Research and Development, Francisco Silva, presented 26–52 week blinded data from the first 15 patients (up from 10 reported previously) with chronic lumbar disc disease ("cLDD") enrolled in the ongoing Phase 2 clinical trial of BRTX-100 at the Orthopaedic Research Society ("ORS") annual meeting, taking place February 7-11, 2025 in Phoenix, AZ.

ORS is the only international research society focused on orthopaedics and musculoskeletal care. For over 70 years, the Society's basic, translational, and scientific research has been used to treat patients with musculoskeletal disorders to ultimately enhance their quality and equity of care. Mr. Silva's presentation at this year's ORS annual meeting was part of the "2025 Winners in Industry Innovations in MSK Health" award program, where winners were invited to highlight specific technical advancements that have been introduced to the market within the past two years from the orthopaedic industry.

BRTX-100, a novel cell-based therapeutic engineered to target areas of the body that have little blood flow, is the Company's lead clinical candidate. The safety and efficacy of BRTX-100 in treating cLDD is being evaluated in a Phase 2, prospective, randomized, double-blinded and controlled study. A total of up to 99 eligible subjects will be enrolled at up to 16 clinical sites in the United States. Subjects included in the trial will be randomized 2:1 to receive either BRTX-100 or placebo.

No serious adverse events (SAEs) were reported, and there was no dose ($40X10^6$ cells) limiting toxicity at 26-52 weeks.

In addition to safety outcomes, changes compared to baseline in Visual Analog Scale ("VAS"), which measures pain, and Oswestry Disability Index ("ODI"), which measure function, are used by the U.S. Food and Drug Administration ("FDA") to help determine whether the Phase 2 BRTX-100 trial will be allowed to proceed and ultimately gain Biologics License Application (BLA) approval.

As reported at ORS 2025, preliminary blinded VAS and ODI data collected at weeks 26 and 52 post-injection demonstrated an exceptionally positive trend compared to baseline. With respect to decrease in pain at 26 weeks, the average improvement in VAS versus baseline was 71.20%, and at 52 weeks, the average improvement was 73.58%. Improvement in ODI versus baseline at 26 weeks averaged 69.04%, and at 52 weeks, the average improvement was 65.16%. These results are significantly better than the requisite FDA minimum threshold of 30% improvement in VAS and ODI, respectively.

Furthermore, in a new analysis reported for the first time, 52 week comparison of MRI images to baseline appear to demonstrate morphological changes, such as increase in T2 signal (hydration), decrease in protrusion size, as well as resolutions of annular tears. This potentially demonstrates disc microenvironment remodeling as a result of cLDD treatment with BRTX-100.

“This news is incredibly energizing; with each new blinded preliminary data analysis, like the one presented this past weekend at ORS 2025, our confidence grows that the ongoing Phase 2 BRTX-100 trial in cLDD will meet its Primary and Secondary endpoints, and thereby surpass what we believe are the requisite function and pain improvement thresholds for FDA approval. In addition, we have, for the first time, observed digital objective improvements in the disc on radiographic measures, which may translate into transformational outcomes never seen before in the industry,” said Lance Alstodt, Chief Executive Officer of BioRestorative. “We look forward to updating all stakeholders as we progress.”

Mr. Silva’s ORS 2025 presentation, titled “Next Generation Orthobiologic Therapy for Chronic Lumbar Disc Disease: Initial Phase 2 Data of Hypoxic Cultured Mesenchymal Stem Cells,” can be accessed on the Company’s website at www.biorestorative.com under “Scientific Publications” in the Product Candidate section.

About BioRestorative Therapies, Inc.

BioRestorative (www.biorestorative.com) develops therapeutic products using cell and tissue protocols, primarily involving adult stem cells. As described below, our two core clinical development programs relate to the treatment of disc/spine disease and metabolic disorders, and we have also recently begun offering BioCosmeceutical products:

• Disc/Spine Program (brtxDISC™): Our lead cell therapy candidate, BRTX-100, is a product formulated from autologous (or a person’s own) cultured mesenchymal stem cells collected from the patient’s bone marrow. We intend that the product will be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complementary therapeutic to a surgical procedure. The BRTX-100 production process utilizes proprietary technology and involves collecting a patient’s bone marrow, isolating and culturing stem cells from the bone marrow and cryopreserving the cells. In an outpatient procedure, BRTX-100 is to be injected by a physician into the patient’s damaged disc. The treatment is intended for patients whose pain has not been alleviated by non-invasive procedures and who potentially face the prospect of surgery. We have commenced a Phase 2 clinical trial using BRTX-100 to treat chronic lower back pain arising from degenerative disc disease.

• Metabolic Program (ThermoStem®): We are developing cell-based therapy candidates to target obesity and metabolic disorders using brown adipose (fat) derived stem cells (“BADSC”) to generate brown adipose tissue (“BAT”), as well as exosomes secreted by BADSC. BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research indicates that increased amounts of brown fat in animals may be responsible for additional caloric burning as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. BADSC secreted exosomes may also impact weight loss.

• BioCosmeceuticals: We operate a commercial BioCosmeceutical platform. Our current commercial product, formulated and manufactured using our cGMP ISO-7 certified clean room, is a cell-based secretome containing exosomes, proteins and growth factors. This proprietary biologic serum has been specifically engineered by us to reduce the appearance of fine lines and wrinkles and bring forth other areas of cosmetic effectiveness. Moving forward, we also intend to explore the potential of expanding our commercial offering to include a broader family of cell-

based biologic aesthetic products and therapeutics via Investigational New Drug (IND)-enabling studies, with the aim of pioneering U.S. Food and Drug Administration (FDA) approvals in the emerging BioCosmeceuticals space.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. You are cautioned that such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events or results to differ materially from those projected in the forward-looking statements as a result of various factors and other risks, including, without limitation, those set forth in the Company's latest Form 10-K, as amended, and Form 10-Q filed with the Securities and Exchange Commission. You should consider these factors in evaluating the forward-looking statements included herein, and not place undue reliance on such statements. The forward-looking statements in this release are made as of the date hereof and the Company undertakes no obligation to update such statements.

CONTACT:

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Email: skilmer@biorestorative.com

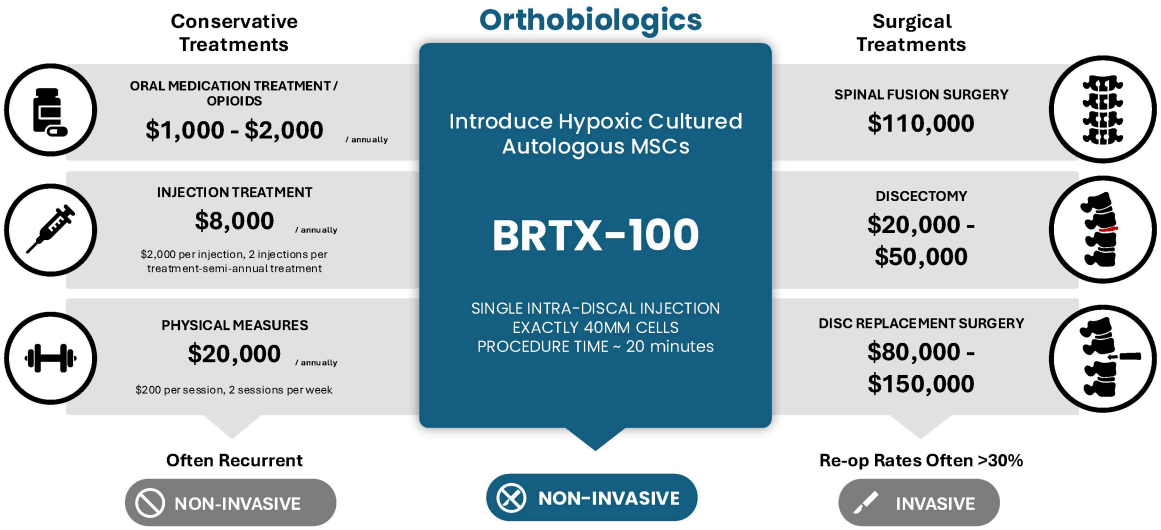
Exhibit 99.2


Next Generation Orthobiologic Therapy for Chronic Lumbar Disc Disease: Initial Phase 2 Data of Hypoxic Cultured Mesenchymal Stem Cells
biorestorative therapies
Francisco Silva
Founder
Chief Scientific Officer
Nasdaq: BRTX

Disclaimer

This presentation contains "forward-looking statements" within the meaning of the federal securities laws, including statements concerning the ability of BioRestorative Therapies, Inc. (the "Company") to develop its adult stem cell business, the future of regenerative medicine and the role of adult stem cells in that future, and the potential revenue growth of the Company's business. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: (1) the Company's limited operating history, lack of significant revenues, substantial losses since inception, and substantial working capital deficiency and stockholders' deficiency, (2) the Company's ability to obtain sufficient financing to satisfy its debt obligations and funds its operations, (3) the ability of the Company to obtain reimbursement for its therapies from private and governmental insurers, (4) the Company's ability to build management, human resources and infrastructure necessary to support the growth of its business, (5) competitive factors beyond the Company's control, (6) scientific and medical developments beyond the Company's control, (7) the Company's ability to comply with applicable federal, state, local, and international governmental requirements, (8) the Company's ability to protect its proprietary rights both within and outside the United States, and (9) other factors discussed in the Company's periodic documents filed with the Securities and Exchange Commission (which are available for review at www.sec.gov). Given these uncertainties, you are cautioned not to place undue reliance on such forward-looking statements. We assume no obligation to update these forward-looking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements.

Back Pain


Conservative Treatments
Orthobiologics
Surgical Treatments
ORAL MEDICATION TREATMENT / OPIOIDS
$1,000 - $2,000 / annually
INJECTION TREATMENT
$8,000 / annually
$2,000 per injection, 2 injections per treatment-semi-annual treatment
PHYSICAL MEASURES
$20,000 / annually
$200 per session, 2 sessions per week
Introduce Hypoxic Cultured Autologous MSCs
BRTX-100
SINGLE INTRA-DISCAL INJECTION
EXACTLY 40MM CELLS
PROCEDURE TIME ~ 20 minutes
SPINAL FUSION SURGERY
$110,000
DISCECTOMY
$20,000 - $50,000
DISC REPLACEMENT SURGERY
$80,000 - $150,000
Often Recurrent
NON-INVASIVE
NON-INVASIVE
Re-op Rates Often >30%
INVASIVE

Targeting Disc Microenvironment

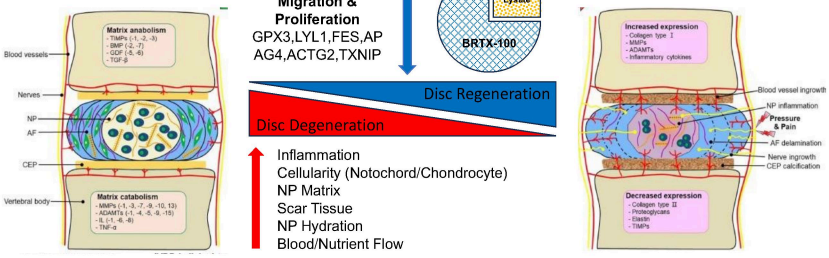
HYPOXIA

⬆ NP Cellularity Notochord/Chondrocyte Cells
Sox9,ACAN,BGLAP,ALPL,KRT19,BARX1,MDFI,DCHS1,TGFB3, BMP-4,GDF-5,VEGF

⬆ Vasculogenesis & Angiogenesis
VEGF,FGF1,TGFB1,MDK ,GRN,SPHK1,Desmin,RASIP1,LYL1,TXNIP,FES

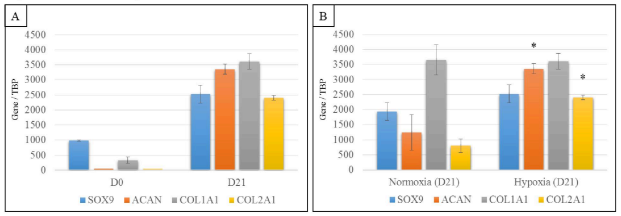
⬇ Inflammation & Poorly Immunogenic
SFN,TNFAIP6,Low CXCL5, Low chemokines

⬆ Tissue Remodeling & Regeneration
SFN,DES,ACAN,TIMP 1/3,ADAMTS4,MMP2, ANKH

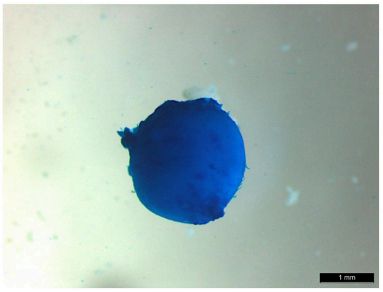


BRTX-100 Hypoxic BM-MSCs

Figure 1. Chondrocyte Differentiation



Expression of SOX9, Aggrecan (ACAN), Collagen Type I Alpha 1 Chain (COL1A1) and Collagen Type II Alpha 1 Chain (COL2A1) by qPCR. A) Hypoxic cultured bone marrow derived mesenchymal stem cells (HC-BMMSCs) at day 0 (D0, undifferentiated) and 21 days after chondrocyte differentiation (D21). B) HC-BMMSC versus Normoxic cultured-BMMSC 21 days after chondrocyte differentiation. Data represent mean +/- SEM (n = 3 donor-matched hypoxic and normoxic samples).



BRTX-100 Hypoxic BM-MSCs

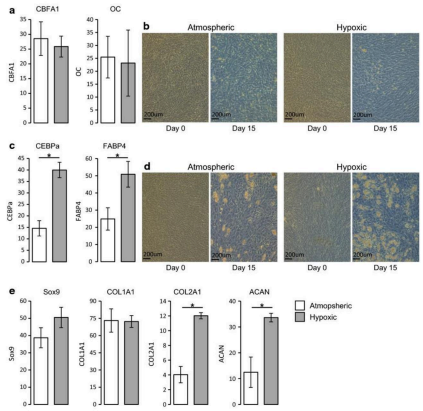
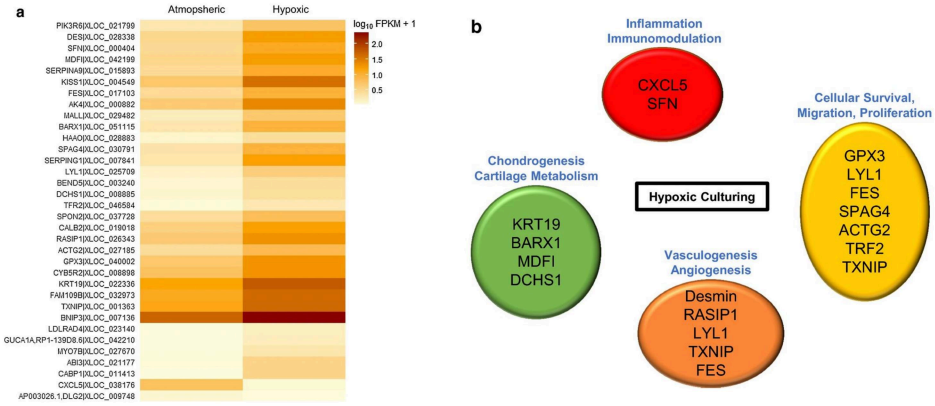


Table 1. Chondrogenic Growth Factor and Notochord Transcripts Expressed by HC-BMMSCs

	Hypoxia (H)	Normoxia (N)	Fold Difference
Human Notochord Markers	Value (FPKM)	Value (FPKM)	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

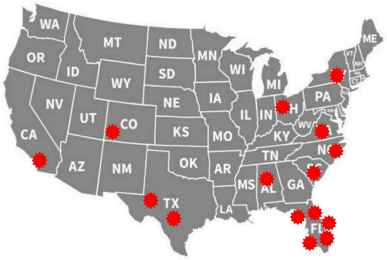
Gene expression by RNA sequencing of donor matched HC-BMMSC and NC-BMMSC. FPKM (Fragments Per Kilobase of Exon Per Million Fragments Mapped). HC-BMMSCs are presented in the "hypoxia" column and are compared to cells cultured under normoxic conditions. The FPKM value cut off for transcripts expression is set to values superior or equal to 1 (any value under 1 is considered not expressed). n = 3 donor-matched hypoxic and normoxic samples.

BRTX-100 Hypoxic BM-MSCs

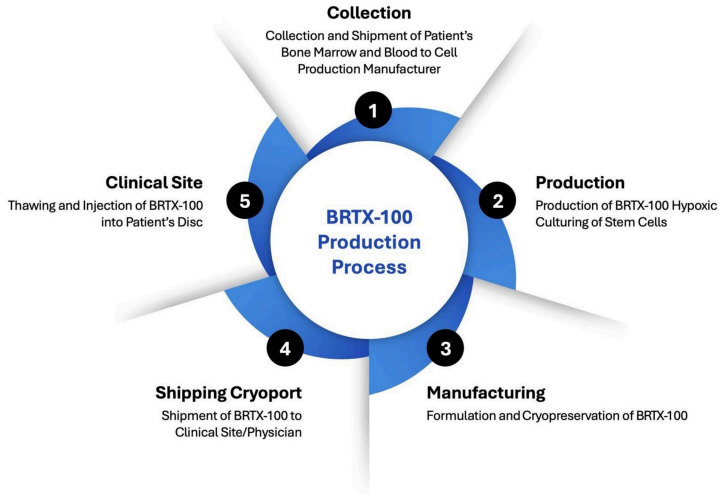


Phase 2 Clinical Trial – BRTX-100/IND 17275

- **A Phase 2, Double-Blind, Sham-Controlled, Randomized Study to Evaluate the Safety and Preliminary Efficacy of a Single Dose Intradiscal Injection of BRTX-100 for Patients with Chronic Lumbar Disc Disease (cLDD)**
  - BRTX-100 ($40x10^6$/1.5cc)
    - Hypoxic preconditioned
    - Targeted to avascular zones
  - 99 Subjects randomized 2:1
  - 16 active U.S. clinical sites U.S.



Phase 2 Clinical Trial – BRTX-100/IND 17275



Phase 2 Clinical Trial – BRTX-100/IND 17275

- **Double-blind, sham-controlled, randomized study with blinded assessments using a single dose.**
  - BRTX-100 ($40x10^6$/1.5cc)
- **Primary Objective: Safety**
  - To investigate the safety of a single dose of BRTX-100 via intradiscal injection in patients with chronic lumbar disc disease

Measured by the following Endpoints

- ❖ Report of adverse events (AEs), clinical review and questionnaires for pain, disability and quality of life at Baseline, **Week 2, Week 12, Week 26, Week 52**, and **Week 104**
- ❖ Vital Signs
- ❖ Physical Examination
- ❖ Laboratory Evaluation (hematology and chemistry)
- ❖ Clinical review of MRI changes from Baseline to Week 104 (MRI density measurements in T2 weighted images performed at Baseline, Week 52 and Week 104)

Phase 2 Clinical Trial – BRTX-100/IND 17275

- **Secondary Objective:**
  - To investigate the preliminary efficacy of single dose of BRTX-100 delivered via intradiscal injection in patients with chronic lumbar disc disease
- **Preliminary Primary Efficacy Endpoint**
  - **Clinical Response at Week 52**
    - At least a ***30% decrease in pain*** as measured on the VAS – Pain scale

      AND
    - At least a ***30% increase in function*** based on the Oswestry Disability Index

- **Secondary Efficacy Endpoints**
  - **Clinical Response** at Weeks 26 and 104
  - **VAS – Pain:** Δ from BL in pain based at Weeks 2, 12, 26, 52 and 104
  - **ODI:** Δ from BL in function at Weeks 2, 12, 26, 52 and 104
  - **RMDQ:** Δ from BL in function at Weeks 2, 12, 26, 52 and 104
  - **FRI:** Δ from BL in function at Weeks 2,12, 26, 52 and 104
  - **SF-12v2:** Δ from BL in quality of life at Weeks 2, 12, 26, 52 and 104

Phase 2 Clinical Trial – BRTX-100/IND 17275

- **Inclusion Criteria:**
  - High index of suspicion **degenerative disc disease** (DDD)/**discogenic pain**
    - Chronic lower back pain for at least 6 mos
    - Failure of at least 6 mos of conservative back pain care
    - Modified Pfirrmann score of 2 to 7 on MRI, may contain a contained protrusion and/or annular tear on MRI
    - Modic Grade I or II changes, or no change on MRI
    - Maintained intervertebral disc heights of at least 50% on MRI
    - Screening score of ≥ 40 mm and ≤ 80 mm on low back pain VAS
    - Screening Oswestry Disability Index score ≥ 30 and < 90 on a 100-point scale

- **Exclusion Criteria:**
  - High index as relating to underlying spine pathology
    - Acute or chronic **L/S spine fracture**
    - Clinically significant nerve or sacroiliac joint pain
    - Clinically significant facet pain as determined by a diagnostic medial branch block or facet joint injection
    - **Disc extrusions, sequestered frags, facet cysts, > moderate stenosis**
    - **Grade V annular fissure** **Modified Pfirrmann Grade 8**
    - **Previous L/S spine surgery** or **therapeutic percutaneous disc intervention**
    - Previous **treatment with cellular or biological investigational therapy or device**

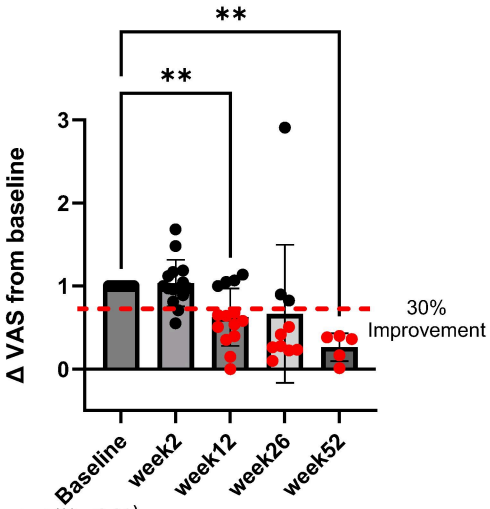
Phase 2 Clinical Trial – BRTX-100/IND 17275 Adverse Events

- **No serious adverse events (SAEs)**
- 9 adverse events (AEs) in 3 of the 10 safety run-in subjects
  - 5 AEs (2 subjects) related to treatment
    - 3 episodes of increased post-procedural back pain in 2 subjects
    - 2 MRI changes (worsening disc protrusion, acute Modic Type II changes) in 1 subject
  - 4 AEs (1 subject) unrelated to treatment
    - Ulnar nerve entrapment, trigger thumbs, trigger finger, non-alcoholic fatty liver disease in 1 subject

Good safety profile demonstrated in the first 10 subjects enrolled, passed DSMB safety review

Phase 2 Clinical Trial – BRTX-100/IND 17275 VAS

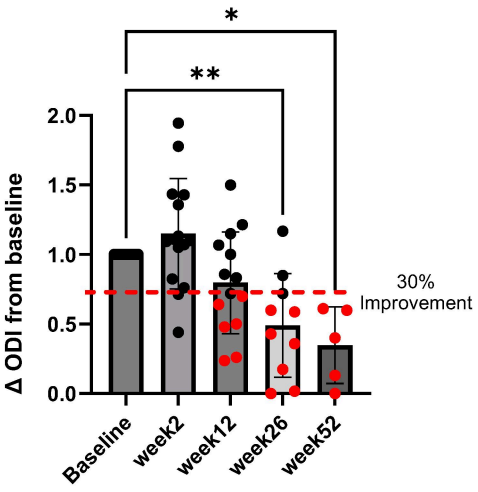
- At 26 weeks 70% of patients report > 30% improvement VAS score (n=10).
- At 52 weeks 100% of patients report > 30% Improvement VAS score (n=5)
- 12 week avg improvement > 30% = 51.70%
- 12 week avg improvement < 30% = -6.38%
- 26 week avg improvement > 30% = 71.20%
- 26 week avg improvement < 30% = -54.42%
- 52 week avg improvement = 73.58%



Mixed-effects analysis, with Geisser-Greenhouse correction and Dunnett's multiple comparison test (**p<0.01)

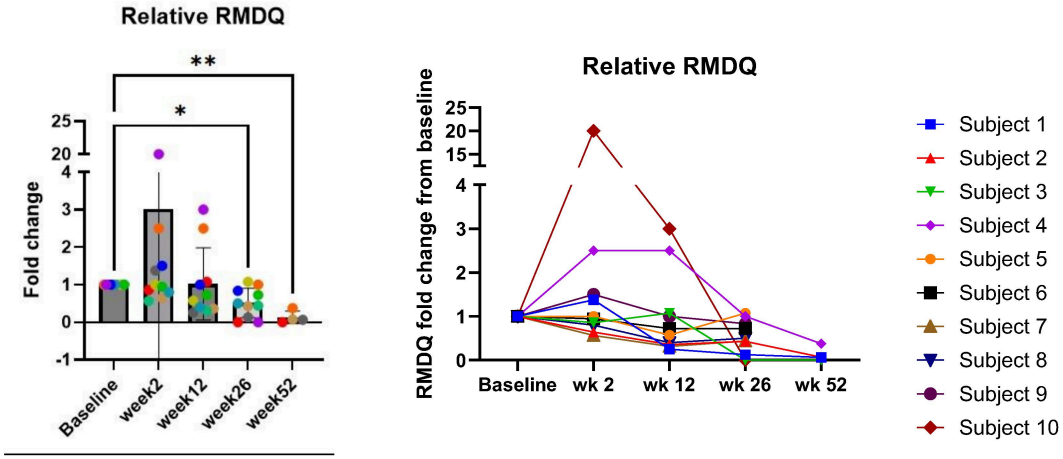
Phase 2 Clinical Trial – BRTX-100/IND 17275 ODI

- At 12 & 26 weeks 70% of patients had >30% improvement in reported ODI from their baseline (n=10).
- At 52 weeks all patients reported greater than 30% improvement in reported ODI (n=5)
- 12 week avg improvement > 30% = 43.63%
- 12 week avg improvement < 30% = -10.8%
- 26 week avg improvement > 30% = 69.04%
- 26 week avg improvement < 30% = 8.82%
- 52 week avg improvement = 65.16%



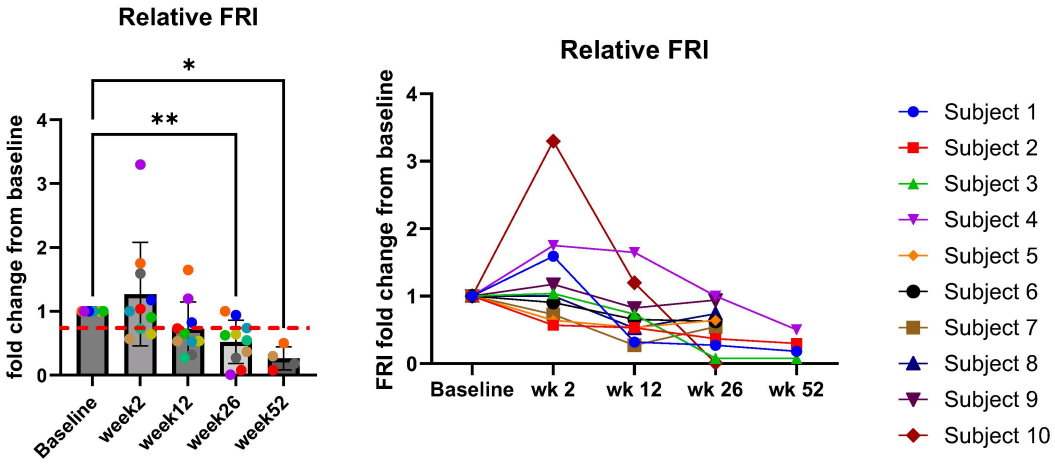
Mixed-effects analysis, with Geisser-Greenhouse correction and Dunnett's multiple comparison test (* p<0.05, **p<0.01)

Phase 2 Clinical Trial – BRTX-100/IND 17275 RMDQ



Mixed-effects analysis, with Geisser-Greenhouse correction and Dunnett's multiple comparison test (*p< 0.05, **p<0.01)

Phase 2 Clinical Trial – BRTX-100/IND 17275 FRI

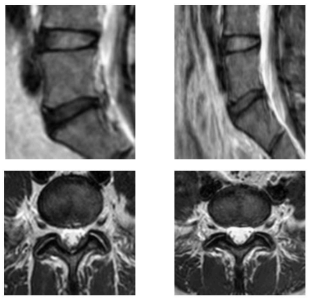


Mixed-effects analysis, with Geisser-Greenhouse correction and Dunnett's multiple comparison test (*p< 0.05, **p<0.01)

Phase 2 Clinical Trial – BRTX-100/IND 17275
MRI Baseline vs 52 Weeks

L5/S1 disc

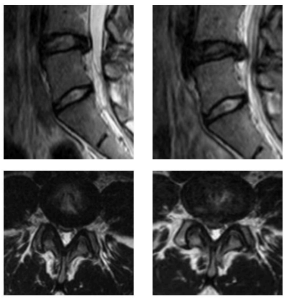
- Initial Screen vs 52 weeks:
- Increased T2 signal
- Decreased size protrusion
- Decreased annular tear signal



Baseline 52 weeks

L4/5 disc

- Initial Screen vs 52 weeks:
- Increase size of initial and more notable protrusion
- Evolution of an extruded disc lesion



Baseline 52 weeks

Phase 2 Clinical Trial – BRTX-100/IND 17275

- **Preliminary Safety End Points**
  - Blinded clinical data of a single dose of BRTX-100 ($40x10^6$) is well tolerated with no SAE or dose limiting toxicity at 26-52 weeks (n=15)
- **Preliminary Efficacy End Points**
  - Blinded clinical data of preliminary efficacy end points is encouraging
    - VAS and ODI 30% changes compared to baseline (MCID/Efficacy end point target)
    - 70% response rate trend
- **Potential Evidence of Disc Microenvironment Remodeling**
  - Blinded MRI data baseline vs 52 weeks
- **Potential interim analysis at 26 weeks to assess safety and preliminary efficacy end points**
- **Expansion of BRTX-100 to include cervical indications**

Next Generation Orthobiologic: BRTX-100

Thank you!