

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 24, 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") has prepared presentation materials (the "Presentation Materials") that management intends to use from time to time on and after May 24, 2018 in presentations about the Company's business. 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 Exhibit 99.1 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 Exhibit 99.1 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 Exhibit 99.1 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 Presentation Materials.

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 24, 2018

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



BRTX-100 Overview

Spring 2018

FORWARD LOOKING STATEMENTS; RESTRICTIONS ON USE

Statements in this BRTX-100 Overview ("Presentation"), including the information set forth as to the future financial or operating performance of BioRestorative Therapies, Inc. ("we" or the "Company"), that are not current or historical factual statements may constitute "forward looking" information within the meaning of securities laws. When used in this Presentation, such statements may include, among other terms, such words as "may," "will," "expect," "believe," "plan," "anticipate," "intend," "estimate," "project," "target" and other similar terminology. These statements reflect current expectations, estimates and projections regarding future events and operating performance and speak only as to the date of this Presentation. Readers should not place undue importance on forward looking statements and should not rely upon this information as of any other date.

Forward looking statements involve known and unknown risks, uncertainties and other important factors that could cause our actual results, performance or achievements, or industry results, to differ materially from our expectations of future results, performance or achievements expressed or implied by these forward looking statements. These forward looking statements may not be realized due to a variety of factors, including without limitation: (i) our limited operating history, lack of significant revenues, substantial losses since inception, and substantial working capital deficiency and stockholders' deficiency; (ii) our ability to obtain sufficient financing to initiate and complete our clinical trials, satisfy our debt obligations and fund our operations; (iii) our ability to timely and successfully develop and commercialize brtxDISC, our lead product candidate for the treatment of chronic lumbar disc disease; (iv) delays in enrolling patients in our clinical trials; (v) disruption to our access to the media (including cell culture media) and reagents we are using in the clinical development of our cell therapy product candidates; (vi) failure of our clinical trials to demonstrate adequately the safety and efficacy of our product candidates; (vii) our lack of manufacturing capabilities to produce our product candidates at commercial scale quantities and lack of alternative manufacturing supply; (viii) a loss of our exclusive license rights with regard to our disc/spine technology; (ix) safety problems encountered by us or others developing new stem cell-based therapies; (x) ethical and other concerns surrounding the use of stem cell therapy which negatively impact the public perception of our stem cell products and/or services; (xi) our limited experience in the development and marketing of cell therapies; (xii) our reliance on novel technologies that are inherently expensive and risky; (xiii) significant product liability claims and litigation to which we may be subject, including potential exposure from the use of our product candidates in human subjects; (xiv) our inability to obtain reimbursement for our products and services from private and governmental insurers; (xv) our inability to protect our proprietary rights; and (xvi) compliance with applicable federal, state, local, and international requirements. See also "Management's Discussion and Analysis of Financial Condition and Results of Operations - Factors That May Affect Future Results and Financial Condition" set forth in the Company's most recent annual report filed with the SEC.

Many of these issues can affect the Company's actual results and could cause the actual results to differ materially from those expressed or implied in any forward looking statements made by, or on behalf of, the Company. Readers are cautioned that forward looking statements are not guarantees of future performance, and should not place undue reliance on them. In formulating the forward looking statements contained in this Presentation, it has been assumed that business and economic conditions affecting the Company will continue substantially in the ordinary course. These assumptions, although considered reasonable at the time of preparation, may prove to be incorrect.

This Presentation is for review by the recipient only. The recipient, by accepting delivery of this Presentation, agrees the Presentation is furnished for the sole use of the recipient and for the sole purpose of providing information to the recipient. Any distribution of the Presentation to any other person or entity and any reproduction of the Presentation, or the divulgence of any of its contents, without our prior written consent, is prohibited. The delivery of this Presentation does not imply that the Presentation or other information furnished in connection therewith is correct as of any time subsequent to the date of delivery.



COMPANY BACKGROUND

BioRestorative Therapies, Inc. (“BRT”) develops therapeutic treatments from adult stem cells

- Full-service research lab, based in Melville, NY
- Publicly-listed (OTC: BRTX)
- 10 employees, most with technical/science backgrounds
- Leadership and scientific advisors are pioneers in stem cell therapeutics space

We have developed BRTX-100®, a stem-cell based treatment for chronic lumbar disc disease (“cLDD”):

- Autologous stem cell-based biologic
- Hypoxic cultured, bone marrow-derived
- Single intradiscal injection

BRTX-100 is our lead clinical candidate because:

- Prior human data provides insight into the potential efficacy of BRTX-100
- FDA authorized commencement of Phase 2 clinical trial
- Large indication with few comparable therapies



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LOW BACK PAIN IS A LEADING CAUSE OF DISABILITY AND HAS ENORMOUS SOCIAL AND ECONOMIC IMPACT

Chronic Lumbar Disc Disease is degenerative:

- Compromised disc with lower back pain
- Over time, functionality is also limited
- Disc degeneration is presently irreversible

80% of adults experience lower back pain:

- More than 30% of people aged 30-50 have some degree of disc degeneration
- In people over 60, disc degeneration is a normal finding on MRI scans

Standard of care focuses on pain management with limited efficacy:

- Failed conservative intervention leads to surgery
- Conservative interventions include physical therapy, steroids, and narcotics
- Surgical interventions include spinal fusions and discectomies



- Katz J.N. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. J Bone Joint Surg Am. 2006;88 (Suppl 2):21-24.
- Lumbar Degenerative Disc Disease (DDD) (Peter F. Ullrich, Jr., MD, 2013)

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CURRENT TREATMENT OPTIONS INCLUDE CONSERVATIVE INTERVENTIONS THAT OFTEN LEAD TO INVASIVE SURGICAL PROCEDURES

Conservative Treatment Options



Oral Medication Treatment

- OTC pain medications (NSAIDs, analgesics)
- Narcotics (codeine, oxycodone-acetaminophen combination)
- Nerve pain medications (gabapentin, pregabalin, duloxetine, tramadol)



Injection Treatment

- Epidural steroid injections
- Epidural anesthetic injections



Physical Measures

- Physical therapy
- Chiropractic/osteopathic manipulation
- Exercise or activity modifications

- Minimal long term efficacy; mostly pain management
- Frequent and continuous need for treatment
- Very costly over sustained periods of treatment

Surgical Treatment Options



Spinal Fusion Surgery

- Posterior lumbar fusion (PLF)
- Posterior lumbar interbody fusion (PLIF) & Transforaminal lumbar interbody fusion (TLIF)
- Anterior lumbar interbody fusion (ALIF)
- Extreme lateral interbody fusion (XLIF)



Discectomy

- Microdiscectomy
- Open discectomy



Disc Replacement Surgery

- Artificial disc replacement (ADR)

- Highly invasive, with surgical risk
- Variable efficacy (35%) with risk of long term disability
- Very expensive

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BRTX-100 SHOWS GREAT PROMISE TO TREAT COMPROMISED DISCS WITHOUT SURGERY

Description

- Targeted for patients whose pain and disabilities have not been alleviated by conservative treatments and face the prospect of surgery
- Product formulated from autologous hypoxic cultured mesenchymal stem cells (or MSCs) collected from the patient's bone marrow and co-administered with an autologous biomaterial carrier (human platelet lysate)
- **Production/Treatment Process (5 weeks):**
 - Physician extracts bone marrow and blood from patient's hip; unprocessed samples are shipped to BRT
 - BRT initiates culturing of stem cells, selecting and expanding cells that are able to survive in hypoxic (low oxygen) environments
 - BRT formulates and cryopreserves BRTX-100 with autologous platelet lysate. BRTX-100 is shipped back to the physician
 - Physician administers in 30-min outpatient procedure

Key Attributes

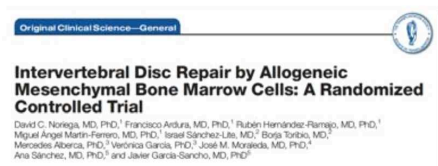
- One-time, intradiscal injection performed as a 30-minute outpatient procedure
- Autologous product minimizing safety concerns
- Potent hypoxic-cultured MSCs designed to survive in disc microenvironment
- Co-administered with biomaterial carrier (Platelet Lysate) to increase potency, viability and survivability
- Robust, scalable, highly-reproducible, proprietary formulation process
- Prior human studies have shown safety and therapeutic benefit
- Low cost and minimally invasive
- Early evidence of improved efficacy over alternatives

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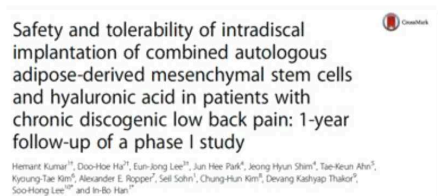
HUMAN DATA FROM STUDIES OF THERAPIES SIMILAR TO BRTX-100 SHOW REDUCED PAIN, INCREASED FUNCTION, AND AN ABSENCE OF SIGNIFICANT SAFETY ISSUES



- **Description:** 33 patients diagnosed with degenerative disc disease received an intradiscal injection of autologous, hypoxic cultured, bone marrow-derived MSCs (15.1 to 51.6 million cells) as part of a US based investigator initiated study. Prospective registry data was obtained at multiple time intervals up to 6 years post-treatment.
- **Results:** Study results on the use of hypoxic cultured autologous MSCs demonstrated no safety issues, substantially reduced pain, increased function, and reduced disc bulge size. Pain change score relative to baseline were significant at 3, 36, 48, 60 and 72 months post-treatment. Single assessment numeric evaluation ratings showed improvement of 60% at 3 years post-treatment. Functional rating index post-treatment change scores exceeded the minimally clinically important difference. 85% of the patients (n=20) who underwent post-treatment MRIs had a 25 % reduction in disc bulge size.



- **Description:** 24 patients with chronic back pain were randomized into either treatment group or control group. Treatment group received 25x10⁶ bone marrow-derived MSCs. Clinical outcomes were followed up for 1 year and included evaluation of pain, disability and quality of life.
- **Results:** Feasibility and safety of a 25x10⁶ cell dose was confirmed and clinical efficacy was identified. MSC-treated patients displayed a quick and significant improvement in algo-functional indices versus controls. VAS and ODI were significantly reduced at 3 months after MSC transplantation and the improvement maintained at 6 and 12 months. Degeneration, quantified by Pfirrmann grading, improved in the MSC-treated patients and worsened in the control group



- **Description:** 10 patients with chronic back pain received a single injection of 20x10⁶ and 40x10⁶ of autologous adipose-derived MSCs. Safety and clinical outcomes were evaluated by assessing VAS, ODI, Short Form-36 (SF-36), and imaging at regular intervals over 1 year.
- **Results:** No serious or adverse events were reported during the 1-year follow up period. VAS, ODI, and SF-36 scores significantly improved in both dosing cohorts compared to base line. In addition three patients of the ten included in the study were determined to have increased water content based on an increased diffusion coefficient on diffusion MRI.



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INDEPENDENT CONSULTING FIRM HAS VALIDATED BRTX-100 APPROACH





In May 2018, Defined Health conducted a study with relevant key opinion leaders (KOLs) to provide an informed, independent review of BRTX-100, its supporting data, and its potential to treat cLDD. Key findings include:

- Stem-cell therapies have “great potential” to treat cLDD (and related therapeutic areas)
- Autologous products (as opposed to allogeneic) are the “future of cell-based therapies”
 - Autologous approaches (1) contain reduced risk of host rejection and infection and (2) are more durable
- KOLs held positive reactions to preclinical/clinical data and were “optimistic that the clinical data presented to date is likely to be mirrored in future [trials]”
- KOLs anticipate that if approved, BRTX-100 would be “integrated into the standard of care for eligible cLDD patients”



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BRTX-100 IS SAFER AND MORE POTENT THAN ITS CLOSEST COMPARABLE

				BRTX-100's Advantages
Drug name and description	BRTX-100: adult stem cell biologic, administered via 30-minute outpatient intradiscal injection	MPC-06-ID: adult stem cell biologic, administered via 30-minute outpatient intradiscal injection		
Key attributes				
	Autologous – uses patients own stem cells	Allogeneic – uses cadaver-derived human stem cells (not from patient)	✓	Autologous cells means low to no risk of rejection, greater safety profile (introduction of viral/genetic), streamlined regulatory path
	Hypoxic cultured – in low oxygen environment (5%)	Normoxic cultured – with normal oxygen environment (~20%)	✓	Hypoxic culturing creates increased cell proliferation, greater plasticity, increased paracrine effect and increased cell survival after application
	Autologous Platelet Lysate Carrier	Hyaluronic Acid Carrier	✓	Autologous platelet lysate provides growth factors that interact with the cells, allowing for better cell survival
	100% Animal-Free Manufacturing Process	Animal Products Used in Manufacturing Process	✓	Low to no risk of safety concerns related to immunological and zoonotic transmission
Stage of Development	Phase 2 clinical trial approved under active IND 17275	Phase 3 clinical trial currently enrolling participants	✗	



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CHRONIC BACK PAIN IS A \$100B MARKET IN U.S. ALONE, WITH SPINAL FUSION COSTS APPROACHING \$40B ANNUALLY

“Back pain is a \$100-billion-per-year industry in the US.”¹

“Spinal fusion surgery is the form of elective surgery that people spend the most on in the US, costing a total of \$40 billion per year. The problem is, it rarely works.”²



250 million
American adult population



25 million
American adults with chronic lower back pain prevalence



12 million
American adults with diagnosed and treated disc degeneration



5.6 million
American adults with disc protrusion, herniation, or bulge



500,000
Spinal fusion surgeries per year



¹ Katz JN. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. J Bone Joint Surg Am. 2006;88 (Suppl 2):21–24.

² The \$100 billion per year back pain industry is mostly a hoax, (Quartz, June 26, 2017) available at <https://qz.com/1010259/the-100-billion-per-year-back-pain-industry-is-mostly-a-hoax/>

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OUR ANALYSIS INFERS PRICING CAN EXCEED \$25K PER TREATMENT, ACHIEVING HIGHER QUALITY OUTCOMES AT LOWER COST THAN CURRENT SUBSTITUTES

Conservative Treatments



\$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 x 2 sessions per week)

Surgical Treatments



Spinal Fusion Surgery

\$80,000-\$150,000



Discectomy

\$20,000-\$50,000



Disc Replacement Surgery

\$80,000-\$150,000

\$25,000 for a single treatment using BRTX-100 is easily justifiable based on the cost of alternatives

Compares favorably to conservative treatment costs, which persist for years

AND

Significantly less expensive than the most common surgical procedures

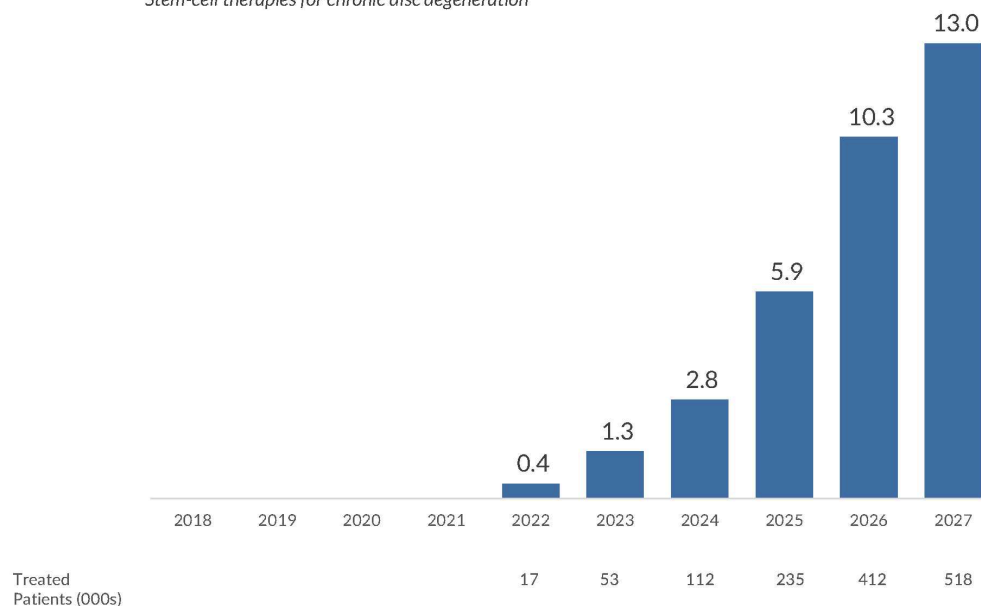


- Low Back Treatment Trends Affecting Health Insurance Payers (ChiroCare, 2014)
- Degenerative Disc Treatment Cost, available at <http://health.costhelper.com/degenerative-disc.html>
- <https://www.mdsave.com/procedures/epidural-steroid-injection/d583f9c4>

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CONSERVATIVE PROJECTIONS SHOW \$13B+ MARKET POTENTIAL FOR BRTX-100

Total Sales Potential (Billions)
Stem-cell therapies for chronic disc degeneration



Key Assumptions

- Spinal fusion surgeries projection as baseline, with 464k surgeries per year (2014), growing at 4.9% per annum¹
- Replacement rate of regenerative biologics starting at 2.5% in 2022 (17k treatments) to steady-state 60% of all surgeries by 2027 (518k treatments)
- \$25,000 reimbursable price per treatment²

Opportunities not modeled

- Additional discs in treated patients
- First-line interventions
- Treating other lower back pain (beyond cLDD)
- Indications for other musculoskeletal disorders
- International markets



1. Surgeries in Hospital-Based Ambulatory Surgery and Hospital Inpatient Settings, 2014 (AHRQ, revised Feb 2018) available at <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb223-Ambulatory-Inpatient-Surgeries-2014.jsp>; Global lumbar spinal fusion market to see 4.9% CAGR through 2020 (Becker Spine Review, Jan 2017) reviewing Market Reports World analysis.
2. Team analysis

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BRTX-100 HAS BEEN DEVELOPED, HAS AN ACTIVE IND, AND AUTHORIZATION FROM THE FDA TO BEGIN ITS PHASE 2 TRIAL



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BRTX-100 HAS A FAVORABLE PHASE 2 TRIAL DESIGN

The Phase 2 trial is a double-blinded, placebo controlled, randomized study

- **Study includes 72 subjects (2:1 product to placebo)**
- **Included subjects will have only one diseased disc**
- **Endpoints are based on a 30% reduction in pain and a 30% increase in function**
 - Considered by FDA and key opinion leaders as minimal clinically important differences
 - Functional improvement based on the Oswestry questionnaires (ODI)
 - Pain reduction measured using the Visual Analogue Scale (VAS)
- **Primary endpoints are measured at 6 months, with expected Phase 2 study to last 24 months. MRI evaluations—at screening and semi-annually thereafter—will also be used**
- **Comparative control cohort consists of saline injection**



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PATENTS PENDING AND DATA EXCLUSIVITY SHOULD ALLOW BRTX-100 TO EXPLOIT THE MARKET OPPORTUNITY

IP and legislative protections include:

- **Licensed patent application covering methods of culturing cells under hypoxic conditions and their use in avascular areas, currently being reviewed by the US Patent and Trademark Office (PTO)**
 - Pending claims include method of treatment and method of manufacture
 - BRT has responded to the PTO's latest action, and is awaiting its response
- **As a reference product, BRTX-100 will be afforded 12 years of data exclusivity via the Biologics Price Competition and Innovation Act**

K&L Gates, a highly reputable law firm in biotechnology intellectual property, is representing BRT in its patent prosecutions, with John Desmarais, a BRT board member and well-known patent counsel supervising the work



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EXPERIENCED LEADERSHIP AND RECOGNIZED ADVISORS



Mark Weinreb, M.S., CEO & Chairman

Mr. Weinreb is an early pioneer in the field of regenerative medicine and cellular therapy and has significant experience in running public companies. He has been CEO since 2010 and board Chairman since 2011. He previously served as the CEO/Chairman of Phase III Medical, Inc. where he acquired NeoStem, Inc. (NS California), an adult stem cell collection company that became Caladrius Biosciences, Inc. (NASDAQ: CLBS). Mr. Weinreb operated and owned Bio Health Laboratories, Inc., a state-of-the-art medical diagnostic laboratory providing clinical testing services for physicians, hospitals, and other medical laboratories Northwestern (BA); CW Post, Long Island University MS (Medical Biology)



John M. Desmarais, J.D., Board Member

Mr. Desmarais is the founding partner of Desmarais LLP, an intellectual property trial boutique, and the founder and owner of Round Rock Research LLC, a patent licensing company. From 1997-2009, he was a partner at Kirkland & Ellis LLP, where he headed its intellectual property group and served on the firm's management committee from 2004-2009. In 2016 and 2017, U.S. News & World Report, ranked Mr. Desmarais' law firm, among the Best Law Firm's for Patent Litigation, and in 2017, Mr. Desmarais himself was ranked by Best Lawyers in America as New York Patent Law Lawyer of the Year. Manhattan College (B. Ch. E., Chemical Engineering); NYU (JD)



Adam Bergstein, SVP, Planning & Development

Mr. Bergstein joined BRT in January 2018 to support drug development efforts. Prior to BRT, Mr. Bergstein was the founder and Managing Member of PharmaShield, an entity created to insure branded pharmaceutical companies against premature generic entry caused by invalidation of drug patents before their expiry dates. Prior to PharmaShield, he worked in the health economics group at the RAND Corporation, during which time he created derivatives to help mitigate risk within the broader healthcare markets. Earlier in his career, Mr. Bergstein was a private equity investor on both the East Coast and in the Midwest.

U. Penn (BA, Economics); Northwestern-Kellogg (MBA)



Wayne Marasco, M.D., Ph.D., Chairman, Scientific Advisory Board

Dr. Marasco is Chairman of BRT's Scientific Advisory Board. He is a principal faculty member of Harvard Stem Cell Institute, Professor at the Dana-Farber Cancer Institute, and Professor of Medicine at Harvard Medical School. Dr. Marasco is a licensed physician-scientist with training in internal medicine and specialty training in infectious diseases. Most recently, Dr. Marasco was co-founder and Chairman of the Scientific Advisory Board and Medical Advisory Board of NeoStem, Inc., a publicly traded adult stem cell company. He has authored over 110 peer-reviewed scientific publications, over 25 reviews, chapters, monographs and editorials and is listed as the inventor on 36 patents.



Francisco Silva, Chief Scientist, VP of R&D

Mr. Silva joined BRT in April 2011 and is responsible for all laboratory operations and the development and growth of our stem cell programs. Prior to BRT, Mr. Silva served as CEO of DV Biologics LLC, and as President of DaVinci Biosciences LLC, companies engaged in the commercialization of human-based biologics. Before that, he was CP, R&D for PrimeGen Biotech LLC. He has obtained a number of patents relating to stem cells and is a well published in stem cell research.

California State Polytechnic University (BS, Biology) with Graduate Presidential Fellowship and MBRS Fellowship.



Wayne Olan, M.D., Clinical Director, Regenerative Disc Program

Dr. Olan, a board-certified interventional neuroradiologist, is the director of endovascular and minimally invasive image guided neurosurgery in Washington, D.C. at the George Washington University Medical Center, and is also an associate professor at The George Washington University School of Medicine & Health Sciences. Dr. Olan has over 150 published papers, posters, abstracts and lectures on endovascular treatment of cerebrovascular disorders, including the treatment of cerebral aneurysms, arteriovenous malformations, and the treatment of stroke. A great deal of his research has covered the interventional treatment of spinal disorders.



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PHASE 2 CLINICAL TRIAL TO COST \$18M

(thousands)	Year 1	Year 2	Year 3	Total
Clinical Development				
Patient Costs		\$3,089		\$3,089
Salaries/Consultants	\$313	\$313	\$250	\$875
CRO	\$598	\$2,763	\$2,357	\$5,717
Manufacturing/Quality	\$1,593	\$3,286	\$738	\$5,617
G&A	\$510	\$720	\$720	\$1,950
R&D	\$200	\$300		\$500
Total	\$3,213	\$10,470	\$4,065	\$17,748



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SUMMARY AND KEY TAKEAWAYS

FDA granted authorization to commence a Phase 2 clinical trial using BRTX-100 under active IND 17275

Independent review was optimistic that existing clinical results are likely to be mirrored in Phase 2 trial

BRTX-100 is targeting a large indication that has few comparable treatment options

- 25M Americans suffer from chronic lower back pain, with 5.6M experiencing major disc issues (i.e. protrusion, bulging) and 500K undergoing spinal fusion surgery each year
- Less expensive and likely more efficacious than current treatments

IP protection includes pending patent applications, as well as 12 years of data exclusivity



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