

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: August 30, 2019
(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, New York		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))

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 ☒ [X]

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 5.07**Submission of Matters to a Vote of Security Holders.**

On August 30, 2019, BioRestorative Therapies, Inc. (the “Company”) held a Special Meeting of Stockholders (the “Special Meeting”). The following is a listing of the votes cast for and against, as well as abstentions, with respect to the matters voted upon at the Special Meeting. At the Special Meeting, the Company’s stockholders (i) approved the Securities Purchase Agreement between the Company and Arena Investors LP, dated as of July 26, 2019, and the transactions contemplated thereby; and (ii) approved the Amended and Restated Exchange Agreements between the Company and each of John M. Desmarais and Tuxis Trust, dated as of July 26, 2019.

1. Approval of the Securities Purchase Agreement between the Company and Arena Investors LP, dated as of July 26, 2019, and the transactions contemplated thereby:

For	9,865,381
Against	34,178
Abstentions	1,721
Broker Non-Votes	-0-

2. Approval of the Amended and Restated Exchange Agreements between the Company and each of John M. Desmarais and Tuxis Trust, dated as of July 26, 2019:

For	9,864,013
Against	34,979
Abstentions	2,288
Broker Non-Votes	-0-

Item 7.01**Regulation FD Disclosure.**

The Company has prepared presentation materials (the “Presentation Materials”) that management intends to use from time to time on and after September 6, 2019 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 (the “Securities Act”), except as shall be expressly set forth by specific reference in such filing.

Item 3.02 Unregistered Sales of Equity Securities.

Between August 30, 2019 and September 3, 2019, the Company repaid certain outstanding promissory notes in the aggregate amount of \$262,076, inclusive of accrued interest and prepayment premiums.

On August 30, 2019, the Company issued convertible promissory notes in the aggregate principal amount of \$470,000 for aggregate cash proceeds of \$420,000. The convertible notes bear interest at the rate of 12% per annum payable at maturity with original maturity dates in August 2020. The convertible notes and respective accrued interest are convertible into shares of the Company's common stock at the election of the respective holders at a fixed price of \$1.00 per share for the first six months following the respective issue date, and thereafter at a conversion price generally equal to 58% of the fair value of the Company's stock, subject to adjustment, until the respective notes have been paid in full.

Between September 3, 2019 and September 4, 2019, the Company issued an aggregate of 613,143 shares of common stock of the Company in exchange for outstanding indebtedness in the aggregate amount of \$72,953, inclusive of accrued and unpaid interest.

For each of the securities issuances, the Company relied upon Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering or Section 3(a)(9) of the Act as a security exchanged by an issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. For each such transaction, the Company did not use general solicitation or advertising to market the securities, the securities were offered to a limited number of persons, the investors had access to information regarding the Company (including information contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, Quarterly Reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019 and Current Reports on Form 8-K filed with the Securities and Exchange Commission, and press releases made by the Company), and management of the Company was available to answer questions from prospective investors. The Company reasonably believes that each of the investors is an accredited investor.

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: September 6, 2019

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



biorestorative
therapies

"BIOLOGIC PROBLEMS - BIOLOGIC SOLUTIONS"

DISCLAIMER AND CAUTIONARY NOTE ON FORWARD LOOKING STATEMENTS

STATEMENTS IN THIS PRESENTATION, INCLUDING THE INFORMATION SET FORTH AS TO THE FUTURE FINANCIAL OR OPERATING PERFORMANCE OF BIORESTORATIVE THERAPIES, INC. (THE "COMPANY") THAT ARE NOT CURRENT OR HISTORICAL FACTUAL STATEMENTS MAY CONSTITUTE "FORWARD LOOKING" INFORMATION WITHIN THE MEANING OF THE U.S. FEDERAL AND STATE SECURITIES LAWS. WHEN USED IN THIS SUMMARY, 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, BUSINESS PLAN 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 BRTX-100, 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, THE COMPANY IS 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 AN 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 THE COMPANY 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. YOU ARE CAUTIONED THAT FORWARD LOOKING STATEMENTS ARE NOT GUARANTEES OF FUTURE PERFORMANCE, AND YOU SHOULD NOT PLACE 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 AND THE ECONOMY GENERALLY WILL CONTINUE SUBSTANTIALLY IN THE ORDINARY COURSE. THESE ASSUMPTIONS, ALTHOUGH CONSIDERED REASONABLE AT THE TIME OF PREPARATION, MAY PROVE TO BE INCORRECT.

THE DESCRIPTION OF THE COMPANY AND ITS BUSINESS IN THIS PRESENTATION DOES NOT PURPORT TO BE COMPLETE AND IS SUBJECT TO THE MORE DETAILED DESCRIPTION OF THE COMPANY AND ITS BUSINESS IN THE COMPANY'S ANNUAL, QUARTERLY AND CURRENT REPORTS FILED WITH THE SEC.

THE COMPANY HAS NO OBLIGATION TO UPDATE ANY INFORMATION SET FORTH IN THIS PRESENTATION EXCEPT TO THE EXTENT REQUIRED BY LAW.



Who is BRTX?

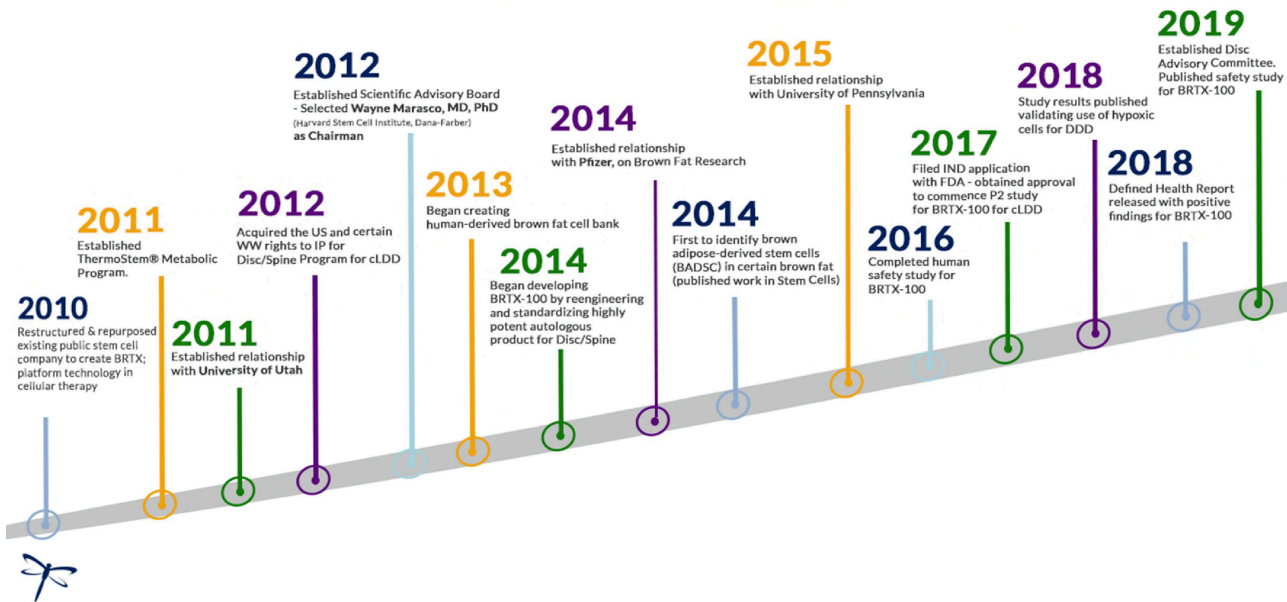
- BioRestorative Therapies, Inc. ("BRTX") was founded by a team of scientists and researchers committed to developing stem cell therapies to address unmet medical needs
- We believe that our advances in cell biology harbor great promise in conditioning our bodies' own regenerative potential to treat major diseases more effectively than current interventions
- We are an FDA compliant drug development company pursuing a biologics license application (BLA) pathway for our lead product BRTX-100, a product formulated from autologous (or a person's own) mesenchymal stem cells designed to increase quality of life for those suffering from back pain caused by disc degeneration
- A company with a multi-product pipeline developing a clinical stage spinal disc program and engaging in research efforts to produce what we believe is a very promising allogeneic cell-based therapy targeted to treat obesity, type 2 diabetes and metabolic disorders using brown fat cells
- Our mission is to continue to develop programs that aim to revolutionize the quality of care for both (i) chronic back pain caused by disc degeneration, as well as (ii) metabolic disorders including obesity and diabetes, with an effort to better patient outcomes and improve lives



COMPANY HIGHLIGHTS

- 
- Disruptive Platform Technology in Cellular Therapy
 - Addressing Large Unmet Needs; Multi-Billion Dollar Market Opportunities
 - Exploring Diverse Pipeline Opportunities within and outside of Spine and Obesity
 - We Believe that Preliminary Data May Be Indicative of Positive Trial Outcomes
 - Many Clinical & Regulatory Accomplishments
 - Intellectual Property Protection
 - Multiple Value Enhancing Inflection Points
 - Experienced Management Team & Scientific Advisory Board
 - Exploring Key Strategic Partnership Opportunities

CORPORATE HISTORY & ACCOMPLISHMENTS



DISC/SPINE
BRTX-100

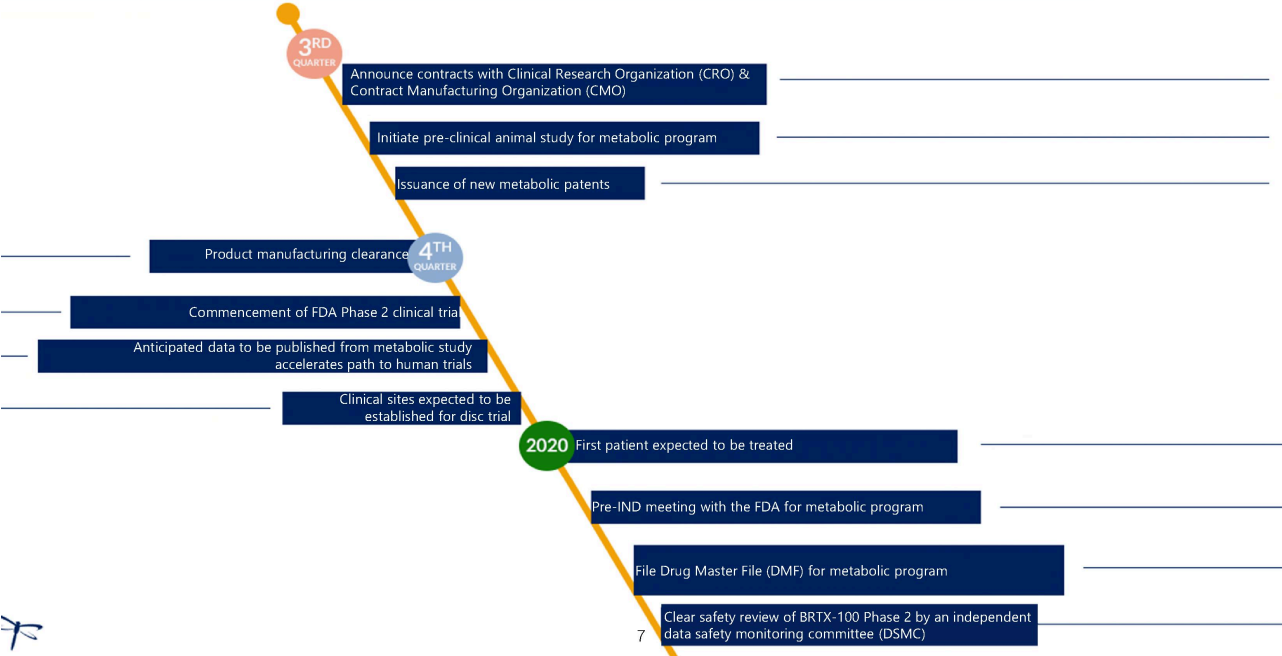
- Lead investigational therapeutic product
- Autologous (patient's own) cell-based biologic
- Hypoxic (low oxygen) cultured, bone marrow-derived
- Single intradiscal injection – anticipated 30 minute in-office procedure
- Prior human data provides insight into the potential safety and efficacy of BRTX-100
- FDA authorized commencement of Phase 2 clinical trial
- Large growing market with few comparable autologous therapies

METABOLICS
THERMOSTEM®

- Cell-based therapy to target obesity, type 2 diabetes and other metabolic disorders using brown adipose derived stem cells
- "Off the shelf" cell-based therapy
- Library of human adipose (fat) tissue and cells
- Initial proof of concept completed in small animal model featured in peer-reviewed publication
- Patent portfolio, issued patents in the U.S., Australia and Japan
- Large markets with multiple co-morbidities



NEAR-TERM GOALS



In May 2018, Defined Health (a bio-consulting company) conducted a company sponsored blinded study with relevant key opinion leaders to provide an independent review of BRTX-100

Key Findings Include:



- Stem-cell therapies have “great potential” to treat cLDD (and related therapeutic areas)
- KOLs had positive reactions to preclinical/clinical data and were “optimistic that the clinical data presented to date is likely to be mirrored in the future [trials]”
- 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 anticipate that, if approved, **BRTX-100** would be “integrated into the standard of care of eligible cLDD patients”

SCIENTIFIC ADVISORY BOARD

WAYNE MARASCO, MD, PhD

Chairman of SAB

Wayne Marasco, M.D., Ph.D. is a principal faculty member of Harvard Stem Cell Institute as well as a Professor in the Department of Cancer Immunology & AIDS at the Dana-Farber Cancer Institute and a Professor of Medicine at Harvard Medical School.

JASON LIPETZ, MD

Chairman of SAB Sub Committee -
Disc Advisory Board

Dr. Lipetz is chief of Spine Medicine for the Northwell Health Spine Center and the founder of Long Island Spine Rehabilitation Medicine.

HARVINDER SANDHU, MD

Member - Disc Advisory Board

Dr. Harvinder Sandhu is an orthopedic spine surgeon at the Hospital for Special Surgery, specializing in minimally invasive spine surgery, endoscopic spine surgery, microsurgery, computer-assisted surgery, and the study and use of spinal biologics.

GERALD A. MALANGA, MD

Member - Disc Advisory Board

Dr. Malanga is the Founder and Partner of New Jersey Sports Medicine, LLC and New Jersey Regenerative Institute in Cedar Knolls, New Jersey and President of Interventional Orthopedic Foundation.

WAYNE OLAN, MD

Clinical Director of
Regenerative Disc / Spine Program

Dr. Olan is a board-certified Interventional Neuroradiologist and the director of Endovascular and Minimally Invasive Neurosurgery in Washington, D.C. at The George Washington University Medical Center.

CHRISTOPHER PLASTARAS, MD

Member - Disc Advisory Board

Dr. Plastaras is MossRehabs' Clinical Director of Musculoskeletal Spine & Sports Rehabilitation Medicine.

JOY CAVAGNARO, PHD

Member

Dr. Joy Cavagnaro is currently the President and Founder of Access BIO, L.C., located in Boyce, Virginia, a company specializing in science-based regulatory strategies. Dr. Cavagnaro held positions with the FDA Center for Biologics Evaluation and Research (CBER), for a decade.

NAIYER IMAM, MD, MSC

Member

Naiyer Imam, M.D. is serving as the Chairman and President of First Medicine, Inc, an International telemedicine corporation dedicated to virtual physician services and chronic disease management.

IMPACT ON PUBLIC HEALTH & COST ASSOCIATED WITH NATIONAL OPIOID CRISIS

Curbed National Life Expectancy (age 25-54)

- 99% of global consumption of hydrocodone occurs in the United States (4.6% of the world's population) and 83% for oxycodone ¹
- The US leads the world in per capita consumption, twice as much as second ranked Canada ¹
- 30,000 Americans die from overdose annually ¹.
- Enough prescribed in US in 2012 for every adult to have a bottle of pills.
Pain (Musculoskeletal / Spine Prevails) : opioids – heroin – fentanyl / synthetics ¹



1. <https://pdfs.semanticscholar.org/fb86/a560d0e6250d4bc2e553731d9dc0df9be644.pdf>
2. https://www.cdc.gov/dhdds/data_statistics/fact_sheets/fs_heart_disease.htm
3. <https://www.fightcancer.org/sites/default/files/Costs%20of%20Cancer%20-%20Final%20Web.pdf>
4. <https://care.diabetesjournals.org/content/diacare/early/2018/03/20/dci18-0007.full.pdf>
5. <https://www.thegoodbody.com/chronic-pain-statistics/>

Healthcare Costs

Total annual pain costs
(healthcare / lost productivity) approximately
\$600 Billion ⁵

Double annual cost of heart disease ²

Greater than combined cancer & diabetes ⁴

Leading causes of recurrent / persistent pain
in US workforce⁵:

- Headache
- Back Pain
- Neck Pain

LARGE AND GROWING MARKET OPPORTUNITY



250 MILLION¹

American
adult population



25 MILLION¹

American adults with
chronic lower back
pain prevalence



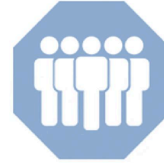
12 MILLION¹

American adults with
diagnosed and treated disc
degeneration



5.6 MILLION¹

Americans have pain
caused by a protruding
or injured disc



BETWEEN
**500,000
& 1 MILLION**
Invasive Surgical Procedures
per year



1. Trinity Partners Report, "Degenerative Disc Disease US Market Assessment (Phase I)," Feb. 2016, Slide 9 of report.

STANDARD OF CARE: CLINICAL AND ECONOMIC PROBLEM

CONSERVATIVE TREATMENTS OFTEN RECURRENT



ORAL MEDICATION TREATMENT
\$1,000 - \$2,000 ^{1, 4}
Annually



INJECTION TREATMENT
\$8,000 ³
Annually
\$2,000 per injection,
2 injections per treatment - semi-annual treatment



PHYSICAL MEASURES
\$20,000 ²
Annually
\$200 per sessions x 2 sessions per week

SURGICAL TREATMENTS WITH RE-OP RATES OFTEN 10-20%



SPINAL FUSION SURGERY
\$110,000 ^{1, 5}



DISCECTOMY
\$20,000 - \$50,000 ²



DISC REPLACEMENT SURGERY
\$80,000 - \$150,000 ²

THE **BRTX-100** DIFFERENCE

A single treatment using
BRTX-100 is justifiable
based on the cost of alternatives

Compares favorably to
conservative treatment
costs, which persist for
years

Less expensive than the most
common surgical procedures

1. <https://www.debt.org/medical/hospital-surgery-costs/>

2. <http://health.costhelper.com/degenerative-disc.html>

3. <https://www.mdsave.com/procedures/epidural-steroid-injection/d583f9c4>

4. <https://www.sciencedirect.com/science/article/pii/S0091743515001036?via=ih3dihub>

5. Buttacavoli FA, Delamarter RB, Kanim LE. Cost comparison of patients with 3-level artificial total lumbar disc replacements versus 360° fusion at 3 contiguous lumbar vertebral levels: an analysis of compassionate use at 1 site of the US investigational device exemption clinical trial. *SAS J*. 2010;4(4):107-114. Published 2010 Dec 1. doi:10.1016/j.esas.2010.07.002

FDA Cleared IND 17275: Phase 2 Randomized, Controlled Study Design in Patients with cLDD

Study Design and Patient Population

- Study includes 99 subjects (randomized 2:1 BRTX-100 to placebo)
- 40,000,000 cells/dose
- Included subjects will have only one symptomatic diseased disc
- Primary efficacy endpoint at 12 months, F/U at 24 months
 - 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 a Visual Analogue Scale (VAS)
- Subjects must have current diagnosis of cLDD, typical pain with degeneration of a single disc confirmed by history, exam, radiography, or other acceptable means
- Subjects will have exhausted previous conservative non-operative therapies

Primary Endpoints:

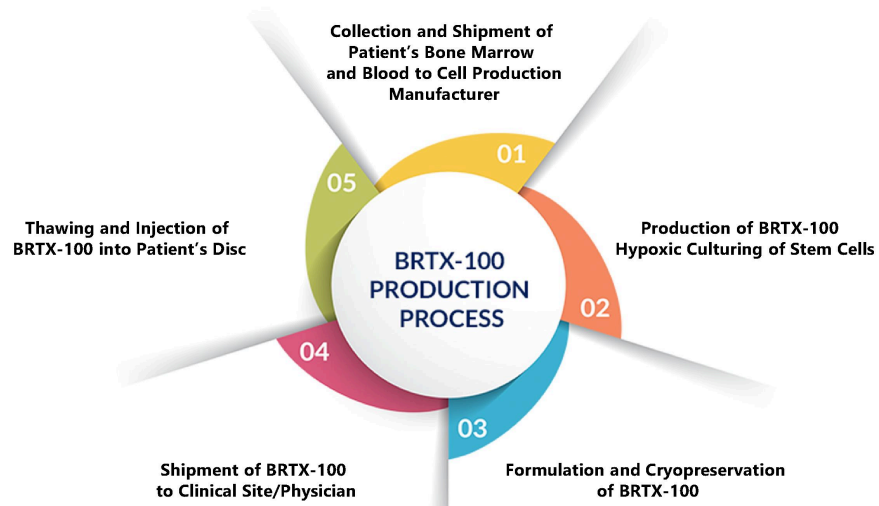
Primary Outcome Measure: Safety

Efficacy Endpoint: The efficacy endpoint is clinical response, defined as at least a 30% decrease in pain as measured on the VAS scale and at least a 30% increase in function based on the ODI at Week 52

Secondary Efficacy Endpoint:

- Clinical response at 12 months
- Changes from baseline in pain as assessed with the (VAS) score and function (ODI) at Weeks: 2, 12, 26, 52, 104
- Changes from Baseline in function as assessed with the ODI at Weeks 2, 12, 26, 52, 104
- Changes from Baseline in function as assessed by Roland Morris Disability Questionnaire (RMDQ) at Weeks: 26, 52, 104
- Changes from Baseline function as assessed by Functional Rating Index (FRI) at Weeks: 12, 52, 104
- Changes from Baseline Quality of Life assessment at (SF-12 questionnaire) scores at Weeks: 2, 12, 26, 52, 104

BRTX-100 PRODUCTION PROCESS



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



- 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.



COMPETITIVE LANDSCAPE



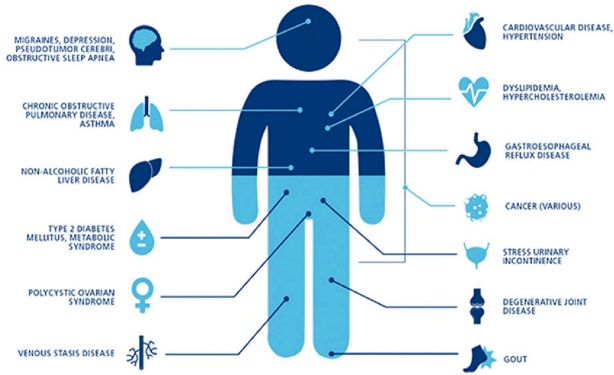
BRTX-100 ADVANTAGES

- Autologous cells means low to no risk of rejection, greater safety profile (introduction of viral/genetic), potentially streamlined regulatory path
- Hypoxic culturing creates increased cell proliferation, greater plasticity, increased paracrine effect and increased cell survival after application
- Autologous platelet lysate provides growth factors that interact with the cells, allowing for better cell survival
- Low to no risk of safety concerns related to immunological and zoonotic (animal to people) transmission
- Strong runway for value creation with successful clinical results

PRODUCT & DESCRIPTION	BRTX-100 adult stem cell biologic, administered via anticipated 30-minute in-office intradiscal injection	MPC-06-ID: adult stem cell biologic, administered via 30-minute outpatient intradiscal injection
KEY ATTRIBUTES	Hypoxic cultured – in low oxygen environment (5%)	Normoxic cultured – with normal oxygen environment (~20%)
	Autologous – uses patients own stem cells	Allogeneic – uses human derived stem cells (not from patient)
	Autologous Platelet Lysate Carrier	Hyaluronic Acid Carrier
	100% Animal-Free Manufacturing Process	Animal Products Used in Manufacturing Process
STAGE OF DEVELOPMENT	Phase 2 clinical trial approved under active IND 17275	Phase 3 clinical trial currently enrolling participants



METABOLIC PROGRAM



THERMOSTEM[®] PROGRAM

- “Off the shelf” allogeneic cell-based therapy targeted to treat obesity, Type 2 diabetes and metabolic disorders using brown fat stem cells
- Brown fat has been shown to regulate metabolic homeostasis in the body
- Large library of human brown adipose tissue (BAT), white adipose tissue (WAT) and brown adipose-derived stem cells (BADSC)
- Initial proof of concept completed in small animal model
- Related BAT patent portfolio, including issued patents in the U.S., Australia and Japan
- Platform program for the development of cell and small molecule therapies

INTELLECTUAL PROPERTY



PROGRAM:
DISC/SPINE



PATENT TITLES

- Methods and Compositions to facilitate repair of avascular tissue
- Surgical Methods and Compositions to facilitate repair of avascular tissue
- Therapeutic Delivery Device

OF APPLICATIONS

- 4

STATUS

- 3 PENDING
- 1 GRANTED



PROGRAM:
METABOLIC
(THERMOSTEM®)

PATENT TITLES

- Brown Fat Compositions and Methods
- Human Brown Adipose Derived Stem Cells and Uses
- Non-naturally occurring three-dimensional (3D) Brown Adipose-Derived Stem Cell aggregates and methods of generating and using the same


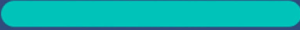






OF APPLICATIONS

- 15

STATUS

- 11 PENDING
- 4 GRANTED

RESEARCH & DEVELOPMENT

PRODUCT	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
BRTX-100 Hypoxic BM-MSC	 CHRONIC LUMBAR DISC DISEASE				
BADSC <i>THERMOSTEM</i> ®	 TYPE 2 DIABETES				
	 OBESITY				
	 POLYCYSTIC OVARIAN SYNDROME				



LEADERSHIP



MARK WEINREB
CEO & PRESIDENT

Mark Weinreb has served as CEO of the Company since October 2010 and has significant experience in running public companies. He previously served as the Chief Executive Officer and Chairman of the Board of Directors of Phase III Medical, Inc. where he orchestrated the acquisition of an adult stem cell collection company that became NeoStem, Inc. (now Caladrius Biosciences, Inc. – NASDAQ: CLBS), a public international biopharmaceutical company engaged in, among other things, adult stem cell-related science. From June 2006 through October 2009, Mr. Weinreb served as President and a director of NeoStem.

In 1976, Mr. Weinreb joined Bio Health Laboratories, Inc., a state-of-the-art medical diagnostic laboratory providing clinical testing services for physicians, hospitals, and other medical laboratories. As an owner and Chief Operating Officer, he oversaw all technical and business facets, including finance and laboratory science technology. Bio Health Laboratories was acquired by Enzo Biochem (NYSE: ENZ). Mr. Weinreb received a Bachelor of Arts degree from Northwestern University and a Master of Science degree in Medical Biology from C.W. Post, Long Island University.



LANCE ALSTODT
EVP & CHIEF STRATEGY OFFICER

Lance Alstodt joined BioRestorative Therapies as its Executive Vice President and Chief Strategy Officer in October 2018. Mr. Alstodt is responsible for developing and refining the Company's overall strategy and implementing investment decisions. Mr. Alstodt brings over 25 years of experience in operations, strategy and mergers & acquisitions. Mr. Alstodt was the Founder and CEO of MedVest Consulting Corporation ("MedVest"), an advisory and capital firm focused exclusively within the healthcare sector, focusing on growth and channel strategy, strategic planning, merger and acquisition support and investor activities. Prior to MedVest, Mr. Alstodt was a career investment banker with over 25 years of experience in healthcare investment banking, including mergers and acquisitions. In 2011, Mr. Alstodt joined Leerink Partners as Managing Director to help lead its medical technology sector. Mr. Alstodt brings significant domain experience within the orthopedic and spine specific sectors. From 2008-2011, Mr. Alstodt was a Managing Director and Head of Medical Technology at Oppenheimer & Co. From 2000-2008, he was a Managing Director in the Healthcare Group and Global M&A Group at Bank of America Merrill Lynch ("BAML"). Prior to BAML, Mr. Alstodt spent seven years in the Global M&A Group at J.P. Morgan Chase, where he worked extensively on acquisitions, leveraged buyouts, private and public financings, exclusive sales and general advisory assignments. Mr. Alstodt received a B.A. in Economics from the State University of New York at Albany, with a secondary concentration in Finance and Marketing.



FRANCISCO SILVA
CHIEF SCIENTIST & VP, R&D

Francisco Silva joined BRT in April 2011 and is Vice President of Research and Development. Mr. Silva is responsible for all laboratory operations and is involved in the development and growth of our stem cell programs. Mr. Silva previously served as Chief Executive Officer of two companies engaged in the commercialization of human-based biologics for both research and therapeutic applications. From 2003 to 2007, Mr. Silva was Vice President of Research and Development for PrimeGen Biotech LLC, a company engaged in the development of cell-based platforms. He was responsible for the development of experimental designs that focused on germ line reprogramming stem cell platforms.

Mr. Silva has taught courses in biology, anatomy and advanced tissue culture at California State Polytechnic University. He has obtained a number of patents relating to stem cells and has had numerous articles published with regard to stem cell research.

Mr. Silva graduated from California State Polytechnic University with a degree in Biology.

He also obtained a Graduate Presidential Fellowship and MBRS Fellowship from California State Polytechnic University.

BOARD OF DIRECTORS

A. JEFFREY RADOV

Director

Mr. Radov is an entrepreneur and businessman with 35 years of experience in media, communications and financial endeavors. He was a founding executive of About.Com, Inc., an online information source, and was its EVP of Business Development and Chief Financial Officer from its inception. Previously, Mr. Radov was the Director of Finance at Rainbow Programming Enterprises, a joint venture among Cablevision Systems Corporation, Cox Broadcasting and Daniels & Associates. Prior to that, he was Director of Marketing at Winklevoss & Associates.

CHARLES RYAN, JD, PHD

Director

Dr. Ryan is an experienced executive with an extensive background in pharmaceuticals and biotechnology, including strategic planning, IP, and research and business development. He is presently the CEO of Neurotrope Bioscience, Inc. Previously, Dr. Ryan was the CEO of Orthobond, Inc. and served as the Vice President, General Counsel for Cold Spring Harbor Laboratory. Prior to this, he spent over a decade at Forest Laboratories as its Senior Vice President & Chief Intellectual Property Counsel.

PAUL JUDE TONNA

Director

Mr. Tonna serves as Molloy College's Executive Director for The Energeia Partnership, a leadership academy dedicated to identifying and addressing the serious, complex and multi-dimensional issues challenging the Long Island, New York region. He is Managing Partner of Praxis Public Relations, Inc., a business consulting and government relations company. Mr. Tonna served from 1994 to 2005 as a Suffolk County Legislator and for three years, his fellow legislators chose him to lead the Suffolk County Legislature as its Presiding Officer.

JOHN DESMARAI, JD

Director

John Desmarais is the founding partner of Desmarais LLP, an Intellectual Property trial boutique that specializes in jury trials and alternative fee structures. After practicing in the area of intellectual property litigation and counseling for several years at Fish & Neave, in 1992, he left private practice to serve as an Assistant United States Attorney. After leaving the government, Mr. Desmarais returned to Fish & Neave. In 1997, he joined the New York office of Kirkland & Ellis as a partner. In 2010, Mr. Desmarais left to found Desmarais LLP.

ROBERT CATELL

Director

Robert B. Catell is an accomplished global energy industry leader and is the recipient of the 2009 United States Energy Award. Mr. Catell began his career at Brooklyn Union Gas, a small regional gas distribution utility that he built into one of the largest electric power/natural gas companies in the United States. He also orchestrated the merger of KeySpan Energy with National Grid, a strategic move to foster the growth of a world-scale energy company. Following National Grid's acquisition of KeySpan Corporation, Mr. Catell became Chairman of National Grid, U.S. and Deputy Chairman of National Grid plc.



COMPANY HIGHLIGHTS

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- Disruptive Platform Technology in Cellular Therapy
 - Addressing Large Unmet Needs; Multi-Billion Dollar Market Opportunities
 - Exploring Diverse Pipeline Opportunities within and outside of Spine and Obesity
 - We Believe that Preliminary Data May Be Indicative of Positive Trial Outcomes
 - Many Clinical & Regulatory Accomplishments
 - Intellectual Property Protection
 - Multiple Value Enhancing Inflection Points
 - Experienced Management Team & Scientific Advisory Board
 - Exploring Key Strategic Partnership Opportunities



biorestorative therapies

"BIOLOGIC PROBLEMS - BIOLOGIC SOLUTIONS"

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