

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

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**FORM 8-K**

**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report: April 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)
<hr/>		
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))
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**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 April 30, 2019 in presentations about the Company’s business. The Company intends to use the Presentation Materials, possibly with modification, at the 2019 American Society of Gene and Cell Therapy being held from April 29, 2019 through May 2, 2019 and may use the Presentation Materials 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 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](http://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.

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## 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: April 30, 2019

By: /s/ Mark Weinreb

Mark Weinreb

Chief Executive Officer



**ASGCT 2019– General Presentation**

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# Disclaimer

STATEMENTS IN THIS INVESTMENT SUMMARY ("SUMMARY"), INCLUDING THE INFORMATION SET FORTH AS TO THE FUTURE FINANCIAL OR OPERATING PERFORMANCE OF BIORESTORATIVE THERAPIES, INC. (THE "COMPANY" OR "BRT"), THAT ARE NOT CURRENT OR HISTORICAL FACTUAL STATEMENTS MAY CONSTITUTE "FORWARD LOOKING" INFORMATION WITHIN THE MEANING OF 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 SUMMARY. READERS SHOULD NOT PLACE UNDUE IMPORTANCE ON FORWARD LOOKING STATEMENTS AND SHOULD NOT RELY UPON THIS INFORMATION AS OF ANY OTHER DATE.

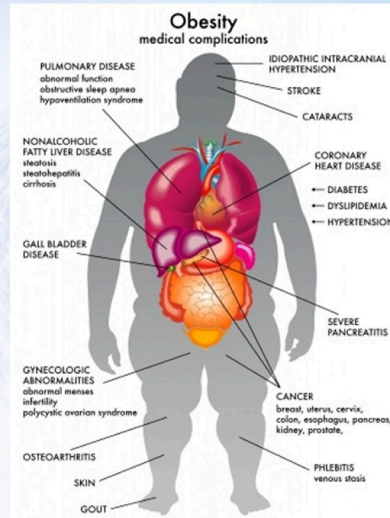
FORWARD LOOKING STATEMENTS INVOLVE KNOWN AND UNKNOWN RISKS, UNCERTAINTIES AND OTHER IMPORTANT FACTORS THAT COULD CAUSE OUR ACTUAL RESULTS, PERFORMANCE OR ACHIEVEMENTS, OR INDUSTRY RESULTS, TO DIFFER MATERIALLY FROM OUR EXPECTATIONS OF FUTURE RESULTS, PERFORMANCE OR ACHIEVEMENTS EXPRESSED OR IMPLIED BY 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, 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. 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 SUMMARY, 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.

THE DESCRIPTION OF THE COMPANY AND ITS BUSINESS IN THIS SUMMARY 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.

# Mass of BAT is Inversely Correlated with Obesity and Unhealthy Metabolism

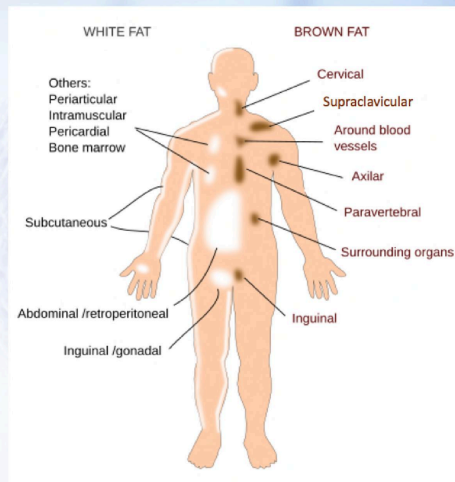
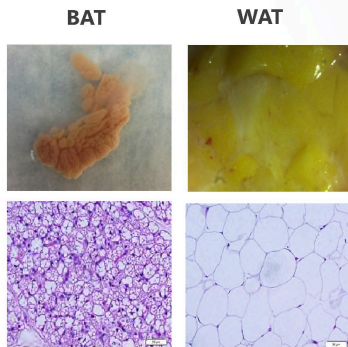
- Obesity is a worldwide epidemic
- In the U.S., 37% of adults and 16.9% of children and adolescents are obese
- Obesity is a risk factor for insulin-resistance, metabolic syndrome, and cardiovascular disease
- In 2012, the total estimated cost of diagnosed diabetes was \$245 billion



# Brown Adipose Tissue – Novel Therapeutic to Treat Obesity and Related Metabolic Disorders

## BAT is a specialized adipose tissue

- High metabolic activity
- Able to dissipate energy, fatty acids, glucose to produce heat
- Present in adult humans in small quantities

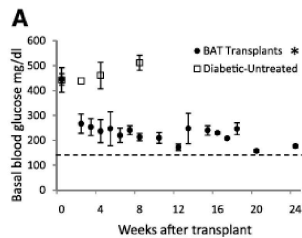


# Pre-clinical studies demonstrate that BAT transplants have therapeutic benefits

ORIGINAL ARTICLE

## Reversal of Type 1 Diabetes in Mice by Brown Adipose Tissue Transplant

Subhadra C. Gunawardana and David W. Piston

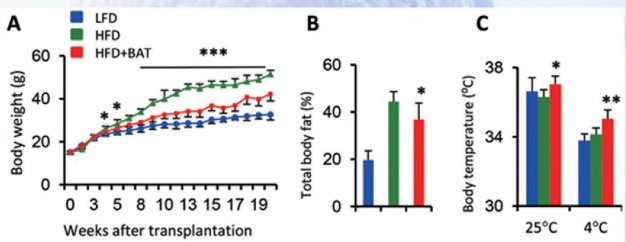


LETTER TO THE EDITOR

## Brown adipose tissue transplantation improves whole-body energy metabolism

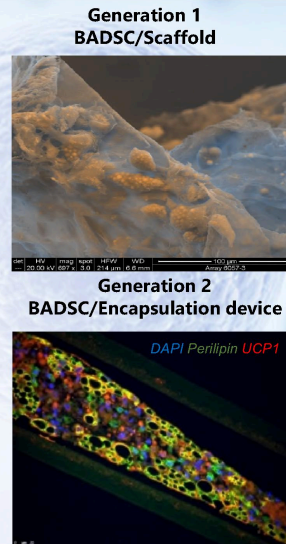
Cell Research (2013) 23:851-854  
© 2013 BICD, SIBS, CAS. All rights reserved 1001-9602/13 \$ 32.00  
www.nature.com/cr

Cell Research (2013) 23:851-854. doi:10.1038/cr.2013.64; published online 7 May 2013

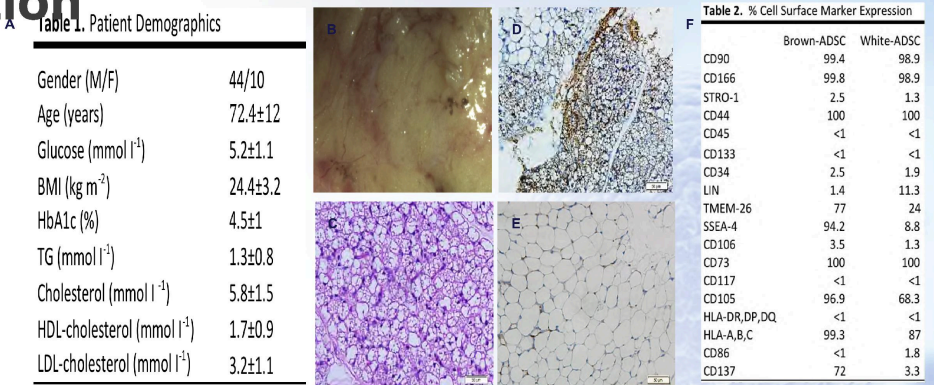


## ThermoStem® - development of a bioengineered human BAT construct

- BRT has procured a large collection of human brown and white adipose tissues and cellular library
- Isolated and characterized a novel allogeneic brown adipose stem cell population
- **Generation 1: BADSC/Scaffold**
  - Successful proof of concept completed in small animals
  - Published in Stem Cells in 2014: "Metabolically active human brown adipose tissue derived stem cells"
- **Generation 2: BADSC/Encapsulation device**
  - Selection of optimal BADSC line from library
  - Development of xeno-free and chemically defined culture conditions allowing for the generation of clinically significant numbers of functional brown adipocytes (>90%)
  - Testing of biocompatible, immune protective and retrievable encapsulation device (FDA cleared for human use) for safe and efficient delivery of bioengineered BAT

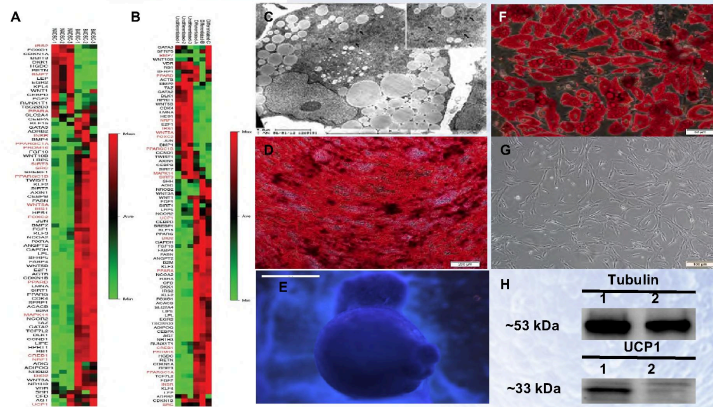


# Generation 1-Tissue procurement/cell isolation



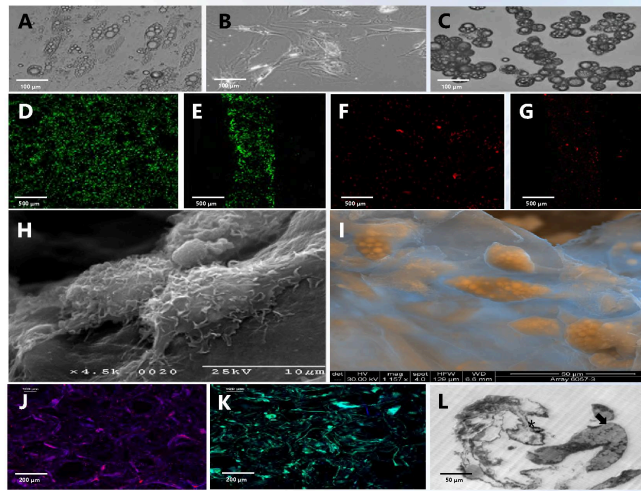


# Generation 1-Cell characterization



**Fig. 2.** (A) Gene expression profile comparing undifferentiated brown adipose derived stem cells to undifferentiated white adipose derived stem cells derived from subcutaneous adipose tissue. Genes in red are associated with brown fat phenotype (B) Gene expression profile comparing undifferentiated brown adipose derived stem cells to differentiated brown adipocytes. (C) Transmission electron microscopy of 21 day brown adipocyte differentiation induced with FNDC5 demonstrate multiocular intracytoplasmic lipid vacuoles. (D) Alizarin red staining of brown adipose derived stem cells induced to undergo osteogenesis. (E) Alcian blue staining of brown adipose derived stem cells directionally differentiated into chondrocytes. (F) Fatty acid binding protein 4 (FABP4) immunocytochemistry of brown adipose derived stem cells induced to undergo white adipogenesis. (G) Undifferentiated BADSCs. (H) Western blot 21 days post FNDC5 induction. Lane 1 brown adipose derived stem cells directionally differentiated into brown adipocytes. Lane 2 non-FNDC5 cells

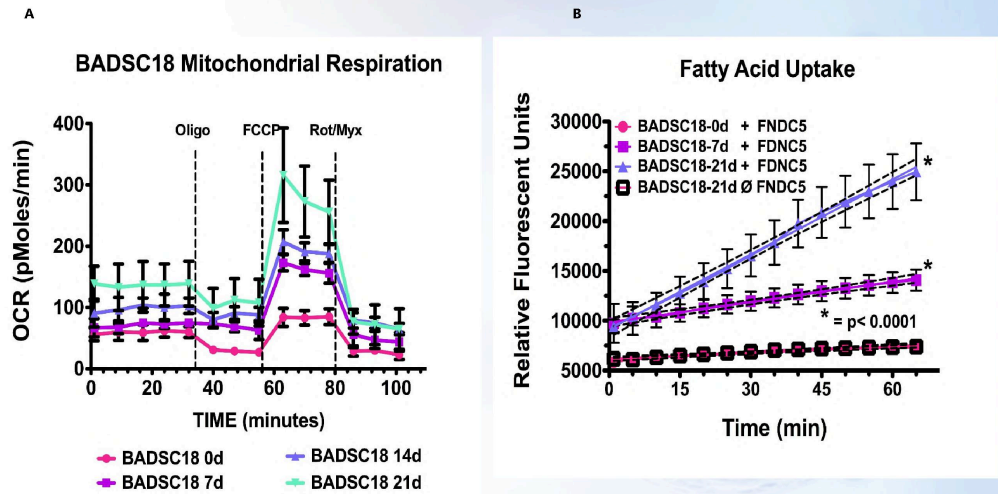
# Generation 1-Scaffold delivery



**Fig.4.** *In vitro* culture of BADSCs. Representative bright field images of differentiated cells (**A**) prior to passaging and post-passaging and centrifugation (**B**) adherent and (**C**) floating in the supernatant. Representative confocal images of live BADSCs stained with Calcein AM on the (**D**) surface and (**E**) through the center of 3D scaffolds, and dead cells stained with propidium iodide on the (**F**) surface and (**G**) through the center. (**H-I**) Representative scanning electron micrographs of BADSCs on scaffolds in a (**H**) non-differentiated state and (**I**) 21 days directionally differentiated towards brown adipocytes on scaffolds. (**J-K**) Representative confocal images of (**J**) Actin (red) and DAPI (blue) staining and (**K**) Lipid (FABP4-green) and DAPI (blue) staining of brown fat-differentiated BADSCs in 3D scaffolds. (**L**) Representative bright field image of a histology section of differentiated brown fat cells (arrow) within a scaffold (\*) after 21 days. N=3 separate scaffolds or 3 separate wells during 2D culture.

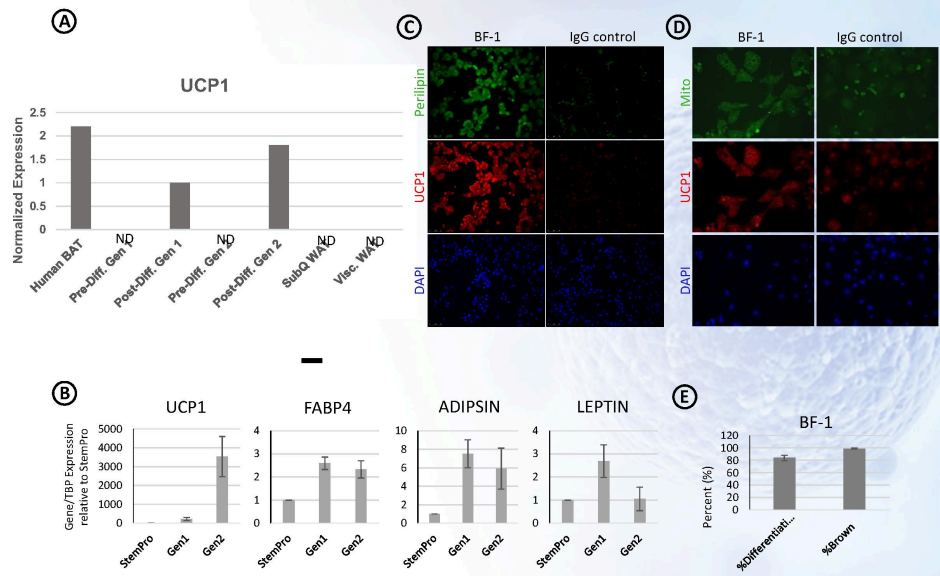


# Generation 1-Metabolic function

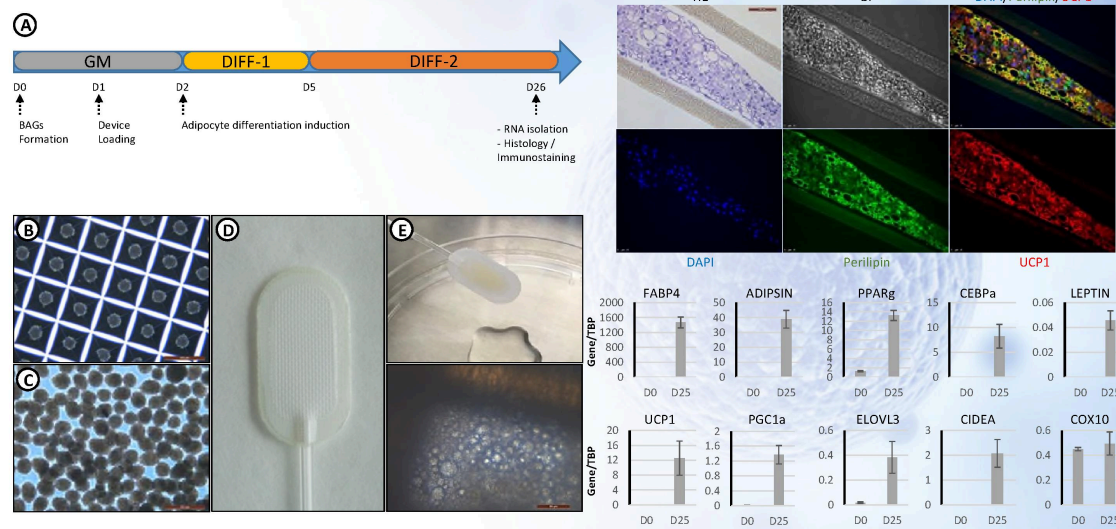


**Fig. 3. (A)** Functional mitochondrial respiration assay of brown adipose derived stem cells differentiated into brown adipocytes at 7, 14 and 21 days post differentiation. **(B)** Fatty acid uptake of brown fat differentiated brown adipose derived stem cells at 7, 14 and 21 days post differentiation.

# Generation 2-UCP-1 Expression



# Generation 2-Delivery Device Loading/Human BAT Construct



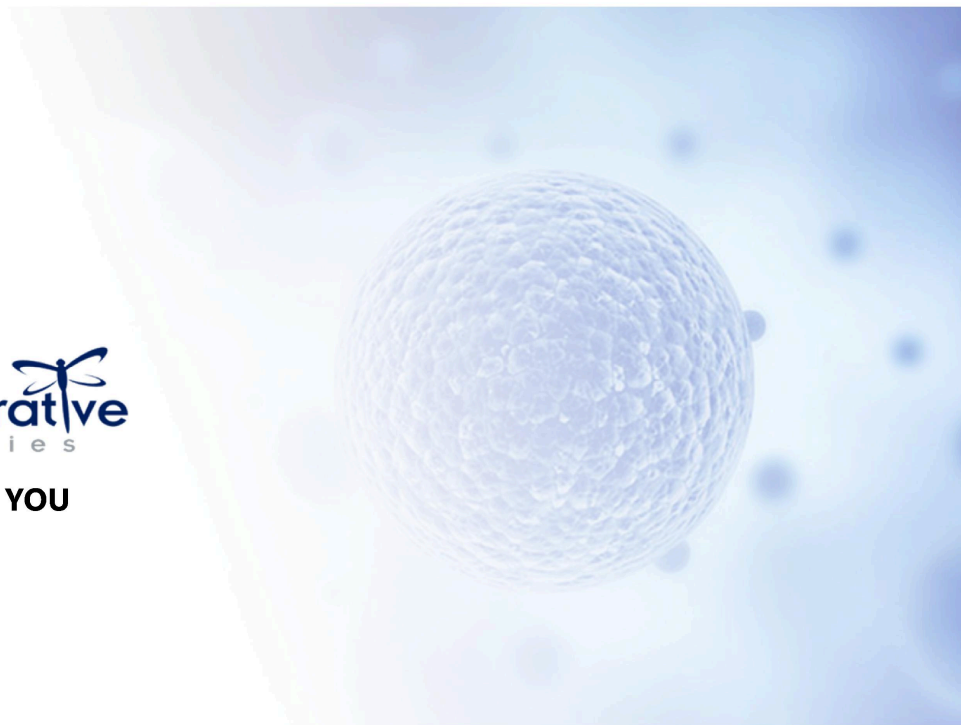
# Next Steps

- Small animal model using generation 2 device.
- Explore other delivery systems
- Study secretome of BADSC
- Explore use for other indications





**THANK YOU**



## Abstract

The prevalence of obesity and metabolic disorders has increased dramatically over the past decades and has become a pandemic. By 2030, more than 50% of Americans will suffer from obesity, resulting in over 500 billion dollar loss in economic productivity. Obesity is a major risk factor for type II diabetes mellitus, hypertension, cardiovascular disease, osteoarthritis, and certain forms of cancer. Current therapeutic approaches, such as caloric restriction and exercise, which rely mainly on patient's will power to reduce energy intake and/or increase energy expenditure, are generally of limited effectiveness in obese patients. Bariatric surgery is the only clinically proven therapy in terms of weight loss and decreased morbidity and mortality in patients with a body mass index (BMI) over 40; however it has associated risks, high costs and requires proper management of patient's nutrition and physical activity. Alternative ways to increase energy expenditure could augment the current therapeutic options for treating obese patients and ultimately lead to successful clinical outcomes. Targeting brown adipose tissue (BAT) in humans, in order to increase BAT mass and/or activity, has emerged as a potential way to increase energy expenditure by energy wasting. Due to the lack of transplantable BAT, tissue engineering of metabolically active transplantable BAT has recently emerged.

We have previously described the isolation of human brown adipose derived mesenchymal stem cells (BADSCs) from mediastinal adipose tissue. We have demonstrated that these cells can be expanded in culture and differentiated into functional brown adipocytes *in vitro*. Additionally, we demonstrated that *in vivo* transplantation of differentiating BADSCs in a biological scaffold significantly reduced blood glucose levels and body weight in obese mice. In the present study, we have characterized multiple BADSCs populations isolated from mediastinal and cervical anatomical locations. We have also evaluated *in vitro* differentiation potential and their ability to express brown specific markers using a xeno-free chemically defined medium in an FDA approved immunoprotecting encapsulation medical device as a delivery system for bioengineered BAT transplantation.

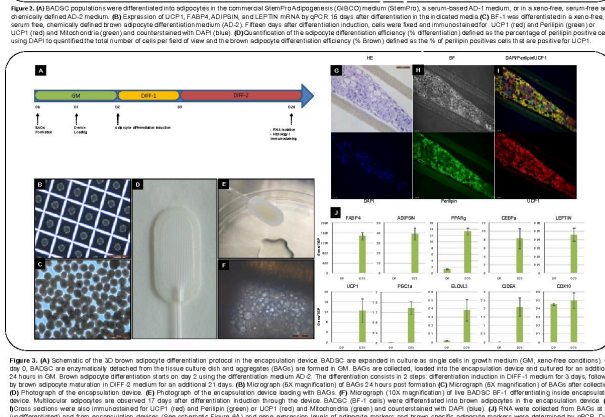
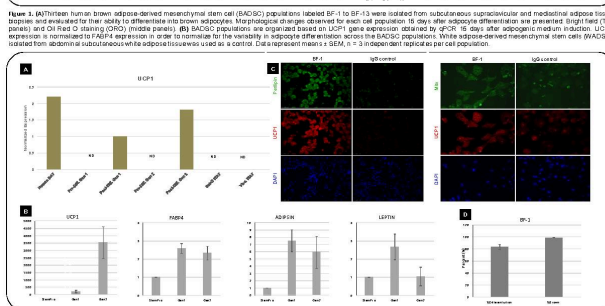
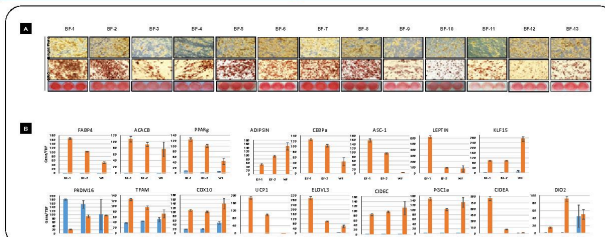
## Methods

Brown adipose derived stem cells (BADSCs) were isolated from fresh brown adipose tissue and were cultured for up to 3 passages. Adipocyte differentiation was induced by addition of the brown adipocyte differentiation medium 1 (AD-1), adipocyte differentiation medium 2 (AD-2), or the commercially available StemPro™ adipogenesis differentiation kit (Gibco). AD-1 is a serum based differentiation medium AD-2 is a two-step xeno-free, serum free, chemically defined differentiation medium. BADSC aggregates (BAGs) were generated and were loaded into an encapsulation device followed by an AD-2 brown adipose induction Data from Oil Red O, flow cytometry and gene expression of brown specific markers by quantitative PCR were analyzed.

## Results

We have previously demonstrated the isolation of a mesenchymal stem cell population from brown adipose tissue. In the following study we have further characterized them *in vitro*, and their ability to differentiate into UCP-1 expressing brown adipocytes. Under xeno-free and chemically defined conditions we have successfully developed a protocol to generate greater than 80% brown adipocytes and load them into a delivery device for *in vivo* transplantation. This represents a promising source of transplantable BAT to increase energy expenditure and for the treatment of metabolic disorders

## Figures



## Conclusion

- 1). Developing a novel bioengineered brown adipose tissue transplant may offer a new paradigm for treating obesity and associated metabolic disorders. The disorders cause serious health concern affecting over 1/3 of adults and 1/6 of children in the United States, which include psychological, orthopedic and sleep disorders, genetic syndromes, chronic inflammation, high blood pressure, hyperinsulinaemia, insulin resistance, Type II diabetes, cardiovascular disease, metabolic syndrome, and more.
- 2). Our technology will ultimately serve as a robust platform for drug discovery and development allowing researchers to transplant engineered cells that are accessible for monitoring with common clinical imaging systems and easily retrievable for late stage pre-clinical screening of lead compounds, perform cellular pathway assays, biochemical, molecular and immunocytochemistry studies.
- 3). This study enables a better understanding of tissue-engineering principles to brown adipose biology and further our mechanistic understanding of the factors required for brown/beige fat function and development.