

677 Ala Moana Boulevard, Suite 1100 • Honolulu, HI 96813 • (808) 539-9331

"an emerging leader in adipose derived cell therapy"



Highlights

Tissue Genesis focuses on the clinic:

- Methodist Hospital, San Antonio, TX
- McGowan Institute, Pittsburgh, PA
- Dr. Kotaro Yoshimura, University of Tokyo

Tissue Genesis receives \$3.6 million contract from the U.S. Army for Peripheral Vascular Disease work

Nationwide collaborations for NIH "Challenge Grants"

Study in the Dominican Republic on adipose derived stem cell treatment for Multiple Sclerosis

First Quarter 2009 Financial Statements prepared by Director of Finance, Kerry Nagai

Table of Contents

Letter from CEO	1
Are there \$\$'s in the Stimulus Package for Tissue Genesis?	2
In the Field Report	3
Financial Statements	4



Letter from the CEO

During the first half of 2009, Tissue Genesis focused on moving its know-how and technology into the clinical environment in humans.

As mentioned in our previous shareholder update, Tissue Genesis has been participating with our consortium partner, SpineSmith, LP in an Internal Review Board (IRB) clinical study at Methodist Hospital in San Antonio, Texas. Under the direction of orthopedic surgeon Dr. Robert Johnson, the team performs spinal fusion procedures using adipose derived stem cells. Dr. Johnson's study will compare the results of bone marrow stem cells versus adipose derived stem cells used in the procedure. We are optimistic regarding Dr. Johnson's findings and hope to demonstrate the advantages of adipose derived stem cells over the already accepted bone marrow stem cell treatment.

Tissue Genesis is also supporting Dr. Peter Rubin at the University of Pittsburgh's McGowan Institute in collecting data to begin a clinical study with the Department of Defense for wound repair.

Tissue Genesis plans to

conduct its own clinical studies in several hospitals across the nation using our ePTFE vascular graft for Peripheral Vascular Disease. We currently have an application in process with the Food and Drug Administration for approval to proceed.

Additionally, we have a study planned to begin in the second half of 2009 with Dr. Kotaro Yoshimura from the University of Tokyo, a renowned expert in aesthetics applications of adipose derived cell therapies for reconstructive surgeries. Twenty patients are planned for facial and breast reconstruction.

Besides the clinical front, the company is actively pursuing opportunities in stem cell research presented by President Obama's administration. Later in this report you will see a series of grant proposals to the National Institute of Health (NIH) and National Institute of Standards and Technology (NIST), in which Tissue Genesis is a collaborator.

This spring, Tissue Genesis was awarded another \$3.6 million contract with the U.S. Army for work in Peripheral Vascular Disease. This represents continued confidence by the U.S. Army in our work. To date, we

have received \$1.6 million on this contract.

At the end of 2008 we closed \$1.4 million in the first phase of our Series C Round. With authorized shares still remaining we expect to have the next phase of the Series C offered this fall. In a previous update to shareholders, we explained the situation with the State of Hawaii regarding the Act 221. The bill, SB199, was passed by the legislature and is on the Governor's list for potential vetoes. We will need to wait until that is finalized before our Series C round is re-opened. The current legislation does not affect investments made prior to 2009. We appreciate your previous investments and encourage you to contact us if you have any questions or continuing investment interest.

In these uncertain economic times and difficult capital markets, we will continue to manage our cash flows closely.

We are proud to be an emerging leader in adipose derived cell therapy.

Mahalo,

Are there monies for Tissue Genesis in the Stimulus Package?

Are there funds and research activities for Tissue Genesis in the stimulus package? That is a question we asked ourselves, and which prompted some initiatives that we hope to launch. In addition the potential of further funding, these activities would also allow us to demonstrate our emerging leadership in adipose derived cell therapies, and the opportunity for world class collaborations. Here is a list of the grant applications we have made thus far.

NIST/TIP White Paper

- Title: Fundamental Study of Adipose-Derived Stromal Cell Biology for Critical National Health Care Needs
- This program will allow us to evaluate ASC (Adipose Stem Cells) applications for chronic diseases
- Submitted on 3/9/09
- Projected Amount: \$9 million over five years
- Tissue Genesis Institute, LLC is the leading organization, and we are planning to work with Drs. Rocky Tuan (University of Pittsburgh) and Jeffrey Morgan (Brown University)

NIH Challenge Grant

- Title: Development of Point-of-Care Therapies for Osteoarthritis
- Broad Challenge Area: Enabling Technologies
- Specific Challenge Topic: Point-of-Care Technologies
- Submitted on 4/27/09
- Requested Amount: \$1 million over two years
- Tissue Genesis Institute, LLC is the leading organization, and Dr. Tuan will be working with us
- Expect to receive a response by August 2009

NIH Recovery Act

- Recovery Act Limited Competition: Small Business Catalyst Award for Accelerating Innovative Research (R43)
- Topic: ASCs in cancer therapies
- To be submitted by 9/1/09 (Letter of Intent to be submitted by 8/3/09)
- Available Funds: \$200,000 over one year
- Tissue Genesis Institute, LLC will be the leading organization, and will work with Dr. Michelle Matter at JABSOM (University of Hawaii Medical School)
- Expect to receive a response by February 2010

NIH Recovery Act

- Recovery Act Limited Competition: Small Business Catalyst Award for Accelerating Innovative Research (R43)
- Topic: Application of ASCs in area to be determined
- To be submitted by 9/1/09 (Letter of Intent to be submitted by 8/3/09)
- Available Funds: \$200,000 over one year
- Expect to receive a response by February 2010

Consulting in Grant Applications of Others

NIH Challenge Grant

- Title: Defining Adipose Stem and Progenitor Cells for Cardiovascular Diseases
- Submitted on 4/27/09
- Dr. Chris Cogle of University of Florida is the principle investigator

NIH Challenge Grant

- Dr. Stuart Williams and Dr. Gene Boland at Cardiovascular Innovation Institute submitted an application together on vascular regeneration using ASCs

"...allow us to demonstrate our emerging leadership in adipose derived cell therapy and the opportunity for world class collaborations..."

Board of Directors

Anton C. Krucky
Chairman
Tissue Genesis, Inc.
President and Chief Executive Officer

Thomas F. Cannon
Tissue Genesis, Inc.
Executive Vice President
Research and Development

Robert P. Hiam
HMSA
President and Chief Executive Officer

Michael Ruley
Sparkplug, Inc.
Chief Executive Officer

Jeffrey Watanabe, Esq.
Watanabe Ing LLP
Of Counsel

William P. Wiesmann, M.D.
BioSTAR, Inc.
President and Chief Executive Officer

In the Field

The purpose of this section is to highlight work being done in the field of adipose derived cell therapy. In this study, sponsored by Medistem Inc., three patients with Multiple Sclerosis (MS) were treated. Tissue Genesis was referenced in this published paper.

Link to full journal article: <http://www.translational-medicine.com/content/7/1/29>

Link to Medistem Inc. press release: <http://www.medicalnewstoday.com/articles/147531.php>

Link to MedPage Today article: <http://www.medpagetoday.com/Neurology/MultipleSclerosis/13888>

Non-Expanded Adipose Stromal Vascular Fraction Cell Therapy for Multiple Sclerosis (Excerpt)

Abstract

The stromal vascular fraction (SVF) of adipose tissue is known to contain mesenchymal stem cells (MSC), T regulatory cells, endothelial precursor cells, preadipocytes, as well as anti-inflammatory M2 macrophages. Safety of autologous adipose tissue implantation is supported by extensive use of this procedure in cosmetic surgery, as well as by ongoing studies using in vitro expanded adipose derived MSC. Equine and canine studies demonstrating anti-inflammatory and regenerative effects of non-expanded SVF cells have yielded promising results. Although non-expanded SVF cells have been used successfully in accelerating healing of Crohn's fistulas, to our knowledge clinical use of these cells for systemic immune modulation has not been reported. In this communication we discuss the rationale for use of autologous SVF in treatment of multiple sclerosis and describe our experiences with three patients. Based on this rationale and initial experiences, we propose controlled trials of autologous SVF in various inflammatory conditions.

Introduction

Adipose tissue has attracted interest as a possible alternative stem cell source to bone marrow. Enticing characteristics of adipose derived cells include: a) ease of extraction, b) higher content of mesenchymal stem cells (MSC) as compared to bone marrow, and c) ex vivo expandability of MSC is approximately equivalent, if not superior to bone marrow. With one exception, clinical trials on adipose derived cells, to date, have been limited to ex vivo expanded cells, which share properties with bone marrow derived MSC. MSC expanded from adipose tissue are equivalent, if not superior to bone marrow in terms of differentiation ability, angiogenesis stimulating potential, and immune modulatory effects. Given the requirements and potential contaminations associated with ex vivo cellular expansion, a simpler procedure would be the use of primary adipose tissue derived cells for therapy. Indeed it is reported that over 3000 horses with various cartilage and bone injuries have been treated with autologous lipoaspirate fractions without cellular expansion. In double blind studies of canine osteoarthritis statistically significant improvements in lameness, range of motion, and overall quality of life have been described.

If such approaches could be translated clinically, an easy-to-use autologous stem cell therapy could be implemented that is applicable to a multitude of indications. Indeed, this is the desire of commercial entities that are developing bench top closed systems for autologous adipose cell therapy, such as Cytori's Celution™ system and **Tissue Genesis'** TGI 1000™ platform, which are presently entering clinical trials. Unfortunately, since the majority of scientific studies have focused on in vitro expanded adipose derived cells, relatively little is known about the potential clinical effects of the whole lipoaspirate that contains numerous cell populations besides MSC. From a safety perspective the process of autologous fat grafting has been commonly used in cosmetic surgery, so at least theoretically, autologous cell therapy, with the numerous cellular populations besides MSC that are found in adipose tissue, should be relatively innocuous. However, from an efficacy or disease-impact perspective, it is important to consider the various cellular components of adipose tissue and to develop a theoretical framework for evaluating activities that these components may mediate when administered systemically. For example, while attention is focused on the MSC component of adipose tissue, the high concentrations of monocytes/macrophages, and potential impact these may have on a clinical indication is often ignored.

In this paper we will discuss the potential use of the adipose derived cells for the treatment of inflammatory conditions in general, with specific emphasis on multiple sclerosis. Due to the chronic nature of the disease, the fact that in some situations remission naturally occurs, as well as lack of therapeutic impact on long term progression of current treatments, we examine the possibility of using autologous adipose derived cells in this condition. We will discuss the cellular components of adipose tissue, the biology of these components, how they may be involved in suppression of inflammatory/immunological aspects of MS, and conclude by providing case reports of three patients treatment with autologous adipose derived cells.

Conclusion

The patients treated were part of a compassionate-use evaluation of stem cell therapeutic protocols in a physician-initiated manner. Previous experiences in MS patients using allogeneic CD34+ cord blood cells together with MSC did not routinely result in substantial improvements observed in the three cases described above. While obviously no conclusions in terms of therapeutic efficacy can be drawn from the above reports, we believe that further clinical evaluation of autologous SVF cells is warranted in autoimmune conditions.