



## **Bioheart Makes Breakthrough in Cardiovascular Therapy with Stem Cells Obtained from Fat Tissue**

[www.bioheartinc.com](http://www.bioheartinc.com)

The Bioheart Adipose Derived Stem Cells “ASC’s Treatment”:

- The Fat Tissue in the Patient’s Body is Used to Generate Adipose Derived Stem Cells (ASC’s)
- ASC’s Are Capable of Limiting Damage Due to a Cardiac Event and Promoting Additional Blood Vessel Formation
- Bioheart’s TGI 1200 System, Recovers Regenerative Stem Cells in 60 Minutes, with Minimal Operator Intervention

SUNRISE, Fla. - September 30, 2009 - Bioheart, Inc. (OTCBB:[BHRT](#)) offers yet another medical breakthrough with the next-level stem cell treatment for cardiac patients. The stem cells aid in limiting damage due to a cardiac event and promote angiogenesis or formation of new blood vessels.

Bioheart, in collaboration with Hospital de Clinicas Caracas in Caracas, Venezuela, has already begun three different studies utilizing the ASCs: surgical delivery of cells during a coronary artery bypass grafting (CABG) procedure, percutaneous delivery of cells in chronic heart ischemia and delivery of cells in critical limb ischemia.

Adipose derived stem cells and the TGI 1200 System have three critical advantages: 1) the technique limits damage to heart muscle after an acute injury; 2) the cells serve as a catalyst for new vessel formation; and 3) the system is an easier and faster procedure for obtaining stem cells.

Dr. Karl Groth, Bioheart’s Chairman and CEO commented on the therapy: “Stem cell therapy is not just intended as a temporary solution, but it is developed as a novel adjunctive therapy allowing natural repair of diseased vessels and tissues by using the patient’s own cells.”

“The adipose tissue in the human body can be considered a stem cell reservoir given the large concentration of regenerative cells it contains. This discovery leads to new possibilities and cell therapy treatments in cardiovascular related illnesses,” Dr. Groth added.

Bioheart uses the CE mark approved TGI 1200 System, a fully-automated, point-of-care system that recovers potentially regenerative stem cells from a patient’s own adipose tissue in 60 minutes, to obtain the ASCs.

"The Hospital de Clinicas is extremely excited to be a part of this cutting-edge technology and welcomes the studies," said Dr. Nusen Beer, MD, a cardiologist who has been utilizing the cells for treating his patients. "We believe that this will bring new hope to many patients suffering from diseases related to cardiac dysfunction. By injecting ASCs into areas of low perfusion, these regions may become populated with angiogenic ASCs, thereby potentially improving blood supply to the scar and reducing scar size."

Recent studies have identified adipose tissue as an alternate source of stem cells and the procedure of getting adipose derived stem cells from the patient is simple and easily tolerable by the patient even immediately following a heart attack.

In contrast, the alternative procedure is to use bone marrow to derive stem cells, which is extremely painful and often yields a low volume of stem cells.

The ASC's treatment comes shortly after another of Bioheart's recent clinical trials, MARVEL-1 in which the patient's muscle stem cells or myoblasts are isolated and expanded for use in chronic heart failure. The myoblast treatment, believed to be the most effective for heart failure, is being used in Bioheart's Phase II/III Marvel clinical trial and has seen very positive results. The MARVEL Program is designed to assess the effects of administering autologous skeletal myoblasts on the functional capacity and quality of life in patients with advanced heart failure.

"Bioheart's clinical trials and studies are committed to bringing effective minimally invasive treatments that result in the return to a normal life for cardiac patients," Dr. Groth concluded.

### **Bioheart's TGI 1200 System:**

It is a fully-automated, point-of-care system that recovers potentially regenerative stem cells from a patient's own adipose tissue in about an hour, with minimal operator intervention. Adipose tissue is collected from the patient's abdomen and processed in the TGI 1200 System which separates out and collects adipose stem cells.

The CE mark approved system is distributed by Bioheart under an exclusive license from Tissue Genesis, Inc., accepts adipose tissue from the same device used for liposuctioning the tissue from the patient. The compact desktop unit readily fits into any clinical environment and uses preconfigured disposables for quick and easy operation.

The TGI 1200 System has not been evaluated by the US FDA for human use. It is available in the US for research use only.

### **The Medical Condition Myocardial Ischemia**

- Is a disorder that is usually caused by a critical coronary artery obstruction, which is also known as atherosclerotic coronary artery disease (CAD).

- CAD is the leading cause of death worldwide, and it is the second most common cause of emergency department visits in the United States.
- Coronary artery bypass grafting (CABG) is a type of surgery called revascularization used to improve blood flow to the heart in people with severe [coronary artery disease](#) (CAD).
- CABG is the most common type of open-heart surgery in the United States, with more than 500,000 surgeries performed each year.

### **About Bioheart, Inc.**

Bioheart, Inc. is committed to delivering intelligent devices and biologics that help monitor, diagnose and treat heart failure and other cardiovascular diseases. Its goals are to improve a patient's quality of life and reduce health care costs and hospitalizations. Specific to biotechnology, Bioheart is focused on the discovery, development and, subject to regulatory approval, commercialization of autologous cell therapies for the treatment of chronic and acute heart damage. Its lead product candidate, MyoCell®, is an innovative clinical muscle-derived stem cell therapy designed to populate regions of scar tissue within a patient's heart with new living cells for the purpose of improving cardiac function in chronic heart failure patients. The Company's pipeline includes multiple product candidates for the treatment of heart damage, including Bioheart Acute Cell Therapy, an autologous, adipose tissue-derived stem cell treatment for acute heart damage, and MyoCell® SDF-1, a therapy utilizing autologous cells that are genetically modified to express additional potentially therapeutic growth proteins.

For more information on Bioheart, visit [www.bioheartinc.com](http://www.bioheartinc.com).

### **Forward-Looking Statements:**

*Except for historical matters contained herein, statements made in this press release are forward-looking and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Without limiting the generality of the foregoing, words such as "may," "will," "to," "plan," "expect," "believe," "anticipate," "intend," "could," "would", "estimate", or "continue" or the negative other variations thereof or comparable terminology are intended to identify forward-looking statements.*

*Investors and others are cautioned that a variety of factors, including certain risks, may affect our business and cause actual results to differ materially from those set forth in the forward-looking statements. These risk factors include, without limitation, (i) our ability to obtain additional financing; (ii) our ability to control and reduce our expenses; (iii) our ability to establish a distribution network for and commence distribution of certain products for which we have acquired distribution rights; (iv) our ability to timely and successfully complete our clinical trials; (v) the occurrence of any unacceptable side effects during or after preclinical and clinical testing of our product candidates; (vi) the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; (vii) our dependence on the success of our lead product candidate; (viii) our inability to predict the extent of our future losses or if or when we will become profitable; (ix) our ability to protect our intellectual property rights; and (x)*

*intense competition. The Company is also subject to the risks and uncertainties described in its filings with the Securities and Exchange Commission, including the section entitled "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2008, as amended by its Annual Report on Form 10-K/A, and its Quarterly Reports on Form 10-Q for the quarters ended June 30, 2009 and March 31, 2009.*