

# BIOHEART, INC.

## FORM 8-K

(Current report filing)

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Sector	Healthcare
Fiscal Year	12/31

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K  
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
Date of Report (Date of earliest event reported): August 12, 2009

**BIOHEART, INC.**

(Exact name of registrant as specified in its charter)

<u>Florida</u>	<u>1-33718</u>	<u>65-0945967</u>
(State or other jurisdiction of incorporation)	(Commission File Number Identification No.)	(IRS Employer)
<u>13794 NW 4<sup>th</sup> Street, Suite 212, Sunrise, Florida</u>		<u>33325</u>
(Address of principal executive offices)		(Zip Code)
Registrant's telephone number, including area code: <b>(954) 835-1500</b>		
<u>Not applicable</u>		
(Former name or former address, if changed since last report)		

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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers**

On August 12, 2009, at a meeting of the Board of Directors of Bioheart, Inc. (the "Company"), the Board of Directors decided that several of its Directors will join the Company's executive management team. In addition to assuming the position of Chairman of the Company's Board of Directors, Karl E. Groth, Ph.D., became the Chief Executive Officer; Peggy A. Farley became Chief Operating Officer; and Mark P. Borman became Chief Financial Officer. Howard Leonhardt, who resigned from the Board of Directors, will continue as Chief Scientific and Technology Officer, and Chairman of the Scientific Advisory Board of the Company.

Mr. Leonhardt, informed the Board of Directors that the reason for his resignation as a Director and as the Company's Chief Executive Officer is the desire to concentrate his efforts on enhancing the Company's existing technologies and strengthening its position as the leader within the cardiovascular arena of the stem cell therapy industry.

*Karl E. Groth, Ph.D.* -- Dr. Groth, who is 62, has served as a member of the Company's Board of Directors since January 2009. Dr. Groth is co-founder, along with Ms. Farley, of the Ascent Medical Technology Funds and since May 2000 has served as President and CEO of Ascent Private Equity, the General Partner of the funds, which are focused on investments in medical device, life science and biotechnology. Dr. Groth has over 30 years experience in the health care industry. Dr. Groth received his B.S. from the State University of New York in biology, his M.S. in plant physiology from New York University and his Ph.D. in microbiology from the University of Minnesota. He has published over 30 peer-reviewed articles in professional journals. In addition, Dr. Groth continues to publish and present on topics including vascular disease and endovascular intervention.

*Peggy A. Farley* -- Ms. Farley, who is 62, has served as a member of the Company's Board of Directors since January 2007. Ms. Farley was appointed to the Board as a representative of Ascent Medical Technology Funds. Since January 1998, Ms. Farley has served as a managing director of the general partner and co-founder of the Ascent Medical Technology Funds. She is also the President and Chief Executive Officer of Ascent Capital Management, Inc. From 1984 until 1997, Ms. Farley was Chief Executive Officer of a set of firms that she developed as the locus for investment in the United States for non-US investors, engaging in venture capital investments, identifying and conducting acquisition transactions in the United States and South Asia as well as directing the management of private and corporate assets. From 1978 to 1984, she was with Morgan Stanley & Co. Incorporated, in the International Group of the Corporate Finance Division. Prior to joining Morgan Stanley, Ms. Farley served as consultant to U.S. corporations, including Avon, Ingersoll-Rand, Citibank, and Morgan Stanley. Her career in business began in the mid-1970s in Citibank's Athens-based Middle East and North Africa Regional Office. She received an M.A. from Columbia University in 1972 and an A.B. from Barnard College in 1970.

*Mark P. Borman* -- Mr. Borman, who is 54, has served as a member of the Company's Board of Directors since May 2009. Mr. Borman is a seasoned financial officer with more than 30 years of broad-based financial and investor relations experience. He most recently served as Vice President, Investor Relations and Treasurer of ADC Telecommunications from 1998 to 2008. During his career, Mr. Borman has held positions with General Instrument Corporation, First Chicago Corporation, FMC Corporation, Price Waterhouse, and KMG. Mr. Borman received his B.A. in Accounting from Michigan State University and his MBA from the University of Chicago Graduate School of Business. He is a Certified Public Accountant and Chartered Financial Analyst and has experience as an advisor, board member, faculty, speaker, and mentor.

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The Company issued a press release on August 18, 2009 with regard to the resignation and appointments. A copy of the Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

#### **Financial Statements and Exhibits.**

##### **Item 9.01.**

###### **(d) Exhibits.**

99.1 Press Release of Bioheart, Inc. dated August 18, 2009.

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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.

Date: August 18, 2009

#### **BIOHEART, INC.**

By: /s/ Karl Groth  
Karl Groth  
Chairman of the Board of Directors and  
Chief Executive Officer

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## EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release of Bioheart, Inc. dated August 18, 2009

# Bioheart Strengthens Executive Team in Order to Accelerate Business Plan and Enhance Its Position in the Cardiovascular Stem Cell Therapy Industry

August 18, 2009 – Sunrise, FL - Bioheart, Inc., (BHRT.OB) a company committed to delivering intelligent devices and biologics that help monitor, diagnose and treat heart failure and other cardiovascular diseases announced today that several of its Directors have joined the Company's executive management team. In addition to assuming the position of Chairman of the Company's Board of Directors, Karl E. Groth, Ph.D., became the Chief Executive Officer; Peggy A. Farley became Chief Operating Officer; and Mark P. Borman became Chief Financial Officer. Howard Leonhardt will continue as Chief Scientific and Technology Officer, and Chairman of the Scientific Advisory Board. Mr. Leonhardt, the Company's founder, thus will be able to focus on enhancing the Company's existing technologies and strengthening its position as the leader within the cardiovascular arena of the stem cell therapy industry.

Howard Leonhardt stated: "Karl Groth and I have worked together in the cardiovascular products industry since 1983. He has had many successful harvests of the companies he has developed. His vast experience has been an asset to the Board and will be an even greater asset to the Company's Executive Management with his increased commitment."

Karl Groth has an exceptional record of bringing medical technology companies from development stage to profitable operations and then to achieving exceptional returns for shareholders as the companies were acquired. He has demonstrated the ability to identify market opportunities and technologies, strengthen management, improve operations, focus strategy and guide companies either to acquisition by major companies in the health industry or to an IPO. After his tenure at the University of Minnesota conducting research, Dr. Groth joined Medtronic, having been recruited to help to start up the company's neuro division. His fast track management career there culminated with his position as Director of Business Development, in which he oversaw corporate acquisitions. During his years there, he led marketing, product development, and research units. Subsequent to Medtronic, Karl Groth was Chief Executive Officer or Chief Operating Officer of a number of start-up companies, all of which he took public and subsequently saw divested for exceptional returns to investors in short periods of time. Those companies included InStent, Inc. and Heart Technology, acquired, respectively, by Medtronic and Boston Scientific. Since 1999, Dr. Groth has been working in the venture capital arena quite successfully.

Peggy Farley has a superior record of raising capital and investing both in publicly traded and privately held companies. She started her investment banking career at Morgan Stanley, where she was a member of the international group in the investment banking division. She led a strategic planning task force that was critical to the firm's international positioning in the early '80's, and then worked with sovereign governments, focusing on the People's Republic of China as it emerged from isolation. Earlier, she was a consultant to major U.S. corporations, and advised both manufacturing and financial organizations, among them Morgan Stanley. Subsequent to her time at Morgan Stanley, she founded a firm that engaged in important capital markets activities, including acquisitions and venture capital investments, particularly in health care. Ms. Farley has had a top tier record of returns in the equity management arena and is well regarded for expertise in the IPO markets. Since 1999, Peggy Farley and Dr. Groth have worked together to build the Ascent Group, which has two venture capital funds, both of which have invested in Bioheart.

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Mark Borman has an accomplished record of CFO achievements and has helped technology companies achieve strategic growth, profitability, cash-flow, capital-raising, and valuation goals. His capital market achievements include raising more than \$1 billion for acquisitions and supporting a multi-billion dollar transformation through a leveraged buyout to an IPO to secondary stock and convertible notes offerings to the spin off into three NYSE-listed companies.

Additionally, Mr. Borman's career experience includes management partnering, mergers & acquisitions, restructurings, strategic planning, and turnarounds. During his career, Mr. Borman has held progressively responsible positions with ADC Telecommunications, General Instrument Corporation, First Chicago Corporation, FMC Corporation, Price Waterhouse, and KMG. He is a Certified Public Accountant and Chartered Financial Analyst and his other activities have included board memberships and teaching at the university level.

Of Howard Leonhardt's contributions to Bioheart, Karl Groth says "Howard has grown the company, and he has pioneered a technology that has begun already to save lives that would otherwise be lost. His vision when founding Bioheart was extraordinary and his place within the cell technology industry cannot be matched. He has grown a company with cutting edge products that effectively treat and monitor the growing population wounded by cardiovascular disease. We are fortunate to be able to see him focus on enhancing our technologies."

The Board of Directors is excited about appointing this experienced team of senior executives. In addition to considering a recapitalization of the company, this new leadership will be focused on developing the four main tenets of our business plan. Foremost will be the efforts to expand sales of Bioheart's heart failure home monitoring system and the TGI 1200 system for obtaining adipose derived stem cells. The task force will also focus on initiation of the second part of the MARVEL Phase II/III muscle stem cell therapy study and beginning enrollment in the recently FDA cleared Phase I REGEN trial utilizing muscle derived stem cells transduced to express the SDF-1 protein.

The appointment of this team will enable Mr. Leonhardt to pursue the company's strategic initiatives with respect to strengthening and broadening the Company's technologies. To this end, he has resigned from the Board of Directors.

Of his more focused position, Howard Leonhardt goes on to say:

"As Founder, Chief Scientific and Technology Officer, and Chairman of the Scientific Advisory Board I will remain fully dedicated to assuring that our products are superior to all others in treating and caring for heart failure patients and will continue to be the Company's ambassador in developing relationships worldwide with heart failure physicians."

Mr. Leonhardt emphasized that Bioheart is, in truth, "fully committed to being the 'Go To **Technology** Partner for Heart Failure Specialists and Their Patients.'"

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

Bioheart, Inc. is committed to delivering intelligent devices and biologics that help monitor, diagnose and treat heart failure and cardiovascular diseases. Its goals are to improve a patient's quality of life and reduce health care costs and hospitalizations. Specific to biotechnology,

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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<sup>®</sup>, 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<sup>®</sup> SDF-1, a therapy utilizing autologous cells that are genetically modified to express additional potentially therapeutic growth proteins.

MyoCell SDF-1 is a composition of myogenic stem cells derived from a patient's own thigh muscle that has been modified to over express the SDF-1 protein. The product candidate is prepared with an 18-step proprietary method in Bioheart's cGMP laboratories. Utilizing a needle-tipped catheter inserted into the groin of a patient who is suffering from heart failure, the cells are injected into the scar tissue that has formed in the patient's heart. The goal of MyoCell SDF-1 is to grow new contractile muscle within the scar tissue that will have the ability to release additional beneficial proteins to assist in the tissue repair process and improve the patient's heart function, exercise capacity and quality of life. In preclinical studies, MyoCell SDF-1 provided a 54 percent improvement of heart function compared to 27 percent for the original MyoCell composition while the placebo control treated animals declined by 10 percent. The preclinical studies also demonstrated that this product candidate can enhance blood vessel formation in damaged hearts.. The U.S. trial is expected to begin this year. After completing the REGEN safety protocol with one-month follow-up, the company hopes to transition this second-generation product into its FDA-authorized Phase II/III MARVEL study. MyoCell SDF-1 is substantially similar to the original MyoCell composition that has been active in clinical trials since early 2001 at more than 50 centers worldwide.

The patents Bioheart has acquired covering the myogenic cells and SDF-1 compositions and methods are expected to provide intellectual property protection until 2023.

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

*MyoCell and MyoCell SDF-1 are trademarks of Bioheart, Inc.*

## **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*

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*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, March 31, 2009; June 30, 2008 and September 30, 2008.*

Contact:

*At the Company:*

Karl E. Groth, Ph.D., Chairman and Chief Executive Officer  
(954) 835-1500

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