

# BIOHEART, INC.

## FORM 10-Q (Quarterly Report)

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Industry	Biotechnology & Drugs
Sector	Healthcare
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

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**FORM 10-Q**

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2009

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: **001-33718**

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**BIOHEART, INC.**

(Exact name of registrant as specified in its charter)

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**Florida**

(State or other jurisdiction of  
incorporation or organization)

**65-0945967**

(I.R.S. Employer Identification No.)

**13794 NW 4<sup>th</sup> Street, Suite 212, Sunrise, Florida 33325**

(Address of principal executive offices) (Zip Code)

**(954) 835-1500**

**(Registrant's telephone number, including area code)**

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.045 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of June 30, 2009 there were 17,554,627 outstanding shares of the registrant's common stock, par value \$0.001 per share.

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**BIOHEART, INC.**

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**PART I — FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**Bioheart, Inc. and Subsidiaries**  
**(A development stage enterprise)**

**Consolidated Balance Sheets**

	<u>June 30,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
	(Unaudited)	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 20,075	\$ 50,091
Receivables	7,994	57,258
Inventory	274,966	395,034
Prepaid expenses and other current assets	<u>201,913</u>	<u>723,882</u>
Total current assets	504,948	1,226,265
Property and equipment, net	190,902	281,107
Deferred loan costs, net	863,244	278,945
Other assets	<u>68,854</u>	<u>68,854</u>
Total assets	<u>\$ 1,627,948</u>	<u>\$ 1,855,171</u>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
Current liabilities		
Accounts payable	\$ 2,260,833	\$ 1,700,841
Accrued expenses and other current liabilities	5,490,712	4,970,518
Deferred revenue	465,286	465,286
Notes payable — current	<u>5,943,432</u>	<u>7,898,960</u>
Total current liabilities	14,160,263	15,035,605
Deferred rent	5,999	11,141
Subordinated related party loan	3,000,000	—
Note payable — long term	<u>—</u>	<u>1,044,472</u>
Total liabilities	17,166,262	16,091,218
Commitments and contingencies		
Shareholders' deficit		
Preferred stock (\$0.001 par value) 5,000,000 shares authorized; none issued and outstanding	—	—
Common stock (\$0.001 par value) 75,000,000 shares authorized; 17,554,627 and 15,739,196 shares issued and outstanding as of June, 30, 2009 and December 31, 2008, respectively	17,555	15,739
Additional paid-in capital	84,721,282	82,532,746
Deficit accumulated during the development stage	<u>(100,277,151)</u>	<u>(96,784,532)</u>
Total shareholders' deficit	(15,538,314)	(14,236,047)
Total liabilities and shareholders' deficit	<u>\$ 1,627,948</u>	<u>\$ 1,855,171</u>

The accompanying notes are an integral part of these consolidated financial statements.

	For the Three-Month Period Ended June 30,		For the Six-Month Period Ended June 30,		Cumulative Period from August 12, 1999 (date of inception) to June 30, 2009
	2009	2008	2009	2008	(Unaudited)
	(Unaudited)				
Revenues	\$ 97,795	\$ 16,786	\$ 206,885	\$ 42,781	\$ 991,758
Cost of sales	63,484	4,521	112,781	7,646	438,142
Gross profit	34,311	12,265	94,104	35,135	553,616
Development revenues	—	15,000	—	76,500	117,500
Expenses:					
Research and development	415,330	1,477,634	1,041,693	2,835,691	63,909,077
Marketing, general and administrative	472,152	1,876,442	1,119,034	2,948,711	29,623,838
Depreciation and amortization	44,908	45,921	90,204	91,549	707,210
Total expenses	932,390	3,399,997	2,250,931	5,875,951	94,240,125
Loss from operations	(898,079)	(3,372,732)	(2,156,827)	(5,764,316)	(93,569,009)
Interest income	6	8,256	16	42,202	762,269
Interest expense	(778,126)	(496,875)	(1,335,808)	(1,430,285)	(7,470,411)
Net interest expense	(778,120)	(488,619)	(1,335,792)	(1,388,083)	(6,708,142)
Loss before income taxes	(1,676,199)	(3,861,351)	(3,492,619)	(7,152,399)	(100,277,151)
Income taxes	—	—	—	—	—
Net loss	<u>\$ (1,676,199)</u>	<u>\$ (3,861,351)</u>	<u>\$ (3,492,619)</u>	<u>\$ (7,152,399)</u>	<u>\$ (100,277,151)</u>
Loss per share — basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.27)</u>	<u>\$ (0.21)</u>	<u>\$ (0.51)</u>	
Weighted average shares outstanding — basic and diluted	<u>17,260,868</u>	<u>14,447,138</u>	<u>16,596,241</u>	<u>14,150,984</u>	

The accompanying notes are an integral part of these consolidated financial statements.

**Bioheart, Inc. and Subsidiaries**  
(A development stage enterprise)

**Consolidated Statement of Shareholders' Deficit**  
(Unaudited)

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
<b>Balance as of December 31, 2008</b>	15,739,196	\$15,739	\$82,532,746	\$ (96,784,532)	\$ (14,236,047)
Exercise of stock options	71,250	71	41,960	—	42,031
Stock-based compensation	—	—	(47,750)	—	(47,750)
Issuance of warrants in connection with notes payable	—	—	974,639	—	974,639
Issuance of warrants as a loan fee paid to officers	—	—	133,531	—	133,531
Issuance of common stock	1,127,767	1,128	650,872	—	652,000
Common stock issued in exchange for services	45,000	45	45,855	—	45,900
Common stock issued in connection with the issuance of note payable	200,000	200	189,801	—	190,001
Common stock issued upon the conversion of note payable	371,414	372	199,628	—	200,000
Net loss	—	—	—	(3,492,619)	(3,492,619)
<b>Balance as of June 30, 2009</b>	<u>17,554,627</u>	<u>\$17,555</u>	<u>\$84,721,282</u>	<u>\$ (100,277,151)</u>	<u>\$ (15,538,314)</u>

**Bioheart, Inc. and Subsidiaries**  
(A development stage enterprise)

**Consolidated Statements of Cash Flows**

	For the Six-Month Period Ended June 30,		Cumulative Period from August 12, 1999 (date of inception) to June 30, 2009
	2009	2008	(Unaudited)
	(Unaudited)		(Unaudited)
<b>Cash flows from operating activities</b>			
Net loss	\$(3,492,619)	\$(7,152,399)	\$(100,277,151)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	90,204	91,549	707,210
Bad debt expense	—	—	165,000
Discount on convertible debt	200,000	—	200,000
Amortization of warrants issued in exchange for licenses and intellectual property	—	—	5,413,156
Amortization of warrants issued in connection with notes payable	337,654	561,757	3,508,962
Amortization of loan costs	78,616	257,919	1,007,356
Warrants granted as a loan fee to officers	133,531	—	133,531
Warrants issued in exchange for services	—	—	285,659
Equity instruments issued in connection with settlement agreement	—	—	3,381,629
Common stock issued in exchange for services	45,900	87,200	1,322,917
Common stock issued in exchange for distribution rights and intellectual property	—	—	99,997
Stock-based compensation	(47,750)	1,071,546	8,871,966
Changes in assets and liabilities			
Receivables	49,265	(1,228)	(7,993)
Inventory	120,067	(3,779)	(274,967)
Prepaid expenses and other current assets	521,969	(2,067,411)	(201,913)
Other assets	40,000	2,294	(28,854)
Accounts payable	534,063	(22,932)	2,225,209
Accrued expenses and deferred rent	475,052	401,814	5,834,497
Deferred revenue	—	(61,500)	465,287
Net cash used in operating activities	(914,048)	(6,835,170)	(67,168,502)
<b>Cash flows from investing activities</b>			
Acquisitions of property and equipment	—	(17,560)	(898,112)
Net cash used in investing activities	—	(17,560)	(898,112)
<b>Cash flows from financing activities</b>			
Proceeds from (payments for) initial public offering of common stock, net	—	4,236,653	1,447,829
Proceeds from private placements of common stock, net	652,000	—	58,264,553
Proceeds from exercise of stock options	42,031	—	302,147
Proceeds from notes payable	190,001	—	11,390,001
Proceeds from subordinated related party loan	3,000,000	—	3,000,000
Payment of notes payable	(3,000,000)	(808,866)	(5,256,568)
Payment of loan costs	—	(187,219)	(1,061,273)
Net cash provided by financing activities	884,032	3,240,568	68,086,689
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(30,016)</b>	<b>(3,612,162)</b>	<b>20,075</b>

Cash and cash equivalents, beginning of period	50,091	5,492,157	—
Cash and cash equivalents, end of period	<u>\$ 20,075</u>	<u>\$ 1,879,995</u>	<u>\$ 20,075</u>
<b>Disclosures of cash flow information:</b>			
Interest paid	\$ 5,366	\$ 282,799	\$ 862,450
Income taxes paid	\$ —	\$ —	\$ —

The accompanying notes are an integral part of these consolidated financial statements.

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**Bioheart, Inc. and Subsidiaries**  
(A development stage enterprise)

**Notes to Consolidated Interim Financial Statements**  
(Unaudited)

**1. Organization and Summary of Significant Accounting Policies**

**Organization and Business**

Bioheart, Inc. (the “Company”) 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, the Company 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. MyoCell® is an innovative clinical muscle-derived 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 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. The Company was incorporated in Florida on August 12, 1999.

**Development Stage**

The Company has operated as a development stage enterprise since its inception by devoting substantially all of its effort to raising capital, research and development of products noted above, and developing markets for its products. Accordingly, the financial statements of the Company have been prepared in accordance with the accounting and reporting principles prescribed by Statement of Financial Accounting Standards (“SFAS”) No. 7, *Accounting and Reporting by Development Stage Enterprises* (“SFAS No. 7”), issued by the Financial Accounting Standards Board (“FASB”).

Prior to marketing its products in the United States, the Company’s products must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process implemented by the Food and Drug Administration (“FDA”) and other regulatory authorities. There can be no assurance that the Company will not encounter problems in clinical trials that will cause the Company or the FDA to delay or suspend clinical trials. The Company’s success will depend in part on its ability to successfully complete clinical trials, obtain necessary regulatory approvals, obtain patents and product license rights, maintain trade secrets, and operate without infringing on the proprietary rights of others, both in the United States and other countries. There can be no assurance that patents issued to or licensed by the Company will not be challenged, invalidated, or circumvented, or that the rights granted thereunder will provide proprietary protection or competitive advantages to the Company. The Company will require substantial future capital in order to meet its objectives. The Company currently has no committed sources of capital. The Company will need to seek substantial additional financing through public and/or private financing, and financing may not be available when the Company needs it or may not be available on acceptable terms.

**Basis of Presentation**

The accompanying unaudited consolidated interim financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the “SEC”) for reporting of interim financial information. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted.

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**Bioheart, Inc. and Subsidiaries**  
**(A development stage enterprise)**

**Notes to Consolidated Interim Financial Statements — (Continued)**  
**(Unaudited)**

In the opinion of management, the accompanying unaudited consolidated interim financial statements of the Company contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position of the Company as of June 30, 2009, the results of its operations for the six-month periods ended June 30, 2009 and 2008 and its cash flows for the six-month periods ended June 30, 2009 and 2008. The results of operations and cash flows for the six-month period ended June 30, 2009 are not necessarily indicative of the results of operations or cash flows which may be reported for future periods or for the year ending December 31, 2009.

The accompanying unaudited consolidated interim financial statements include the accounts of Bioheart, Inc. and its wholly-owned subsidiaries. All intercompany transactions are eliminated in consolidation.

The accompanying unaudited consolidated interim financial statements and notes thereto should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations contained in this report and the audited financial statements for the year ended December 31, 2008 and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008.

**Reverse Stock Split**

On August 31, 2007, the Company's Board of Directors approved a 1-for-1.6187 reverse stock split of the Company's capital stock, which became effective on September 27, 2007. All share numbers and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect the reverse stock split. In lieu of issuing fractional shares of stock resulting from the reverse stock split, the number of shares held by each shareholder following the reverse stock split was rounded up to the nearest whole share.

**Initial Public Offering**

On February 22, 2008 (the "Closing Date") the Company completed its initial public offering of common stock (the "IPO") pursuant to which it sold 1,100,000 shares of common stock at a price per share of \$5.25, for net proceeds of approximately \$1.45 million after deducting underwriter discounts of approximately \$400,000 and offering costs of approximately \$3.92 million. The Company's common stock commenced trading on February 19, 2008 on the NASDAQ Global Market under the symbol "BHRT" and subsequently transferred to the NASDAQ Capital Market in June 2008.

The Consolidated Statement of Cash Flows for the quarter ended June 30, 2008 reflects the Company's receipt of approximately \$4.24 million of "Proceeds from (payments for) initial public offering of common stock, net". The \$4.24 million cash proceeds figure is approximately \$2.79 million higher than the \$1.45 million IPO net proceeds figure identified above due to payment of \$2.82 million of various offering expenses prior to January 1, 2008.

The net cash proceeds from the IPO were primarily used for commencement of full-scale enrollment in a planned clinical trial of MyoCell, milestone payments due under licensing agreements, repayment of a portion of certain debt obligations and general corporate purposes.

On the Closing Date, the Company issued to Dawson James Securities, Inc. a warrant to purchase 77,000 shares of its common stock with an exercise price of \$6.5625 per share. Dawson James Securities, Inc. acted as the representative of the several underwriters of the IPO. The warrant, which became exercisable on the first anniversary of the date of issuance, expires on October 2, 2012.

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**Bioheart, Inc. and Subsidiaries**  
**(A development stage enterprise)**

**Notes to Consolidated Interim Financial Statements — (Continued)**  
**(Unaudited)**

**NASDAQ Delisting**

On October 15, 2008, the Company received notification from The NASDAQ Stock Market indicating that the Company was not in compliance with certain of the NASDAQ Capital Market continued listing requirements, including a minimum \$35 million market value of its

listed securities. The Company was permitted until November 14, 2008, to regain compliance with the minimum market value of listed securities requirement. On November 17, 2008, the Company received a NASDAQ Staff Determination indicating that the Company had failed to regain compliance with the \$35 million minimum market value of listed securities requirement, and that the Company's securities were, therefore, subject to delisting from The NASDAQ Capital Market. The Company appealed the Staff Determination and requested a hearing before a NASDAQ Listing Qualifications Panel (the "Panel") to review the Staff Determination. This stayed the delisting of the Company's securities pending the Panel's decision.

On February 25, 2009, the Company received notification from The NASDAQ Stock Market of its determination to discontinue the Company's NASDAQ listing effective February 27, 2009.

On May 13, 2009, the Company's common stock was approved for quotation on the Over-The-Counter Bulletin Board.

### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities as of the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

### Fair Value of Financial Instruments

Fair value estimates, assumptions and methods used to estimate the fair value of the Company's financial instruments are made in accordance with the requirements of SFAS No. 107, *Disclosures about Fair Value of Financial Instruments*. The Company has used available information to derive its estimates. However, because these estimates are made as of a specific point in time, they are not necessarily indicative of amounts the Company could realize currently. The use of different assumptions or estimating methods may have a material effect on the estimated fair value amounts. The fair value of cash equivalents, receivables, accounts payable and short term debt approximate their carrying amounts due to their short term nature. The carrying value of long-term debt consisting of a note payable approximated fair value as of June 30, 2009 and December 31, 2008, based on the time to maturity, interest rate environment and borrowing rates available to the Company.

### Inventory

Inventory consists of raw materials and finished product. Finished product consists primarily of finished catheters. Cost of finished product, consisting of raw materials and contract manufacturing costs, is determined by the first-in, first-out (FIFO) method for valuing inventories. Costs of raw materials are determined using the FIFO method. Inventory is stated at the lower of costs or market (estimated net realizable value).

Inventory consisted of the following at June 30, 2009 and December 31, 2008:

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**Bioheart, Inc. and Subsidiaries**  
(A development stage enterprise)

**Notes to Consolidated Interim Financial Statements — (Continued)**  
(Unaudited)

	June 30, 2009	December 31, 2008
Finished product	\$218,212	\$338,280
Raw materials	56,754	56,754
Total inventory	\$274,966	\$395,034

### Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets at December 31, 2008, mainly consisted of upfront payments under an agreement with the contract research organization that the Company was utilizing for its Marvel Clinical Trials, and payments on corporate insurance policies. At June 30, 2009, all the prepayments to the contract research organization were recovered, and prepaid expenses and other current assets included a down payment to a vendor for Clinical Trial equipment, and payments on corporate insurance policies.

### Deferred Loan Costs

Deferred loan costs consist principally of legal and loan origination fees incurred to obtain \$10 million in loans in June 2007 and the fair value of warrants issued in connection with the loans. These deferred loan costs are being amortized to interest expense over the terms of the respective loans using the effective interest rate method. At June 30, 2009 and December 31, 2008, the Company had net deferred loan costs of \$863,244 and \$278,945, respectively. For the Six months ended June 30, 2009 and for the six months ended June 30, 2008, the Company recorded \$749,802 and \$819,677, respectively, of interest expense related to the amortization of deferred loan costs, which included \$471,205 and \$561,757, respectively, related to the fair value of warrants issued in connection with the loans.

## **Stock Options and Warrants**

On January 1, 2006, the Company adopted the provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (“SFAS No. 123R”) using the modified prospective transition method. SFAS No. 123R requires the Company to measure all share-based payment awards granted after January 1, 2006, including those with employees, at fair value. Under SFAS No. 123R, the fair value of stock options and other equity-based compensation must be recognized as expense in the statements of operations over the requisite service period of each award.

Share-based awards granted subsequent to January 1, 2006 are valued using the fair value method and compensation expense is recognized on a straight-line basis over the vesting period of the awards. Beginning January 1, 2006, the Company also began recognizing compensation expense under SFAS No. 123R for the unvested portions of outstanding share-based awards previously granted under its stock option plans, over the periods these awards continue to vest.

The Company accounts for certain share-based awards, including warrants, with non-employees in accordance with SFAS No. 123R and related guidance, including EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. The Company estimates the fair value of such awards using the Black-Scholes valuation model at

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## **Bioheart, Inc. and Subsidiaries (A development stage enterprise)**

### **Notes to Consolidated Interim Financial Statements — (Continued) (Unaudited)**

each reporting period and expenses the fair value over the vesting period of the share-based award, which is generally the period in which services are provided.

## **Loss Per Share**

Loss per share has been computed based on the weighted average number of shares outstanding during each period, in accordance with SFAS No. 128, *Earnings per Share*. The effect of outstanding stock options and warrants, which could result in the issuance of 7,557,173 and 4,906,532 shares of common stock at June 30, 2009 and 2008, respectively, is antidilutive. As a result, diluted loss per share data does not include the assumed exercise of outstanding stock options and warrants and has been presented jointly with basic loss per share.

## **2. Going Concern**

The accompanying consolidated financial statements have been prepared and are presented assuming the Company’s ability to continue as a going concern. The Company has incurred significant operating losses over the past several years and has a deficit accumulated during the development stage of \$100.3 million as of June 30, 2009. In addition, as of June 30, 2009, the Company’s current liabilities exceed current assets by \$13.7 million. Current liabilities include notes payable of \$5.9 million. As discussed in Note 6, the Company also has an obligation of \$3 million to the Company’s Chairman and spouse. The Company does not have sufficient cash to support its operations through December 2009. The Company has secured additional sources of capital in August 2009 to conduct its business and product candidates as planned, through September 2009.

The Company is seeking substantial additional financing through public and/or private financing, which may include equity and/or debt financings, research grants, and through other arrangements, including collaborative arrangements. As part of such efforts, the Company may seek loans from certain of our executive officers, directors and/or current shareholders. However, financing may not be available to the Company or on terms acceptable to the Company. The Company’s inability to obtain additional financing would have a material adverse effect on its financial condition and ability to continue operations. Accordingly, the Company could be forced to significantly curtail or suspend operations, default on its debt obligations, file for bankruptcy or seek to sell some or all of its assets. As such, the Company’s continuation as a going concern is uncertain.

Due to the Company’s financial condition, the report of the Company’s independent registered public accounting firm on the Company’s December 31, 2008 consolidated financial statements includes an explanatory paragraph indicating that these conditions raise substantial doubt

about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

### 3. Collaborative License and Research/Development Agreements

The Company has entered into a number of contractual relationships for technology licenses and research and development projects. The following provides a summary of the Company's significant contractual relationships:

In February 2000, the Company entered into a license agreement (the "Original License Agreement") with Cell Transplants International, LLC ("CTI"). Pursuant to the Original License Agreement, among other things, CTI granted the Company a license to certain patents related to heart muscle regeneration and angiogenesis for the life of the patents. In July 2000, the Company and CTI, together with Dr. Peter K. Law, executed an

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**Bioheart, Inc. and Subsidiaries**  
**(A development stage enterprise)**

**Notes to Consolidated Interim Financial Statements — (Continued)**  
**(Unaudited)**

addendum to the Original License Agreement, which amended or superseded a number of terms of the Original License Agreement (the "License Addendum").

More specifically, the License Addendum provided, among other things:

- The parties agreed that the Company would issue, and the Company did issue, to CTI a five-year warrant exercisable for 1.2 million shares of the Company's common stock at an exercise price of \$8.00 per share instead of, as originally contemplated under the Original License Agreement, issuing to CTI or Dr. Law 600,000 shares of the Company's common stock and options to purchase 600,000 shares of the Company's common stock at an exercise price of \$1.80 per share. These share amounts and exercise prices do not take into account any subsequent recapitalizations or reverse stock splits.
- The parties agreed that the Company's obligation to pay CTI a \$3.0 million milestone payment would be triggered upon the Company's commencement of a bona fide U.S. Phase II human clinical trial study that utilizes technology claimed under U.S. Patent No. 5,130,141 with FDA approval in the United States, instead of, as originally contemplated under the Original License Agreement, upon initiation of an FDA approved human clinical trial study of such technology in the United States.

In addition, if the Company obtains FDA approval of a method of heart muscle regeneration utilizing the patented technology licensed under the Original License Agreement, the Company will be required to pay CTI \$5 million. Further, the Company would be obligated to pay CTI a royalty of 5% of gross sales of products and services that directly read upon the claims of the licensed patents. During the course of certain litigation initiated by Dr. Law against the Company, see Note 9, the Company learned that CTI, a Tennessee limited liability company, was administratively dissolved by the Secretary of State of Tennessee in 2004.

In February 2006, the Company entered into an exclusive license agreement with The Cleveland Clinic Foundation for various patents to be used in connection with the MyoCell SDF-1 product candidate. In exchange for the license, the Company 1) paid \$250,000 upon the closing of the agreement; 2) paid \$1,250,000 in 2006; 3) paid \$150,000 in 2008; 4) will pay a maintenance fee of \$150,000 per year for the duration of the license; 5) will be required to make various milestone payments; and 6) will pay a 5% royalty on the net sales of products and services that directly rely upon the claims of the patents for the first \$300,000,000 of annual net sales and a 3% royalty for any annual net sales over \$300,000,000. The royalty percentage shall be reduced by 0.5% for each 1.0% of license fees paid to any other entity. However, the royalty percentage shall not be reduced to less than 2.5%.

Bioheart has signed two amendments associated with the license agreement with The Cleveland Clinic Foundation. The amended agreement states that if Bioheart does not complete each milestone activity by the expected completion date then the license will terminate. As part of the original license agreement, Bioheart gained access to multiple product lines. The amended agreement states that if these products are not included in a Bioheart sponsored clinical trial prior to December 31, 2010, Bioheart will lose the rights to those products. On July 1<sup>st</sup>, 2009, the company received notification from the Cleveland Clinic that they are terminating the License Agreement due to failure to pay the annual maintenance fee on June 30, 2009. The termination does not release Bioheart from obligations that accrued prior to the effective date of termination or any other obligations it might have under that Agreement. The company also received a communication from Juventas Therapeutics (now acting on behalf of the Cleveland Clinic for this patent portfolio) that it would like to renegotiate the License Agreement with Bioheart. The Company has developed proprietary techniques to utilize the art identified in the patents, that are pending.

**Bioheart, Inc. and Subsidiaries**  
(A development stage enterprise)

**Notes to Consolidated Interim Financial Statements — (Continued)**  
(Unaudited)

In December 2006, the Company entered into an agreement with Tissue Genesis, Inc. (“Tissue Genesis”) for exclusive distribution rights to Tissue Genesis’ products and a license for various patents to be used in connection with the Bioheart Acute Cell Therapy and TGI 1200™ product candidates. In exchange for the license, the Company agreed to do the following: 1) issue 13,006 shares of the Company’s common stock at a price of \$7.69 per share; and 2) issue a warrant exercisable for 1,544,450 shares of the Company’s common stock to Tissue Genesis at an exercise price of \$7.69 per share, which warrant expires on December 31, 2026. This warrant shall vest in three parts as follows: i) 617,780 shares vesting only upon the Company’s successful completion of human safety testing of the licensed technology, ii) 463,335 shares vesting only upon the Company exceeding net sales of \$10 million or net profit of \$2 million from the licensed technology, and iii) 463,335 shares vesting only upon the Company exceeding net sales of \$100 million or net profit of \$20 million from the licensed technology. Since the vesting of this warrant is contingent upon the achievement of the specific milestones, the fair value of this warrant at the time the milestones are met will be expensed to research and development. In the event of an acquisition (or merger) of the Company with a third party, all unvested shares of common stock subject to the warrant shall immediately vest prior to such event. In addition, the Company will pay a 2% royalty of net sales of licensed products.

#### 4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of June 30, 2009 and December 31, 2008:

	<u>June 30,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
License and royalty fees	\$3,775,000	\$3,670,000
Fees and interest payable to the Guarantors of the Company’s loan agreement with Bank of America	1,405,133	926,628
Interest payable on notes payable	161,165	262,950
Other	149,414	110,940
	<u>\$5,490,712</u>	<u>\$4,970,518</u>

#### 5. Notes Payable

Notes payable were comprised of the following as of June 30, 2009 and December 31, 2008:

	<u>June 30,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
Bank of America note payable. Terms described below	\$ 2,000,000	\$ 5,000,000
BlueCrest Capital Finance note payable. Monthly payments of principal and interest as described below.	2,943,432	2,943,432
Short-term note payable. Terms described below.	1,000,000	1,000,000
	5,943,432	8,943,432
Less current portion.	(5,943,432)	(7,898,960)
Notes payable — long term.	<u>\$ 0</u>	<u>\$ 1,044,472</u>

Notes payable at June 30, 2009 mature as follows:

2010	<u>\$5,943,432</u>
	<u>\$5,943,432</u>

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**Bioheart, Inc. and Subsidiaries**  
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**Notes to Consolidated Interim Financial Statements — (Continued)**  
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***Bank of America Note Payable***

On June 1, 2007, the Company entered into a loan agreement with Bank of America, N.A. for an eight month, \$5.0 million term loan, to be used for working capital purposes. The loan bears interest at the annual rate of the prime rate plus 1.5%. The prime rate was 3.25% and 7.25% at December 31, 2008 and 2007, respectively. As consideration for the loan, the Company paid Bank of America a fee of \$100,000. Effective as of January 31, 2008, the maturity date of the loan was extended until June 1, 2008. As consideration for this extension of the maturity date of the loan, the Company paid Bank of America a fee of \$50,000. Effective as of June 1, 2008, Bank of America agreed to extend the maturity date of the loan until January 5, 2009. As consideration for this extension of the maturity date of the loan, the Company paid Bank of America a fee of \$75,000. Effective January 5, 2009, Bank of America agreed to extend the maturity date of the loan until July 6, 2009. As consideration for this extension of the maturity date of the loan, the Company owes Bank of America a fee of \$50,000 that is payable upon the maturity date of the loan. Effective July 6, 2009, Bank of America agreed to extend the maturity of the loan until January 5, 2010. As consideration for this extension of the maturity date of the loan, the Company owes Bank of America a fee of \$25,000 that is payable upon the maturity date of the loan. Under the terms of the loan, Bank of America is entitled to receive a semi-annual payment of interest and all outstanding principal and accrued interest by the maturity date.

The Company has provided no collateral for the loan. On June 1, 2007, for the Company's benefit, the Company's Chairman of the Board and his spouse, certain other members of the Company's Board of Directors and one of the Company's shareholders (the "Guarantors") provided collateral to guarantee the loan. Except for a \$1.1 million personal guaranty (backed by collateral) provided by the Company's Chairman and his spouse, these guarantees are limited to the collateral each provided to the lender.

The Company and Bank of America have agreed with BlueCrest Capital Finance, L.P., the lender of the BlueCrest Loan (defined below), that the Company will not individually make any payments due under the Bank of America loan while the BlueCrest Loan is outstanding. For the Company's benefit, the Guarantors agreed to provide Bank of America in the aggregate up to \$5.5 million of funds and/or securities to make these payments.

The Company has agreed to reimburse the Guarantors with interest at an annual rate of the prime rate plus 5.0% for any and all payments made by them under the Bank of America loan as well as to pay them certain cash fees in connection with their provision of collateral to guarantee the loan. Upon entering into the loan agreement, the Company issued to each Guarantor warrants to purchase 3,250 shares of common stock at an exercise price of \$7.69 per share for each \$100,000 of principal amount of the loan guaranteed by such Guarantor. The warrants have a ten-year term and became exercisable one year following the date the warrants were issued. Warrants to purchase an aggregate of 216,095 shares of common stock were issued to the Guarantors. These warrants had an aggregate fair value of \$1,437,638, which amount was accounted for as additional paid in capital and reflected as a component of deferred loan costs and amortized as interest expense over the initial term of the loan using the effective interest method. As discussed below, certain of these Guarantors were replaced in September 2007. The unamortized fair value of the warrants issued to the Guarantors that were replaced, which was previously reflected as a component of deferred loan costs, was recorded as interest expense in September 2007.

In September 2007, a member of the Company's Board of Directors and two of the Company's shareholders agreed to provide collateral valued at \$750,000, \$600,000 and \$500,000, respectively, to secure the loan. The collateral provided by these new Guarantors fully replaced the collateral originally provided by one of the members of the Company's Board of Directors and partially replaced the collateral originally provided by another member of the Company's Board of Directors whose collateral now secures \$400,000 of the loan. In consideration for providing the collateral, the Company issued to the new Guarantors warrants to

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**Bioheart, Inc. and Subsidiaries**  
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purchase 3,250 shares of common stock at an exercise price of \$7.69 per share for each \$100,000 of principal amount of the loan guaranteed by such new Guarantor. The warrants have a ten-year term and became exercisable one year following the date the warrants were issued. Warrants to purchase an aggregate of 60,118 shares of the Company's common stock were issued to the new Guarantors. These warrants had an aggregate fair value of \$380,482, which was accounted for as additional paid in capital and reflected as a component of deferred loan costs and amortized

as interest expense over the initial term of the loan using the effective interest method.

In accordance with the provisions of the warrants issued to the Guarantors, the aggregate number of shares of common stock underlying such warrants increased on September 30, 2007 as the Bank of America loan remained outstanding at that date. The additional 38,861 warrant shares had an aggregate fair value of \$244,463. The portion of this amount attributed to the Guarantors that were replaced in September 2007 was accounted for as additional paid in capital and immediately recorded as interest expense with the remainder accounted for as additional paid in capital and reflected as a component of deferred loan costs and amortized as interest expense over the initial term of the loan using the effective interest method.

In October 2007, the Company's Chairman and his spouse agreed to provide an additional \$2.2 million limited personal guarantee of the loan and pledged securities accounts to backup this limited personal guarantee. The additional collateral provided by the Company's Chairman and his spouse fully replaced the collateral provided by one of the original Guarantors. Accordingly, the Company's Chairman and his spouse personally guaranteed an aggregate of \$3.3 million of the loan. The Company's agreement with the Company's Chairman and his spouse with respect to the additional collateral is substantially similar to the Company's agreement with them in connection with the \$1.1 million personal guarantee they originally provided in June 2007. In consideration for providing the collateral, the Company issued to the Company's Chairman and his spouse, a warrant to purchase 81,547 shares of the Company's common stock at an exercise price of \$7.69 per share. The warrant has a ten-year term and became exercisable one year following the date the warrant was issued. The warrant had a fair value of \$516,193, which was accounted for as additional paid in capital and reflected as a component of deferred loan costs and amortized as interest expense over the initial term of the loan using the effective interest method.

As a result of this replacement of the collateral originally provided by one of the original Guarantors in October 2007, the unamortized fair value of the warrant to purchase 81,548 shares of the Company's common stock at an exercise price of \$7.69 per share issued to that Guarantor was recorded as interest expense in October 2007. In October 2007, the Company cancelled the warrant previously issued to such original Guarantor, which warrant included the adjustment provisions discussed above, and, in exchange, issued to them a warrant to purchase 101,934 shares of the Company's common stock at an exercise price of \$7.69 per share, which new warrant does not contain the adjustment provisions discussed above. The additional 20,386 warrant shares had an aggregate fair value of \$128,228, which was accounted for as additional paid in capital and immediately recorded as interest expense.

In accordance with the provisions of the warrants issued to the Guarantors, the aggregate number of shares of common stock underlying such warrants increased on June 1, 2008 as the Bank of America loan remained outstanding at that date. The additional 78,773 warrant shares had an aggregate fair value of \$168,387. The portion of this amount attributed to the Guarantors that were replaced in September 2007 was accounted for as additional paid in capital and immediately recorded as interest expense with the remainder accounted for as additional paid in capital and reflected as a component of deferred loan costs to be amortized as interest expense over the term of the loan using the effective interest method. In the event that as of the second anniversary and third anniversary of the closing date of the loan, the Company has not reimbursed the

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**Bioheart, Inc. and Subsidiaries**  
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**Notes to Consolidated Interim Financial Statements — (Continued)**  
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Guarantors in full for payments made by them in connection with the loan, the number of shares subject to the warrants will further increase.

In March 2009, the Company's Chairman and his spouse repaid \$3.0 million of principal and a pro rata portion of accrued interest on behalf of the Company. The Company now owes this \$3.0 million to the Company's Chairman and his spouse. This liability is reflected on the Company's consolidated balance sheet on a separate line titled "Due to related parties." In accordance with the provisions discussed above, this amount will accrue interest at an annual rate of the prime rate plus 5.0%.

The amount of interest expense on the principal amount of the loan for the six-month periods ended June 30, 2009 and 2008 totaled approximately \$79,000 and \$181,000, respectively. Fees and interest earned by the Guarantors, which are recorded as interest expense, for the six-month periods ended June 30, 2009 and 2008 totaled approximately \$232,000 and \$155,000, respectively. Interest due on the principal amount of the loan has been paid by the Guarantors. As of June 30, 2009 and December 31, 2008, the amount of interest paid by the Guarantors on behalf of the Company totaled approximately \$616,000 and \$445,000, respectively, and was included in accrued expenses at those dates.

***BlueCrest Capital Finance Note Payable***

On June 1, 2007, the Company closed on a \$5.0 million senior loan from BlueCrest Capital Finance, L.P. with a term of 36 months which bears interest at an annual rate of 12.85% (the "BlueCrest Loan"). The first three months required payment of interest only with equal principal and interest payments over the remaining 33 months. As consideration for the loan, the Company issued to BlueCrest Capital Finance, L.P. a warrant to purchase 65,030 shares of common stock at an exercise price of \$7.69 per share. The warrant, which became exercisable one year

following the date the warrant was issued, has a ten year term. This warrant had a fair value of \$432,635, which was accounted for as additional paid in capital and reflected as a component of deferred loan costs and is being amortized as interest expense over the term of the loan using the effective interest method. The Company also paid the lender a fee of \$100,000 to cover diligence and other costs and expenses incurred in connection with the loan. On August 31, 2007, BlueCrest Capital Finance, L.P. assigned its rights, liabilities, duties and obligations under the BlueCrest Loan and warrant to BlueCrest Venture Finance Master Fund Limited (“BlueCrest”).

The loan may be prepaid in whole but not in part. However, the Company is subject to a prepayment penalty equal to 2% of the outstanding principal if prepaid during the second year of the loan and 1% of the outstanding principal if prepaid during the third year of the loan. As collateral to secure its repayment obligations under the loan, the Company granted BlueCrest a first priority security interest in all of the Company’s assets, excluding intellectual property but including the proceeds from any sale of any of the Company’s intellectual property. The loan has certain restrictive terms and covenants including among others, restrictions on the Company’s ability to incur additional senior or pari-passu indebtedness or make interest or principal payments on other subordinate loans.

In the event of an uncured event of default under the loan, all amounts owed to BlueCrest are immediately due and payable and BlueCrest has the right to enforce its security interest in the assets securing the loan. During the continuance of an event of default, all outstanding amounts under the loan will bear interest (payable on demand) at an annual rate of the 14.85%. In addition, any unpaid amounts are subject, until paid, to a service charge in an amount equal to two percent (2%) of the unpaid amount. Events of default include, among others, the Company’s failure to timely make payments of principal when due, the Company’s uncured failure to timely pay any other amounts owing to BlueCrest under the loan, the Company’s material breach of the representations and warranties contained in the loan agreement and the Company’s default in the payment

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**Bioheart, Inc. and Subsidiaries**  
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**Notes to Consolidated Interim Financial Statements — (Continued)**  
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of any debt to any of its other lenders in excess of \$100,000 or any other default or breach under any agreement relating to such debt, which gives the holders of such debt the right to accelerate the debt.

The amount of interest expense on the principal amount of the BlueCrest Loan for the six-month periods ended June 30, 2009 and 2008 totaled approximately \$189,000 and \$266,000, respectively.

On January 2, 2009, the Company failed to make the monthly payment of principal and interest of approximately \$181,000 due on such date. On January 28, 2009, the Company received from BlueCrest notice of this event of default (the “Default Notice”) under the BlueCrest Loan. By reason of the stated event, BlueCrest demanded payment of a 2% late fee of approximately \$3,600, together with the principal and interest payment of approximately \$181,000. On February 2, 2009, the Company received from BlueCrest notice of acceleration of the outstanding principal amount of the BlueCrest Loan and demanded repayment in full of all outstanding principal and accrued interest on the loan, including late fees, in the aggregate amount of \$2,947,045. (The acceleration notice, together with the Default Notice, are referred to as the “Notices”).

The Company and BlueCrest entered into an amendment to the BlueCrest Loan as of April 2, 2009 (the “BlueCrest Loan Amendment”), that, among other things, includes BlueCrest’s agreement to forbear from exercising any of its rights or remedies regarding the defaults described in Notices (the “Forbearance”) as long as there are no new defaults under the BlueCrest Loan, as amended.

The BlueCrest Loan Amendment, (a) increases the amount of permitted unsecured indebtedness of the Company, (b) amended the amortization schedule for the Loan to provide for interest-only payments until July 1, 2009, at which time monthly principal and interest payments of \$262,692 will commence, and (c) prohibits the Company from granting any lien against its intellectual property and grants to BlueCrest a lien against the Company’s intellectual property that will become effective in the event of a default. In addition, the Company issued BlueCrest a warrant to purchase 1,315,542 shares of the Company’s common stock at \$0.53 per share.

In connection with the BlueCrest Loan Amendment the Company paid BlueCrest accrued interest in the aggregate amount of \$126,077. The Company also paid BlueCrest a fee of \$15,000.

Effective July 1, 2009, the Company and BlueCrest agreed to enter into an amendment to the BlueCrest Loan to amend the amortization schedule for the Loan to provide for interest-only payments until January 1, 2010, at which time monthly principal and interest payments of \$139,728 will commence.

In connection with the most recent BlueCrest Loan Amendment the Company will issue BlueCrest a warrant to purchase \$600,000 of the Company’s common shares and pay a fee of \$29,435.

## **Short-term Note Payable**

On August 20, 2008, the Company borrowed \$1.0 million from a third party pursuant to the terms of an unsecured Promissory Note and Agreement. Outstanding principal and interest on the loan, which accrues at the rate of 13.5% per annum, is payable in one balloon payment upon the Company's repayment of the BlueCrest Loan, which is scheduled to mature in May 2010. In the event the Company completes a private placement of its common stock and/or securities exercisable for or convertible into its common stock which generates at least \$19.0 million of gross proceeds, the Company may prepay, without penalty, all outstanding principal and interest due under the loan using the same type of securities issued in the subject private placement. Because repayment of the loan could occur within 12 months from the date of the balance sheet, the Company has classified this loan as short term. Subject to certain conditions, at the end of each calendar

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### **Bioheart, Inc. and Subsidiaries (A development stage enterprise)**

#### **Notes to Consolidated Interim Financial Statements — (Continued) (Unaudited)**

quarter during the time the loan is outstanding, the Company may, but is not required to, pay all or any portion of the interest accrued but unpaid as of such date with shares of its common stock.

The amount of interest expense on the principal amount of the loan for the period ended June 30, 2009 was approximately \$68,000. The Company has not paid any of the interest accrued to date on the principal amount of the loan.

#### **6. Related Party Transactions**

Pursuant to a clinical registry supply agreement entered into in August 2007 with BHK, Inc., the Company received an upfront payment of \$103,000. As of December 31, 2007, the Company had not completed all of the cell-culturing services required by the agreement. Based on the amount of cell-culturing services completed as of December 31, 2007, the Company recorded \$82,000 of the upfront payment as deferred revenue at December 31, 2007. Of this amount, \$61,500 was recognized as revenue in the three months ended March 31, 2008 upon completion of additional cell-culturing services. In February 2005, the Company entered into a joint venture agreement with Bioheart Korea, Inc., BHK's predecessor entity, pursuant to which the Company and BHK agreed to create a joint venture company now known as Bioheart Manufacturing, Inc. As of December 31, 2008, the Company owned an 18% equity interest in Bioheart Manufacturing, Inc. In February 2009, the Company's ownership interest in Bioheart Manufacturing, Inc. was reduced from 18% to approximately 6% as a result of an investment in Bioheart Manufacturing, Inc. by a third party.

As discussed in Note 5, the Company's Chairman and his spouse had provided collateral to guarantee the Bank of America loan. In March 2009, these individuals repaid \$3.0 million of principal and a pro rata portion of accrued interest on behalf of the Company. The Company now owes this \$3.0 million to the Company's Chairman and his spouse. This liability is reflected on the Company's consolidated balance sheet on a separate line titled "Subordinated related party loan." This amount will also accrue interest at an annual rate of the prime rate plus 5.0%.

In April and May 2009, the Company sold to two members of the Board of Directors, in a private placement, an aggregate of 965,570 shares of the Company's common stock and warrants to purchase 289,671 shares of the Company's common stock for aggregate gross cash proceeds of \$535,000.

A cousin of the Company's Chairman is an officer of the Company. The amounts paid to this individual as salary for the six-month periods ended June 30, 2009 and 2008 were \$54,200 and \$65,000, respectively. In addition, the Company utilized a printing entity controlled by this individual and paid this entity \$22,759 and \$3,405 for the six-month periods ended June 30, 2009 and 2008, respectively.

The sister-in-law of the Company's Chairman is an officer of the Company. The amounts paid to this individual as salary for the six-month periods ended June 30, 2009 and 2008 were \$35,896 and \$43,000, respectively.

On July 15, 2009, to settle an amount due to the Ascent Medical Product Development Centre Inc., affiliated with two Board members, Karl Groth and Peggy Farley, Ascent Medical Product Development Centre Inc. accepted options for 203,125 restricted Bioheart common shares.

In July 2009, the Company sold to a member of the Board of Directors, in a private placement 140,850 shares of the Company's common stock and warrants to purchase 42,255 shares of the Company's common stock for gross cash proceeds of \$100,000.

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**7. Shareholders' Equity**

As further discussed in Note 1, on February 22, 2008 the Company completed its IPO pursuant to which it sold 1,100,000 shares of common stock at a price per share of \$5.25 for net proceeds of approximately \$1.45 million after deducting underwriter discounts of approximately \$400,000 and offering costs of approximately \$3.92 million. The Consolidated Statement of Cash Flows for the quarter ended June 30, 2008 reflects the Company's receipt of approximately \$4.24 million of "Proceeds from (payments for) initial public offering of common stock, net". The \$4.24 million cash proceeds figure is approximately \$2.79 million higher than the \$1.45 million net proceeds figure identified above due to payment of \$2.79 million of various offering expenses prior to January 1, 2008.

**8. Stock Options and Warrants**

*Stock Options*

In July 2008, the Board of Directors approved, subject to shareholder approval, the establishment of the Bioheart Omnibus Equity Compensation Plan (the "Omnibus Plan"). The establishment of the Omnibus Plan was approved by the Company's shareholders at the Annual Meeting of Shareholders held on July 30, 2008. Pursuant to the Omnibus Plan, the Company may grant restricted stock, incentive stock options, non-statutory stock options, stock appreciation rights, deferred stock, stock awards, performance shares, and other stock-based awards consisting of cash, restricted stock or unrestricted stock in various combinations to the Company's employees, directors and consultants. 5,000,000 shares of common stock have been reserved for issuance under the Omnibus Plan. As of June 30, 2009, no instruments had been issued under the Omnibus Plan.

In December 1999, the Company adopted two stock option plans; an employee stock option plan and a directors and consultants stock option plan (collectively referred to as the "Stock Option Plans"), under which a total of 1,235,559 shares of common stock were reserved for issuance upon exercise of options granted by the Company. In 2001, the Company amended the Stock Option Plans to increase the total shares of common stock reserved for issuance to 1,698,894. In 2003, the Company approved an increase of 308,890 shares, making the total 2,007,784 shares available for issuance under the Stock Option Plans. In 2006, the Company approved an increase of 1,081,114 shares, making the total 3,088,898 shares available for issuance under the Stock Option Plans. The Stock Option Plans provide for the granting of incentive and non-qualified options. The terms of stock options granted under the Stock Option Plans are determined by the Compensation Committee of the Board of Directors at the time of grant, including the exercise price, vesting provisions and contractual term of such options. The exercise price of incentive stock options must equal at least the fair value of the common stock on the date of grant, and the exercise price of non-qualified stock options may be no less than the per share par value. The options have terms of up to ten years after the date of grant and become exercisable as determined upon grant, typically over either three or four year periods from the date of grant. Certain outstanding options vested over a one-year period and some vested immediately. As of June 30, 2009, 720,667 shares remain available for issuance under the Stock Option Plans.

A summary of options at June 30, 2009 and activity during the six-month period then ended is presented below:

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**Notes to Consolidated Interim Financial Statements — (Continued)**  
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	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (1)
Options outstanding at January 1, 2009	2,279,619	\$5.11		
Granted	491,624	\$0.70		
Exercised	(71,250)	\$0.45		30,688
Forfeited	(356,141)	\$5.58		

Options outstanding at June 30, 2009	2,343,852	\$4.25	5.4	\$35,427
Options exercisable at June 30, 2009	1,912,624	\$4.83	4.6	\$ 7,808
Available for grant at June 30, 2009	5,720,667			

(1) The aggregate intrinsic value represents the amount by which the fair market value of the Company's common stock exceeds the exercise price of options at June 30, 2009. The weighted average fair value of options granted in the six-month periods ended June 30, 2009 and 2008 was \$0.55 and \$2.38 per share, respectively. The total intrinsic value of options exercised in the six-month period ended June 30, 2009 was \$30,688. There were 71,250 options exercised in the six-month period ended June 30, 2009.

For the six month period ended June 30, 2009, the Company recognized a net reversal of \$47,750 in stock-based compensation. This amount consisted of \$52,042 in stock-based compensation that was included in research and development expenses, which was offset by a net reversal of \$99,792 of previously recognized stock-based compensation that was included in marketing, general and administrative expenses. For the six-month period ended June 30, 2008, the Company recognized \$1,071,546 in stock-based compensation costs of which approximately \$91,619 represented research and development expense and the remaining amount was marketing, general and administrative expense. No tax benefits were attributed to the stock-based compensation expense because a valuation allowance was maintained for all net deferred tax assets. The Company elected to adopt the alternative method of calculating the historical pool of windfall tax benefits as permitted by FSP No. SFAS 123R-c, *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards*. This is a simplified method to determine the pool of windfall tax benefits that is used in determining the tax effects of stock compensation in the results of operations and cash flow reporting for awards that were outstanding as of the adoption of SFAS No. 123R. At June 30, 2009, the Company had approximately \$320,000 of unrecognized compensation costs related to non-vested options that is expected to be recognized over the next three years.

The following information applies to options outstanding and exercisable at June 30, 2009:

	Options Outstanding			Options Exercisable	
	Shares	Weighted-Average Remaining Contractual Term	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
\$0.71 – \$1.28	739,984	5.6	\$ 1.00	373,132	\$ 1.15
\$2.83 – \$4.11	51,701	2.3	\$ 3.08	41,701	\$ 2.83
\$5.25 – \$5.67	1,412,312	5.5	\$ 5.61	1,385,797	\$ 5.61
\$7.69	52,423	7.2	\$ 7.69	45,300	\$ 7.69
\$8.47	87,432	4.1	\$ 8.47	66,614	\$ 8.47
	<u>2,343,852</u>	<u>5.4</u>	<u>\$ 4.25</u>	<u>1,912,624</u>	<u>\$ 4.83</u>

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The Company uses the Black-Scholes valuation model to determine the fair value of options on the date of grant. This model derives the fair value of options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rates and dividend yield. For the period through March 31, 2009 the Company's expected volatility is based on the historical volatility of other publicly traded development stage companies in the same industry. Commencing April 1, 2009, the Company began calculating its volatility based on actual fluctuations in its share prices. Prior to January 1, 2008, the Company estimated the expected term for stock option grants by review of similar data from a peer group of companies. The Company adopted SAB 110 effective January 1, 2008 and will apply the simplified method in SAB 107 until enough historical experience is readily available to provide a reasonable estimate of the expected term for stock option grants. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve appropriate for the term of the expected life of the options.

For the six-month periods ended June 30, 2009 and 2008, the fair value of each option grant was estimated on the date of grant using the following weighted-average assumptions.

For the six-month periods ended June 30,

Expected dividend yield	00.0%	00.0%
Expected price volatility	104.0%	75.0%
Risk free interest rate	2.43%	3.3%
Expected life of options in years	6.8	5.1

### Stock Warrants

The Company does not have a formal plan in place for the issuance of stock warrants. However, at times, the Company will issue warrants to non-employees or in connection with financing transactions. The exercise price, vesting period, and term of these warrants is determined by the Company's Board of Directors at the time of issuance. A summary of warrants at June 30, 2009 and activity during the six-month period then ended is presented below:

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## Bioheart, Inc. and Subsidiaries (A development stage enterprise)

### Notes to Consolidated Interim Financial Statements — (Continued) (Unaudited)

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2009	2,951,018	\$6.65		
Issued	2,262,303	.55		
Exercised	—	—		
Forfeited	—	—		
Outstanding at June 30, 2009	<u>5,213,321</u>	<u>\$4.00</u>	<u>10.5</u>	<u>\$648,741</u>
Exercisable at June 30, 2009	<u>3,336,791</u>	<u>\$2.62</u>	<u>8.0</u>	<u>\$597,395</u>

In the six-month period ended June 30, 2008, the Company issued a warrant to purchase 77,000 shares of its common stock to the representative of the several underwriters of the Company's IPO, as discussed in Note 1.

For the six-month periods ended June 30, 2009 and 2008, warrants to purchase 1,940,223 shares were issued in connection with loan renewals. These warrants resulted in the addition of \$974,639 in additional interest expense that will be recognized in future periods. When warrants are issued in transactions that require the recognition of expense, the Company uses the Black-Scholes valuation model to determine the fair value of warrants on the date of issuance. The Company's expected volatility is based on the historical volatility of other publicly traded development stage companies in the same industry. The expected life of the warrants is based primarily on the contractual life of the warrants. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve appropriate for the term of the expected life of the warrants.

The following information applies to warrants outstanding and exercisable at June 30, 2009:

	Warrants Outstanding			Warrants Exercisable	
	Shares	Weighted-Average Remaining Contractual Term	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
\$0.53 – \$0.68	2,150,211	9.1	\$ .54	1,940,223	\$0.53
\$0.81 – \$1.09	117,092	3.0	\$0.86	—	\$ —
\$1.90 – \$2.60	393,409	2.3	\$2.08	393,409	\$2.08
\$3.60 – \$4.93	105,000	4.2	\$4.87	100,000	\$4.93
\$5.67 – \$7.69	2,447,609	13.7	\$7.47	903,159	\$7.09
	<u>5,213,321</u>	<u>10.5</u>	<u>\$4.00</u>	<u>3,336,791</u>	<u>\$2.62</u>

During the six months ended June 30, 2009, the Company issued the following warrants:

Loan Modification and Renewal –

- a warrant to purchase 1,315,542 shares of common stock at an exercise price of \$0.53. This warrant was issued in connection with the BlueCrest Loan Amendment discussed in Note 5. The warrant vested immediately upon issuance and expires on the tenth anniversary of the issuance date.

Loan Subordination –

- a warrant to purchase 451,043 shares of common stock at an exercise price of \$0.53. This warrant was

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**Bioheart, Inc. and Subsidiaries**  
**(A development stage enterprise)**

**Notes to Consolidated Interim Financial Statements — (Continued)**  
**(Unaudited)**

issued in connection with the BlueCrest Loan Amendment discussed in Note 5. The warrant vested immediately upon issuance and expires on the tenth anniversary of the issuance date. Inducement to convert accounts payable to a promissory note

- a warrant to purchase 173,638 shares of common stock at an exercise price of \$0.53. This warrant was issued in connection with the BlueCrest Loan Amendment discussed in Note 5. The warrant vested immediately upon issuance and expires on the tenth anniversary of the issuance date.

Private Placement transaction

Warrants to purchase in aggregate 322,080 shares of common stock were issued during the quarter, as follows:

- 183,672 shares at an exercise price of \$0.59
- 26,316 shares at an exercise price of \$0.68
- 22,059 shares at an exercise price of \$0.82
- 38,823 shares at an exercise price of \$0.82
- 18,801 shares at an exercise price of \$0.90
- 12,972 shares at an exercise price of \$0.89
- 19,437 shares at an exercise price of \$0.85

These warrants were issued in connection with the Private Placement discussed in Note II. These Warrants vest six months after issuance and expire in three years after issuance.

## **9. Legal Proceedings**

On March 13, 2009, Judge Bernice Bouie Donald of the United States District Court for the Western District of Tennessee issued a Memorandum Opinion and Order in litigation brought against Bioheart by Dr. Peter K. Law and Cell Transplants Asia Limited (“CTAL”) (collectively, the “Plaintiffs”), captioned Peter K. Law, et al. v. Bioheart, Inc., No. 2:07-cv-2177 (the “Action”). The Action, which has been the subject of previous disclosures by the Company, was commenced on March 9, 2007, and asserted claims against the Company and Howard J. Leonhardt, individually, with respect to a license agreement entered into between Bioheart, Inc. and Cell Transplants International, LLC (“CTI”) on February 7, 2000 (the “Original License Agreement”). Pursuant to the Original License Agreement, among other things, CTI granted the Company a license to certain patents “related to heart muscle regeneration and angiogenesis for the life of the patents.” In July 2000, Bioheart and CTI, together with Dr. Law, executed an addendum to the Original License Agreement, which amended or superseded a number of the terms of the Original License Agreement (the “License Addendum”).

In their amended complaint, Dr. Law and CTAL asserted 14 breach of contract and related claims pertaining to the Original License Agreement and License Addendum, including, among others, claims that the Company had breached obligations to provide shares of Bioheart common stock to Dr. Law, pay royalties on “gross sales” of MyoCell, pay a \$3 million milestone payment due upon Bioheart’s “commencement of a bona fide Phase II human clinical trial study that utilizes technology claimed under U.S. Patent No. 5,130,141 with FDA approval in the United States,” and to refrain from sublicensing Plaintiffs’ patents. Plaintiffs also sought a declaratory judgment that the License Addendum was unenforceable due to a lack of consideration and/or economic duress. At the outset of the Action, the individual claim against Mr. Leonhardt was dismissed along with Plaintiffs’ claim for civil conspiracy, leaving 12 claims to be adjudicated.

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**Bioheart, Inc. and Subsidiaries**  
**(A development stage enterprise)**

**Notes to Consolidated Interim Financial Statements — (Continued)**  
**(Unaudited)**

The Company denied the material allegations of the amended complaint, denied it had any liability to Plaintiffs, and asserted a number of defenses to Plaintiffs' claims, as well as counterclaims seeking a declaration that the License Addendum was a legally valid and binding agreement and asserting that Dr. Law and/or CTI had breached various obligations in the parties' agreements.

Following the completion of discovery, the Action was tried to the Court, without a jury, from September 22–25, 2008.

On March 13, 2009, the Court rendered its decision in the Action, dismissing the amended complaint after finding that Plaintiffs had failed to establish any of their 12 remaining claims. With respect to Plaintiffs' claim for the \$3 million milestone payment, the Court found that the payment was "payable only to CTI," not the Plaintiffs, and that CTI, a dissolved Tennessee limited liability company, had never been made a party to the Action and therefore was "not properly before the Court." The Court also found that, even assuming Plaintiffs could assert a claim for the milestone payment on behalf of CTI, the payment was not due because "Bioheart's MyoCell process does not utilize technology claimed under the "141 patent." In addition, the Court found that Bioheart owed no royalties because it has not yet made any "gross sales" of MyoCell.

The Court found in Bioheart's favor on its counterclaim seeking a declaration that the License Addendum was a valid and enforceable agreement and its counterclaim that Dr. Law breached his obligation under the License Addendum to provide Bioheart with "all pertinent and critical information" related to our filing of an IND application with the FDA. The Court awarded Bioheart nominal damages of \$1.00 on the latter counterclaim, and dismissed Bioheart's other counterclaims. Judgment upon the Memorandum Opinion and Order was entered on March 18, 2009.

Subsequent to the Court rendering its decision in the Action, the Plaintiffs filed a motion with the Court seeking reconsideration of its decision. The Company's response was filed on April 20, 2009, and the Court's decision is pending. The parties will have 30 days from entry of a decision on Plaintiff's motion for reconsideration to file a notice of appeal with the United States Court of Appeals for the Sixth Circuit.

There is a risk that the Court may find in favor of the Plaintiffs upon reconsideration or appeal. The Company's current cash reserves are not sufficient to satisfy a significant money judgment in favor of the Plaintiffs. The entry of such a judgment would also likely constitute a default under the BlueCrest Loan and Bank of America Loan and have a significant adverse impact on the Company's financial condition, results of operations and MyoCell commercialization efforts.

Due to the uncertainty related to these proceedings, any potential loss cannot presently be determined.

As previously disclosed, on October 24, 2007, the Company completed the MyoCell implantation procedure on the first patient in its MARVEL Trial. As a result of the claim set forth in the litigation discussed above, the Company recorded an accrual for \$3 million in the fourth quarter of 2007, which was included in accrued expenses as of June 30, 2009 and December 31, 2008.

***Other***

The Company is subject to other legal proceedings that arise in the ordinary course of business. In the opinion of management, as of June 30, 2009, the amount of ultimate liability with respect to such matters, if any, in excess of applicable insurance coverage, is not likely to have a material impact on the Company's business, financial position, results of operations or liquidity. However, as the outcome of litigation and other claims is difficult to predict, significant changes in the estimated exposures could occur.

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**Bioheart, Inc. and Subsidiaries**  
**(A development stage enterprise)**

**Notes to Consolidated Interim Financial Statements — (Continued)**  
**(Unaudited)**

**10. Contingency**

The Company believes that it may have issued options to purchase common stock to certain of its employees, directors and consultants in California in violation of the registration or qualification provisions of applicable California securities laws. As a result, the Company intends to make a rescission offer to these persons. The Company will make this offer to all persons who have a continuing right to rescission, which it believes to include two persons. In the rescission offer, in accordance with California law, the Company will offer to repurchase all unexercised options issued to these persons at 77% of the option exercise price multiplied by the number of option shares, plus interest at the rate of 7% from

the date the options were granted. Based upon the number of options that were subject to rescission as of March 31, 2009, assuming that all such options are tendered in the rescission offer, the Company estimated that its total rescission liability would be up to approximately \$377,000. However, as the Company believes there is only a remote likelihood the rescission offer will be accepted by any of these persons in an amount that would result in a material expenditure by the Company, no liability was recorded as of June 30, 2009 or December 31, 2008.

## **11. Subsequent Events**

### ***Private Placement — Common Stock and Warrants***

Commencing on October 1, 2008, the Company conducted a PIPE financing of 2,876,000 shares and 862,500 warrants that has been placed in 16 tranches. Of that amount, 430,270 shares and 129,081 warrants remained as of August 1, 2009. Proceeds have been \$3.12 million.

In July 2009, the Company sold, in a private placement, an aggregate of 140,850 shares of the Company's common stock and warrants to purchase 42,255 shares of the Company's common stock for aggregate gross cash proceeds of \$100,000. The warrants are (i) exercisable solely for cash at an exercise price of \$0.85 per share, (ii) non-transferable for six months following issuance and (iii) exercisable, in whole or in part, at any time during the period commencing on the date that is six months and one day following the date of issuance and ending on the third year anniversary of the date of issuance.

### ***Convertible Debt***

In July 2009, Bruce Meyers and Dana Smith (jointly, the "Lenders") funded a total \$120,000 loan to the Company. The Loan was in the nature of convertible debt and was evidenced by an unsecured promissory note (the "Note"), that was convertible into common stock of the Company at a price that was 22.5% less than the average of the closing bid prices for the Company's shares for the five (5) days prior to the Lenders' election to exercise their conversion right under the Note. The Note was to bear interest at the rate of 10% per annum, with interest payable due at maturity. The terms sheet provides that all unpaid interest (and principal) will be due and payable on the date that is the earlier to occur of the first anniversary of the closing date of the Loan or the closing of a financing in an amount that is equal to or greater than \$3.0 million that will satisfy the Company's obligation under its loan with BlueCrest. However, the Lenders already elected to convert the entire amount of the Loan to shares of the Company's common stock.

Accordingly, the aggregate number of unregistered and restricted shares of the Company's common stock issued in connection with, and as a result of the conversion of, the Loan was 355,294 shares. The Company will have no obligation to file any registration statement with respect to the shares, except that the Lenders will have customary "piggyback" registration rights.

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## **Bioheart, Inc. and Subsidiaries (A development stage enterprise)**

### **Notes to Consolidated Interim Financial Statements — (Continued) (Unaudited)**

#### ***Other***

MyoCell SDF-1 has recently been approved by the US FDA for use in a Phase I dose escalation trial. If we are able to secure additional capital, we intend to begin this trial in 2009 or 2010.

In February 2006, the Company entered into an exclusive license agreement with The Cleveland Clinic Foundation for various patents to be used in connection with the MyoCell SDF-1 product candidate. On July 1<sup>st</sup>, 2009, the company received notification from the Cleveland Clinic that they are terminating the License Agreement due to failure to pay the annual maintenance fee on June 30, 2009. The termination does not release Bioheart from obligations that accrued prior to the effective date of termination or any other obligations it might have under that Agreement. The company also received a communication from Juventas Therapeutics (now acting on behalf of the Cleveland Clinic for this patent portfolio) that it would like to renegotiate the License Agreement with Bioheart. The Company has developed proprietary techniques to utilize the art identified in the patents, that are pending .

Effective July 1, 2009, the Company and BlueCrest agreed to enter into an amendment to the BlueCrest Loan to amend the amortization schedule for the Loan to provide for interest-only payments until January 1, 2010, at which time monthly principal and interest payments of \$139,728 will commence.

In connection with the most recent BlueCrest Loan Amendment the Company will issue BlueCrest a warrant to purchase \$600,000 of the Company's common shares and pay a fee of \$29,435.

Effective July 5, 2009, Bank of America agreed to extend the maturity date of the loan until January 5, 2010. As consideration for this

extension of the maturity date of the loan, the Company owes Bank of America a fee of \$25,000.

On July 15, 2009, to settle an amount due to the Ascent Medical Product Development Centre Inc., affiliated with two Board members, Karl Groth and Peggy Farley, Ascent Medical Product Development Centre Inc. accepted options for 203,125 restricted Bioheart common shares.

On August 12, 2009, the Board of Directors decided that several of its Directors 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. 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.

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## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*Unless otherwise indicated, references in this Quarterly Report on Form 10-Q to "we," "us" and "our" are to the Company. The following discussion and analysis by our management of our financial condition and results of operations should be read in conjunction with our unaudited consolidated interim financial statements and the accompanying related notes included in this quarterly report and our audited consolidated financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2008, as amended by Amendment No. 1 on Form 10-K/A filed with the Securities and Exchange Commission.*

### **Cautionary Statement Regarding Forward-Looking Statements**

This report may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and we intend that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Any such forward-looking statements would be contained principally in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors." Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities and the effects of regulation. Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "could," "estimates," "expects," "hopes," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would" or similar expressions.

The forward-looking statements in this report may include, among other things, statements about:

- our ability to obtain additional financing;
- our ability to control and reduce our expenses;
- our ability to meet our obligations on our outstanding indebtedness, certain of which indebtedness imposes restrictions on how we conduct our business and is secured by all of our assets except our intellectual property;
- our ability to timely and successfully initiate and complete our clinical trials;
- our estimates regarding future revenues and timing thereof, expenses, capital requirements and needs for additional financing;
- our ongoing and planned discovery programs, preclinical studies and additional clinical trials; and
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;

Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We discuss certain of these risks in greater detail in Part II, Item 1A. "Risk Factors." Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this report. You should read this report and the documents that we reference in this report and have filed as exhibits to the report completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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Additional information concerning these and other risks and uncertainties is contained in our filings with the Securities and Exchange Commission, including the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2008, as amended by Amendment No. 1 on Form 10-K/A.

### **Our Ability To Continue as a Going Concern**

Our independent registered public accounting firm issued its report dated April 7, 2009 in connection with the audit of our consolidated financial statements as of December 31, 2008 that included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements as of June 30, 2009 have been prepared under the assumption that we will continue as a going concern. If we are not able to continue as a going concern, it is likely that holders of our common stock will lose all of their investment. Our consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **Overview**

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

#### *Biotechnology Product Candidates*

Specific to biotechnology, we are focused on the discovery, development and, subject to regulatory approval, commercialization of autologous cell therapies for the treatment of chronic and acute heart damage. Our MyoCell product candidate is an innovative clinical muscle-derived 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. Our most recent clinical trials of MyoCell include the SEISMIC Trial, a completed 40-patient, randomized, multicenter, controlled, Phase II-a study conducted in Europe and the MYOHEART Trial, a completed 20-patient, multicenter, Phase I dose-escalation trial conducted in the United States. We have been cleared by the U.S. Food and Drug Administration (the "FDA") to proceed with a 330-patient, multicenter Phase II/III trial of MyoCell in North America and Europe (the "MARVEL Trial"). We completed the MyoCell implantation procedure on the first patient in the MARVEL Trial on October 24, 2007. If the results of the MARVEL Trial demonstrate statistically significant evidence of the safety and efficacy of MyoCell, we anticipate having a basis to ask the FDA to consider the MARVEL Trial a pivotal trial. The SEISMIC, MYOHEART and MARVEL Trials have been designed to test the safety and efficacy of MyoCell in treating patients with severe, chronic damage to the heart. Upon regulatory approval of MyoCell, we intend to generate revenue from the sale of MyoCell cell-culturing services for treatment of patients by interventional cardiologists.

We are currently in the process of evaluating our development timeline for MyoCell and the MARVEL Trial. To date, approximately 50 patients have been enrolled in the MARVEL Trial. We have filed with the FDA an amendment to the clinical protocol for the MARVEL Trial to, among other things, seek to use, as part of the patient protocol, mobile cardiac telemetry monitor recorders. Provided that the protocol amendment is approved and we are able to secure \$5.0 million of additional capital we currently intend to seek to enroll and treat approximately 150 patients in the MARVEL II Trial in 2010. If we meet that timeline, we would expect interim trial data for these 150 patients to be available in 2010. While we are attempting to secure additional capital we have suspended enrollment in the MARVEL Trial. As part of this evaluation process, we expect that we would analyze whether to focus resources towards the development, commercialization and/or distribution of certain of our other product candidates, including, but not limited to MyoCell® SDF-1, a therapy utilizing autologous cells genetically modified to express additional potentially therapeutic growth proteins and certain intelligent devices. In the event we suspend enrollment in the MARVEL II Trial, we

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anticipate that we would continue to use our resources, to the extent available, to collect follow-up data on the patients treated to date in the MARVEL I Trial.

MyoCell SDF-1 has recently been approved by the US FDA for use in a Phase I dose escalation trial. If we are able to secure additional capital, we intend to begin this trial in 2009 or 2010.

In our pipeline, we have multiple product candidates for the treatment of heart damage, including Bioheart Acute Cell Therapy, an autologous, adipose cell treatment for acute heart damage designed to be used in connection with the TGI 1200™ tissue processing system, and MyoCell® SDF-1. Tissue Genesis, Inc., the entity from whom we have obtained the worldwide right to sell or lease the TGI 1200™ announced on November 13, 2008 that the TGI 1200™ had been certified with a CE Marking, thus making the system available throughout the European marketplace. We understand that Tissue Genesis is in the process of evaluating the regulatory pathway in the United States that should be

pursued for the TGI 1200™ device. We hope to demonstrate that our various product candidates are safe and effective complements to existing therapies for chronic and acute heart damage.

### *Intelligent Devices — Distribution Agreements*

Effective as of October 30, 2008, we entered into a distribution agreement with Monebo Technologies, Inc. (“Monebo”) pursuant to which we were granted non-exclusive rights to distribute Monebo’s CardioBelt™ system throughout North America and Western Europe. This system provides ECG monitoring to heart patients from the comfort of their own home. We are required to meet certain annual minimum purchase commitments under the distribution agreement. The agreement has an initial term of two years and is subject to automatic renewal for additional one-year periods unless either party indicates an intent to terminate the agreement prior to the end of the then current term. The distribution agreement may be terminated by either party upon 180 days notice for any reason or by either party immediately upon the other party’s uncured default. In addition, Monebo may terminate the agreement in the event we do not satisfy our annual minimum purchase commitment. We intend to commence distribution of the CardioBelt™ system during 2009 or 2010.

In connection with the distribution agreement, we also entered into a Master Software License Agreement with Monebo pursuant to which Monebo granted us a non-exclusive, non-sublicensable, non-transferable license to certain software and algorithms to be used in connection with the CardioBelt™ system. We paid Monebo an upfront cash fee for this license and will be required to pay certain additional fees upon installation. We will also be required to pay to Monebo royalty fees per patient and software maintenance fees.

Effective as of April 3, 2008, we entered into a distribution agreement with RTX Healthcare A/S (Denmark) (“RTX”) pursuant to which we secured worldwide, non-exclusive distribution rights to the Bioheart 3370 Heart Failure Monitor, an interactive and simple-to-use at-home intelligent device designed specifically to improve available healthcare to patients outside hospitals who are suffering from heart failure. The device, manufactured by RTX, has 510(k) market clearance from the U.S. Food and Drug Administration for marketing in the United States and CE mark approval for marketing in Europe and other countries that follow this mark. The compact Bioheart 3370 Heart Failure Monitor engages patients through personalized daily interactions and questions, while collecting vital signs and transmitting the information directly into a database. The data are regularly monitored by a remotely located medical professional, who watches for any abnormal readings that may signal a change in the patient’s health status. These changes are reported back to the treating physician. We do not have any minimum purchase commitment under the agreement. However, the per unit purchase price payable by us is inversely related to the number of units we purchase per annum. The distribution agreement has an initial term of two years and is subject to automatic renewal for additional one-year periods unless either party indicates an intent to terminate the agreement prior to the end of the then current term. The distribution agreement may be terminated by either party upon the other party’s default.

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We conduct operations in one business segment. We may organize our business into more discrete business units when and if we generate significant revenue from the sale of our product candidates. Substantially all of our revenue since inception has been generated in the United States, and the majority of our long-lived assets are located in the United States.

### **Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following policies are important to understanding and evaluating our reported financial results:

#### ***Share-Based Compensation***

On January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards No. 123R, *Share-Based Payment* (“SFAS No. 123R”) using the modified prospective transition method. SFAS No. 123R requires us to measure all share-based payment awards granted after January 1, 2006, including those with employees, at fair value. Under SFAS No. 123R, the fair value of stock options and other share-based compensation must be recognized as expense in the statements of operations over the requisite service period of each award.

The fair value of share-based awards granted subsequent to January 1, 2006 is determined using the Black-Scholes valuation model and compensation expense is recognized on a straight-line basis over the vesting period of the awards. Beginning January 1, 2006, we also began recognizing compensation expense under SFAS No. 123R for the unvested portions of outstanding share-based awards previously granted under our stock option plans, over the periods these awards continue to vest. Our future share-based compensation expense will depend on the number of equity instruments granted and the estimated value of the underlying common stock at the date of grant.

We account for certain share-based awards, including warrants, with non-employees in accordance with SFAS No. 123R and related

guidance, including EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. We estimate the fair value of such awards using the Black-Scholes valuation model at each reporting period and expense the fair value over the vesting period of the share-based award, which is generally the period in which services are provided.

### ***Revenue Recognition***

Since inception, we have not generated any material revenues from our lead product candidate. In accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, our revenue policy is to recognize revenues from product sales and service transactions generally when persuasive evidence of an arrangement exists, the price is fixed or determined, collection is reasonably assured and delivery of product or service has occurred.

We initially recorded payments received by us pursuant to our agreements with Advanced Cardiovascular Systems, Inc. ("ACS"), originally a subsidiary of Guidant Corporation and now d/b/a Abbott Vascular, a

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division of Abbott Laboratories, as deferred revenue. Revenues are recognized on a pro rata basis as the catheters are delivered pursuant to those agreements.

We initially recorded payments received by us pursuant to a clinical supply agreement entered into in August 2007 with BHK, Inc. ("BHK") as deferred revenue. Revenues are recognized on a pro rata basis as the cell-culturing services are provided and are shown in development revenues. The costs associated with earning these revenues are expensed as incurred and are included in research and development expenses in our statements of operations. In February 2005, we entered into a joint venture agreement with Bioheart Korea, Inc., BHK's predecessor entity, pursuant to which we and BHK agreed to create a joint venture company now known as Bioheart Manufacturing, Inc. As of December 31, 2008, the Company owned an 18% equity interest in Bioheart Manufacturing, Inc. In February 2009, the Company's ownership interest in Bioheart Manufacturing, Inc. was reduced from 18% to approximately 6% as a result of an investment in Bioheart Manufacturing, Inc. by a third party.

### ***Research and Development Activities***

Research and development expenditures, including payments to collaborative research partners, are charged to expense as incurred. We expense amounts paid to obtain patents or acquire licenses as the ultimate recoverability of the amounts paid is uncertain.

### **Results of Operations**

We are a development stage company and our MyoCell product candidate has not received regulatory approval or generated any material revenues and is not expected to until 2010, if ever. We have generated substantial net losses and negative cash flow from operations since inception and anticipate incurring significant net losses and negative cash flows from operations for the foreseeable future as we continue clinical trials, undertake new clinical trials, apply for regulatory approvals, make capital expenditures, add information systems and personnel, make payments pursuant to our license agreements upon our achievement of certain milestones, continue development of additional product candidates using our technology, establish sales and marketing capabilities and incur the additional cost of operating as a public company.

#### *Revenues*

We recognized revenues of \$206,885 in the six-month period ended June 30, 2009 compared to revenues of \$119,281 in the six-month period ended June 30, 2008. In the six-month period ended June 30, 2009 all revenue generated was mainly from the shipment of MyoCath catheters.

#### *Development Revenues*

In the six-month period ended June 30, 2008, we recognized \$76,500 in development revenues from cell-culturing services provided pursuant to the clinical supply agreement entered with BHK, Inc. No such revenues were recognized in the six-month period ended June 30, 2009.

#### *Cost of Sales*

Cost of sales was \$112,781 in the six-month period ended June 30, 2009 compared to \$7,646 in the six months ended June 30, 2008. The cost per catheter sold in the six-month periods ended June 30, 2009 and 2008 were approximately the same. However, a portion of the catheters sold in 2008 had no inventory cost as they had been written off in prior years.

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### *Research and Development*

Research and development expenses were \$1,042,000 for the six-month period ended June 30, 2009 compared to \$2.8 million in the six-month period ended June 30, 2008, a decrease of \$1,794,000. The decrease was primarily attributable to a reduction in the amount of sponsored research and a reduction in costs related to our SEISMIC, MYOHEART and MARVEL Trials.

The timing and amount of our planned research and development expenditures is dependent on our ability to obtain additional financing.

### *Marketing, General and Administrative*

Marketing, general and administrative expenses were \$1,119,000 for the six-month period ended in June 30, 2009, compared to \$2.9 million in the six-month period ended June 30, 2008, a decrease of \$1,830,000. The decrease in marketing, general and administrative expenses is attributable, to a decrease in stock-based compensation expense, salaries & wages, legal fees and accounting fees.

### *Interest Income*

Interest income consists of interest earned on our cash and cash equivalents. Interest income was \$16 in the six months ended June 30, 2009 compared to interest income of \$42,202 in the six-month period ended June 30, 2008. The decrease in interest income was primarily attributable to lower cash balances in the six-month period ended June 30, 2009, compared to the six-month period ended June 30, 2008.

### *Interest Expense*

Interest expense primarily consists of interest incurred on the principal amount of the BlueCrest and the Bank of America Loans, accrued fees and interest earned by the guarantors of the Bank of America Loan, the amortization of related deferred loan costs and the amortization of the fair value of warrants issued in connection with the BlueCrest and Bank of America Loans. The fair value of the warrants originally issued in connection with the Bank of America Loan was amortized by the end of January 2008. Our debt carries interest rates ranging from 4.75% to 13.50% as of June 30, 2009.

Interest expense was \$1,336,000 in the six-month period ended June 30, 2009 compared to \$1,430,000 in the six-month period ended June 30, 2008. Interest incurred on the principal amount of our outstanding loans and interest and fees earned by the guarantors totaled \$581,000,000 and \$603,000 in the six-month periods ended June 30, 2009 and 2008, respectively. Amortization of deferred loan costs and amortization of the fair value of warrants issued in connection with the BlueCrest and Bank of America Loans totaled \$550,000 and \$820,000 in the six-month periods ended June 30, 2009 and 2008. The six-month period ended June 30, 2009 also includes \$200,000 of interest expense related to the discount associated with the convertible debt issued and converted during the period.

## **Liquidity and Capital Resources**

In 2009, we continue to finance our considerable operational cash needs with cash generated from financing activities.

### *Operating Activities*

Net cash used in operating activities was \$914,048 in the six months ended June 30, 2009 as compared to \$6.8 million of cash used in the six months ended June 30, 2008

Our use of cash for operations in the six months ended June 30, 2009 reflected a net loss generated during the period of \$3.5 million. However, our net loss was significantly offset by a decrease in prepaid expenses

and other current assets of \$522,000, an increase in accounts payable of \$534,000 and an increases in accrued expenses of \$475,000. The decrease in prepaid expenses and other current assets was due to the refund of upfront payments under an agreement with the contract research organization that we are utilizing for the MARVEL Trial. Accounts payable increased as we have sought to conserve cash until significant additional financing is obtained.

Our use of cash for operations in the six months ended June 30, 2008 reflected a net loss generated during the period of \$7.2 million and an

increase in prepaid expenses and other current assets of \$2.1 million. The increase in prepaid expenses and other current assets was due to upfront payments under an agreement with the contract research organization that we are utilizing for the MARVEL Trial. Partially offsetting these uses of cash were amortization of the fair value of warrants granted in connection with the BlueCrest Loan and Bank of America Loan of \$562,000, an increase in accrued expenses and deferred rent of \$402,000, a decrease in accounts payable of \$23,000, stock-based compensation of \$1,072,000 and amortization of loan costs incurred in connection with the BlueCrest Loan and Bank of America Loan of \$258,000.

### *Investing Activities*

No cash was used in investing activities in the six-month period ended June 30, 2009. Net cash used in investing activities was \$18,000 in the six-month period ended June 30, 2008. All of the cash utilized in investing activities in the six-month period ended June 30, 2008 related to our acquisition of property and equipment.

### *Financing Activities*

Net cash provided by financing activities was \$884,000 in the six-month period ended June 30, 2009 compared to \$3.2 million in the six-month period ended June 30, 2008.

In the six-month period ended June 30, 2009, we received net proceeds of \$190,001 in connection with the issuance of convertible debt and shares of common stock.

On February 22, 2008 we completed our IPO of common stock pursuant to which we sold 1,100,000 shares of common stock at a price per share of \$5.25 for net proceeds of \$1.45 million. The Consolidated Statement of Cash Flows for the six months period ended June 30, 2008 reflects our receipt of approximately \$4.24 million of "Proceeds from initial public offering of common stock, net." The \$4.24 million cash proceeds figure is approximately \$2.79 million higher than the \$1.45 million IPO net proceeds figure identified above due to our payment of \$2.79 million of various offering expenses prior to January 1, 2008.

In the six-month period ended June 30, 2008, we repaid \$670,000 of principal on the BlueCrest Loan and paid \$95,000 of costs incurred in connection with the extension of the maturity date of the Bank of America Loan.

### *Existing Capital Resources and Future Capital Requirements*

Our MyoCell product candidate has not received regulatory approval or generated any material revenues. We do not expect to generate any material revenues or cash from sales of our MyoCell product candidate until 2010, if ever. We have generated substantial net losses and negative cash flow from operations since inception and anticipate incurring significant net losses and negative cash flows from operations for the foreseeable future. Historically, we have relied on proceeds from the sale of our common stock and our incurrence of debt to provide the funds necessary to conduct our research and development activities and to meet our other cash needs.

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At June 30, 2009, we had cash and cash equivalents totaling \$20,000; however, our working capital deficit as of such date was \$13.7 million. Our independent registered public accounting firm issued its report dated April 7, 2009 in connection with the audit of our consolidated financial statements as of December 31, 2008 that included an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

### **Recent Accounting Pronouncements**

Refer to Note 1. *Organization and Summary of Significant Accounting Policies* in the notes to our consolidated interim financial statements for a discussion of recent accounting pronouncements.

### **Effects of Being a Public Company**

In October 2007, we became subject to the periodic reporting requirements of the Exchange Act and the other rules and regulations of the SEC. We are also subject to various other regulatory requirements, including the Sarbanes-Oxley Act of 2002.

We continue to work with our legal and accounting advisors to identify those areas in which changes should be made to our financial and

management control systems to manage our growth and our obligations as a public company. These areas include corporate governance, corporate control, internal audit, disclosure controls and procedures and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas, including our internal control over financial reporting.

In addition, compliance with reporting and other requirements applicable to public companies will create additional costs for us and will require the time and attention of management. We cannot estimate with reasonable certainty the amount of the additional costs we may incur, the timing of such costs or the degree of impact that our management's attention to these matters will have on our business.

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### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

#### *Interest Rate Risk*

Our primary market risk exposure with respect to interest rates is changes in short-term interest rates in the U.S., particularly because certain of our debt arrangements represent floating rate debt and we are subject to interest rate risk. We do not use any interest rate risk management contracts to manage our fixed-to-floating ratio. The impact on our results of operations from a hypothetical 10% change in interest rates would not be significant.

The majority of our investments are expected to be in short-term debt securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. To reduce risk, we maintain our cash and cash equivalents in short-term interest-bearing instruments, including certificates of deposit and overnight funds. We do not have any derivative financial investments in our investment portfolio.

### **Item 4. Controls and Procedures**

#### *Disclosure Controls and Procedures*

We have established disclosure controls and procedures to ensure that material information relating to us is made known to the officer who certifies our financial reports, as well as to other members of senior management and the Board of Directors.

We carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer, as well as our Principal Financial and Accounting Officer, of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Principal Executive Officer, as well as our Principal Financial and Accounting Officer concluded that, as of June 30, 2009, our disclosure controls and procedures were effective. The controls that management sought to identify and evaluate were those processes designed by, or under the supervision of, the Company's principal financial officer, or persons performing similar functions, and implemented by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors of the Company; and
- (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the issuer's assets that could have a material effect on the financial statements.

#### *Inherent Limitations in Control Systems*

Our controls and procedures were designed at the reasonable assurance level. However, because of inherent limitations, any system of controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired objectives of the control system. In addition, the design of a control system must reflect the fact that there are resource constraints, and management must apply its judgment in evaluating the benefits of controls relative to their costs. Further, no

evaluation of controls and procedures can provide absolute assurance that all errors, control issues and instances of fraud will be prevented or detected. The design of any system of controls and procedures is also based in part on certain assumptions regarding the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

### ***Changes In Internal Control Over Financial Reporting***

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. The Company's Chief Financial Officer and Vice President of Financial Operations resigned during the quarter ended March 31, 2009. We have not yet determined whether or not other internal controls over financial reporting will be sufficient so as to avoid any material affect.

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## **PART II — OTHER INFORMATION**

### **Item 1. Legal Proceedings**

On March 13, 2009, Judge Bernice Bouie Donald of the United States District Court for the Western District of Tennessee issued a Memorandum Opinion and Order in litigation brought against us by Dr. Peter K. Law and Cell Transplants Asia Limited ("CTAL") (collectively, the "Plaintiffs"), captioned Peter K. Law, et al. v. Bioheart, Inc., No. 2:07-cv-2177 (the "Action"). The Action, which has been the subject of previous disclosures by us, was commenced on March 9, 2007, and asserted claims against us and Howard J. Leonhardt, individually, with respect to a license agreement entered into between Bioheart, Inc. and Cell Transplants International, LLC ("CTI") on February 7, 2000 (the "Original License Agreement"). Pursuant to the Original License Agreement, among other things, CTI granted us a license to certain patents "related to heart muscle regeneration and angiogenesis for the life of the patents." In July 2000, we and CTI, together with Dr. Law, executed an addendum to the Original License Agreement, which amended or superseded a number of the terms of the Original License Agreement (the "License Addendum").

In their amended complaint, Dr. Law and CTAL asserted 14 breach of contract and related claims pertaining to the Original License Agreement and License Addendum, including, among others, claims that we had breached obligations to provide shares of Bioheart common stock to Dr. Law, pay royalties on "gross sales" of MyoCell, pay a \$3 million milestone payment due upon our "commencement of a bona fide Phase II human clinical trial study that utilizes technology claimed under U.S. Patent No. 5,130,141 with FDA approval in the United States," and to refrain from sublicensing Plaintiffs' patents. Plaintiffs also sought a declaratory judgment that the License Addendum was unenforceable due to a lack of consideration and/or economic duress. At the outset of the Action, the individual claim against Mr. Leonhardt was dismissed along with Plaintiffs' claim for civil conspiracy, leaving 12 claims to be adjudicated.

We denied the material allegations of the amended complaint, denied we had any liability to Plaintiffs, and asserted a number of defenses to Plaintiffs' claims, as well as counterclaims seeking a declaration that the License Addendum was a legally valid and binding agreement and asserting that Dr. Law and/or CTI had breached various obligations in the parties' agreements.

Following the completion of discovery, the Action was tried to the Court, without a jury, from September 22-25, 2008.

On March 13, 2009, the Court rendered its decision in the Action, dismissing the amended complaint after finding that Plaintiffs had failed to establish any of their 12 remaining claims. With respect to Plaintiffs' claim for the \$3 million milestone payment, the Court found that the payment was "payable only to CTI," not the Plaintiffs, and that CTI, a dissolved Tennessee limited liability company, had never been made a party to the Action and therefore was "not properly before the Court." The Court also found that, even assuming Plaintiffs could assert a claim for the milestone payment on behalf of CTI, the payment was not due because "Bioheart's MyoCell process does not utilize technology claimed under the '141 patent." In addition, the Court found that we owed no royalties because we have not yet made any "gross sales" of MyoCell.

The Court found in our favor on our counterclaim seeking a declaration that the License Addendum was a valid and enforceable agreement and our counterclaim that Dr. Law breached his obligation under the License Addendum to provide Bioheart with "all pertinent and critical information" related to our filing of an IND application with the FDA. The Court awarded us nominal damages of \$1.00 on the latter counterclaim, and dismissed our other counterclaims. Judgment upon the Memorandum Opinion and Order was entered on March 18, 2009.

Subsequent to the Court rendering its decision in the Action, the Plaintiffs filed a motion with the Court seeking reconsideration of its decision. Our response was filed on April 20, 2009, and the Court's decision is

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pending. The parties will have 30 days from entry of a decision on Plaintiff's motion for reconsideration to file a notice of appeal with the United States Court of Appeals for the Sixth Circuit.

There is a risk that the Court may find in favor of the Plaintiffs upon reconsideration or appeal. Our current cash reserves are not sufficient to satisfy a significant money judgment in favor of the Plaintiffs. The entry of such a judgment would also likely constitute a default under the BlueCrest Loan and Bank of America Loan and have a significant adverse impact on our financial condition, results of operations and MyoCell commercialization efforts.

Due to the uncertainty related to these proceedings, any potential loss cannot presently be determined.

As previously disclosed, on October 24, 2007, we completed the MyoCell implantation procedure on the first patient in our MARVEL Trial. As a result of the claim set forth in the litigation discussed above, we recorded an accrual for \$3 million in the fourth quarter of 2007, which was included in accrued expenses as of March 31, 2009 and December 31, 2008.

Except as described above, we are not presently engaged in any material litigation and are unaware of any threatened material litigation. However, the biotechnology and medical device industries have been characterized by extensive litigation regarding patents and other intellectual property rights. In addition, from time to time, we may become involved in litigation relating to claims arising from the ordinary course of our business.

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## **Item 1A. Risk Factors**

Except as set forth below, there have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, as amended by Amendment No. 1 on Form 10-K/A.

The risks and uncertainties described below and disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, as amended by Amendment No. 1 on Form 10-K/A, are not the only ones facing us. Other events that we do not currently anticipate or that we currently deem immaterial also may affect our results of operations and financial condition. If any events described in the risk factors actually occur, our business, operating results, prospects and financial condition could be materially harmed. In connection with the forward-looking statements that appear elsewhere in this quarterly report, you should also carefully review the cautionary statement referred to under Part I. Item 2 "Cautionary Statement Regarding Forward-Looking Statements."

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## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

### ***Private Placement — Convertible Debt***

In February 2009, Bruce Meyers and Robert Seguso (jointly, the "Lenders") funded the remaining \$100,000 of a total \$200,000 loan to the Company. The funds were delivered, net of original issue discount in the amount of \$10,000, pursuant to a terms sheet provided by Bruce Meyers, for a convertible debt financing to be provided to the Company (the "Loan"). Although the terms sheet provided that the Lenders would be provided a complete set of loan documentation, the Lenders delivered to the Company the entire net proceeds of the Loan, in the amount of \$190,000, in advance of receiving any documentation. The initial funding of \$100,000 was made to the Company on January 21, 2009. However, the Company determined that it would not proceed with the Loan unless and until the Lenders funded the balance of the net proceeds which was completed on February 3, 2009 and provided that the Board of Directors of the Company approved the Loan, which approval was obtained on February 11, 2009.

The Loan was in the nature of convertible debt and was evidenced by an unsecured promissory note (the "Note"), that was convertible into common stock of the Company at a price that was 22.5% less than the average of the closing bid prices for the Company's shares for the five (5) days prior to the Lenders' election to exercise their conversion right under the Note. The Note was to bear interest at the rate of 10% per annum, with interest payable due at maturity. The terms sheet provides that all unpaid interest (and principal) will be due and payable on the date that is the earlier to occur of the first anniversary of the closing date of the Loan or the closing of a financing in an amount that is equal to or greater than \$3 million that will satisfy the Company's obligation under its loan with BlueCrest. However, the Lenders already elected to convert the entire amount of the Loan to shares of the Company's common stock.

In addition to the Note, the Company issued to the Lenders 200,000 unregistered and restricted shares of the Company's common stock. We believe that the offer and sale of the securities is made only to accredited investors and, accordingly, is exempt from registration under Section 4

(2) of the Securities Act of 1933, as amended.

Prior to funding the balance of the Loan, the Lenders delivered to the Company, on January 26, 2009, a notice electing to convert \$100,000 of the Loan into shares of the Company's common stock. The price per share for such election was \$0.50995. This required the issuance to the Lenders of 196,098 unregistered and restricted shares of the Company's common stock.

On February 3, 2009, contemporaneously with the funding of the remainder of the Loan, the Lenders delivered to the Company notice of their election to convert the remainder of the Loan into shares of the Company's common stock at a price per share of \$0.5704. This required the issuance to the Lenders of 175,316 unregistered and restricted shares of the Company's common stock.

Accordingly, the aggregate number of unregistered and restricted shares of the Company's common stock issued in connection with, and as a result of the conversion of, the Loan was 571,414 shares. The Company will have no obligation to file any registration statement with respect to the shares, except that the Lenders will have customary "piggyback" registration rights.

#### ***Private Placement — Common Stock and Warrants***

In April 2009, the Company sold, in a private placement, an aggregate of 699,960 shares of the Company's common stock and warrants to purchase 209,988 shares of the Company's common stock for aggregate gross cash proceeds of \$350,000. The warrants are (i) exercisable solely for cash at an exercise price of \$0.59 to \$0.68 per share, (ii) non-transferable for six months following issuance and (iii) exercisable,

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in whole or in part, at any time during the period commencing on the date that is six months and one day following the date of issuance and ending on the third year anniversary of the date of issuance. .

In May 2009, the Company sold, in a private placement, an aggregate of 265,610 shares of the Company's common stock and warrants to purchase 79,683 shares of the Company's common stock for aggregate gross cash proceeds of \$185,000. The warrants are (i) exercisable solely for cash at an exercise price of \$0.82 to \$0.90 per share, (ii) non-transferable for six months following issuance and (iii) exercisable, in whole or in part, at any time during the period commencing on the date that is six months and one day following the date of issuance and ending on the third year anniversary of the date of issuance

In June 2009, the Company sold, in a private placement, an aggregate of 108,030 shares of the Company's common stock and warrants to purchase 32,409 shares of the Company's common stock for aggregate gross cash proceeds of \$78,000. The warrants are (i) exercisable solely for cash at an exercise price of \$0.85 to \$0.89 per share, (ii) non-transferable for six months following issuance and (iii) exercisable, in whole or in part, at any time during the period commencing on the date that is six months and one day following the date of issuance and ending on the third year anniversary of the date of issuance

#### **Item 5. Other Information**

On October 15, 2008, we received notification from The NASDAQ Stock Market indicating that we were not in compliance with certain of the NASDAQ Capital Market continued listing requirements, including a minimum \$35 million market value of our listed securities. We were permitted until November 14, 2008, to regain compliance with the minimum market value of listed securities requirement. On November 17, 2008, we received a NASDAQ Staff Determination indicating that we had failed to regain compliance with the \$35 million minimum market value of listed securities requirement, and that our securities were, therefore, subject to delisting from The NASDAQ Capital Market. We appealed the Staff Determination and requested a hearing before a NASDAQ Listing Qualifications Panel (the "Panel") to review the Staff Determination. This stayed the delisting of our securities pending the Panel's decision.

On February 25, 2009, we received notification from The NASDAQ Stock Market of its determination to discontinue our NASDAQ listing effective February 27, 2009.

On May 13, 2009, our common stock was approved for quotation on the Over-The-Counter Bulletin Board.

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#### **Item 6. Exhibits**

**Exhibit No.**

**Exhibit Description**

3.1(6)	Amended and Restated Articles of Incorporation of the registrant, as amended
3.2(9)	Articles of Amendment to the Articles of Incorporation of the registrant
3.3(8)	Amended and Restated Bylaws
4.1(5)	Loan and Security Agreement, dated as of May 31, 2007 by and between BlueCrest Capital Finance, L.P. and the registrant
4.2(12)	Notice of Event of Default, from BlueCrest Venture Finance Master Fund Limited to the Company, dated January 28, 2009
4.3(12)	Notice of Acceleration, from BlueCrest Venture Finance Master Fund Limited to the Company, dated February 2, 2009
4.4(13)	Amendment to Loan and Security Agreement, between the Company and BlueCrest Venture Finance Master Fund Limited, dated as of April 2, 2009
4.5(13)	Grant of Security Interest (Patents), between the Company and BlueCrest Venture Finance Master Fund Limited, dated as of April 2, 2009
4.6(13)	Security Agreement (Intellectual Property), between the Company and BlueCrest Venture Finance Master Fund Limited, dated as of April 2, 2009
4.7(13)	Subordination Agreement, by Hunton & Williams, LLP in favor of BlueCrest Venture Finance Master Fund Limited, entered into and effective April 2, 2009
4.8(13)	Amended and Restated Promissory Note, dated April 2, 2009, by the Company to BlueCrest Venture Finance Master Fund Limited
4.9(13)	Warrant to purchase 1,315,542 shares of the registrant's common stock, dated April 2, 2009, issued to BlueCrest Venture Finance Master Fund Limited
4.10(14)	Warrant to purchase 451,043 shares of the registrant's common stock, dated April 2, 2009, issued to Rogers Telecommunications Limited
4.11(14)	Warrant to purchase 173,638 shares of the registrant's common stock, dated April 2, 2009, issued to Hunton & Williams, LLP
10.1**(1)	1999 Officers and Employees Stock Option Plan
10.2**(1)	1999 Directors and Consultants Stock Option Plan
10.3(1)	Form of Option Agreement under 1999 Officers and Employees Stock Option Plan
10.4(3)	Form of Option Agreement under 1999 Directors and Consultants Stock Option Plan
10.5**(4)	Employment Letter Agreement between the registrant and Scott Bromley, dated August 24, 2006.
10.6(1)	Lease Agreement between the registrant and Sawgrass Business Plaza, LLC, as amended, dated November 14, 2006.
10.7(1)	Asset Purchase Agreement between the registrant and Advanced Cardiovascular Systems, Inc., dated June 24, 2003.
10.8(4)	Conditionally Exclusive License Agreement between the registrant, Dr. Peter Law and Cell Transplants International, LLC, dated February 7, 2000, as amended.
10.9(4)	Loan Guarantee, Payment and Security Agreement, dated as of June 1, 2007, by and between the registrant, Howard J. Leonhardt and Brenda Leonhardt
10.10(4)	Loan Guarantee, Payment and Security Agreement, dated as of June 1, 2007, by and between the registrant and William P. Murphy Jr., M.D.
10.11(4)	Loan Agreement, dated as of June 1, 2007, by and between the registrant and Bank of America, N.A.
10.12(4)	Warrant to purchase shares of the registrant's common stock issued to Howard J. Leonhardt and Brenda Leonhardt
10.13(4)	Warrant to purchase shares of the registrant's common stock issued to Howard J. Leonhardt and Brenda Leonhardt

Exhibit No.	Exhibit Description
10.14(4)	Warrant to purchase shares of the registrant's common stock issued to William P. Murphy Jr., M.D.
10.15(4)	Warrant to purchase shares of the registrant's common stock issued to the R&A Spencer Family Limited Partnership
10.16(4)	Supply and License Agreement, dated June 7, 2007, by and between the registrant and BioLife Solutions, Inc.***
10.17(5)	Warrant to purchase shares of the registrant's common stock issued to BlueCrest Capital Finance, L.P.
10.18(6)	Loan Guarantee, Payment and Security Agreement, dated as of September 12, 2007, by and between the registrant and Samuel S. Ahn, M.D.
10.19(6)	Loan Guarantee, Payment and Security Agreement, dated as of September 12, 2007, by and between the registrant and Dan Marino
10.20(6)	Warrant to purchase shares of the registrant's common stock issued to Samuel S. Ahn, M.D.
10.21(6)	Loan Guarantee, Payment and Security Agreement, dated as of September 19, 2007, by and between the registrant and Jason Taylor
10.22(7)	Loan Guarantee, Payment and Security Agreement, dated as of October 10, 2007, by and between the registrant and Howard and Brenda Leonhardt
10.23(7)	Warrant to purchase shares of the registrant's common stock issued to Howard and Brenda Leonhardt
10.24(7)	Second Amendment to Loan Guarantee, Payment and Security Agreement, dated as of October 10, 2007, by and between the registrant and Howard and Brenda Leonhardt
10.25(7)	Second Amendment to Loan Guarantee, Payment and Security Agreement, dated as of October 10, 2007, by and between the registrant and William P. Murphy, Jr., M.D.

10.26**	(10)	Bioheart, Inc. Omnibus Equity Compensation Plan
10.27	(11)	Form of Warrant Agreement for October 2008 Private Placement
10.28	(11)	Form of Registration Rights Agreement for October 2008 Private Placement
10.29	(19)	10% Convertible Promissory Note Due July 23, 2010, in the amount of \$20,000, payable to Dana Smith
10.30	(19)	10% Convertible Promissory Note Due July 23, 2010, in the amount of \$100,000, payable to Bruce Meyers
10.31	(19)	Registration Rights Agreement, dated July 23, 2009
10.32	(19)	Subordination Agreement, dated July 23, 2009
10.33	(19)	Note Purchase Agreement, dated July 23, 2009
10.34	(19)	Closing Confirmation of Conversion Election, dated July 23, 2009
31.1	*	Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	*	Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Filed herewith

\*\* Indicates management contract or compensatory plan.

- (1) Incorporated by reference to the Company's Form S-1 filed with the Securities and Exchange Commission on February 13, 2007
- (2) Reserved
- (3) Incorporated by reference to Amendment No. 2 to the Company's Form S-1 filed with the Securities and Exchange Commission on July 12, 2007
- (4) Incorporated by reference to Amendment No. 3 to the Company's Form S-1 filed with the Securities and Exchange Commission on August 9, 2007

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- (5) Incorporated by reference to Amendment No. 4 to the Company's Form S-1 filed with the Securities and Exchange Commission on September 6, 2007
- (6) Incorporated by reference to Amendment No. 5 to the Company's Form S-1 filed with the Securities and Exchange Commission on October 1, 2007
- (7) Incorporated by reference to Post-effective Amendment No. 1 to the Company's Form S-1 filed with the Securities and Exchange Commission on October 11, 2007
- (8) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 3, 2008
- (9) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 8, 2008
- (10) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 14, 2008
- (11) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 14, 2008
- (12) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 3, 2009
- (13) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 8, 2009
- (14) Incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 15, 2009
- (15) Incorporated by reference to the Company's Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on April 30, 2009
- (16) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 18, 2009
- (17) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 20, 2009
- (18) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 9, 2009
- (19) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 23, 2009
- (20) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 3, 2009
- (21) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on 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 thereunto duly authorized.

Bioheart, Inc.

Date: August 19 , 2009

By: /s/ Karl E. Groth, Ph.D.

Karl E. Groth, Ph.D. Chairman of the Board  
and Chief Executive Officer

## INDEX OF EXHIBITS

<b>Exhibit No.</b>	<b>Exhibit Description</b>
31.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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CERTIFICATION

I, Karl E. Groth, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Bioheart, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of registrant’s board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

August 19, 2009

/s/ Karl E. Groth, Ph.D.  
Name: Karl E. Groth, Ph.D.  
Title: Chief Executive Officer

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CERTIFICATION

I, Mark Borman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Bioheart, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 19, 2009

/s/ Mark Borman

Name: Mark Borman

Title: Chief Financial Officer

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CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Bioheart, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. section 906 of the Sarbanes-Oxley Act of 2002, to such officer's knowledge that:

- (i) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2009 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (subject to the Company's position prevailing in regard to the remaining unresolved SEC comment, as more fully described in the Report); and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

August 19, 2009

/s/ Karl E. Groth, Ph.D.

Name: Karl E. Groth, Ph.D.

Title: Chief Executive Officer

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CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Bioheart, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to 18 U.S.C. section 906 of the Sarbanes-Oxley Act of 2002, to such officer's knowledge that:

- (i) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2009 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (subject to the Company's position prevailing in regard to the remaining unresolved SEC comment, as more fully described in the Report); and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

August 19, 2009

/s/ Mark Borman  
Name: Mark Borman  
Title: Chief Financial Officer

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