

Mail Stop 6010

March 9, 2007

Howard J. Leonhardt,  
Chief Executive Officer  
Bioheart, Inc.  
13794 NW 4th Street, Suite 212  
Sunrise, Florida 33325

**Re: Bioheart, Inc.  
Registration Statement on Form S-1  
Filed February 13, 2007  
File No. 333-140672**

Dear Mr. Leonhardt:

We have reviewed your filing and have the following comments. Where indicated, we think you should revise your document in response to these comments. If you disagree, we will consider your explanation as to why our comment is inapplicable or a revision is unnecessary. Please be as detailed as necessary in your explanation. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure. After reviewing this information, we may raise additional comments.

Please understand that the purpose of our review process is to assist you in your compliance with the applicable disclosure requirements and to enhance the overall disclosure in your filing. We look forward to working with you in these respects. We welcome any questions you may have about our comments or any other aspect of our review. Feel free to call us at the telephone numbers listed at the end of this letter.

General

1. Please provide us proofs of all graphic, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note we may have comments regarding these materials.
2. Please note that when you file a pre-effective amendment containing pricing-related information, we may have additional comments. As you are likely aware, you must file this amendment prior to circulating the prospectus.

3. Please note that when you file a pre-effective amendment that includes your price range, it must be bona fide. We interpret this to mean your range may not exceed \$2 if you price below \$20 and 10% if you price above \$20.
4. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not complete lists. If our comments are applicable to portions of the filing that we have not cited as examples, please make the appropriate changes in accordance with our comments.

#### Prospectus Summary

5. You state that you are focused on the discovery, development and commercialization of therapies. We note that you have no products and that your focus to date has been developing your therapy treatments. Also, disclosure in your MD&A section indicates that while you have expended funds to develop these therapies and conduct FDA testing, you have expended little or no funds for marketing, pre-marketing, sales or other commercial activity. Please revise your disclosure in this sentence and throughout the prospectus to reflect that your company is developing therapies that may or may not ever receive FDA or other regulatory approval or ever become commercialized.
6. Throughout this section and the rest of your document, including your Business and Management's Discussion and Analysis sections, you reference several industry sources and various statistics and other figures, including statements relating to the market in which you expect your products to compete. In some places, you do not provide the source of your information. In that regard, please revise your document to indicate the sources of information you have relied on making these statements.
7. We note that much of the statistical information relating to your potential market relates to the estimated worldwide market and the market in the United States. Please revise to highlight the estimate for the market(s) where you expect to market your product candidates to the extent possible.
8. We note your disclosure of the results of your clinical trials throughout this section and the rest of your document. Please revise your discussions to include appropriate caveats indicating that the results do not provide enough evidence regarding efficacy or safety to support an application with the FDA, that additional tests will be conducted and that subsequent results often do not corroborate earlier results. Also, where you discuss the results of your clinical trials, you should note any adverse events or side-effects that were observed.
9. We note you disclose the results of your various clinical trial studies in this section. The disclosure in the summary should be limited to a discussion of the

- extent of testing, such as the drugs, indication(s) and current phase of testing. In that regard, please relocate the disclosure regarding any efficacy results from the summary to your Business section.
10. Please explain what Class II and Class III heart failure are the first time you use the terms.
  11. Please expand the first paragraph of the Summary to indicate that you have never successfully developed and obtained regulatory approval of any drug, device or therapy, and highlight your net losses for 2006 and your accumulated deficit.
  12. Please expand the Summary section to briefly describe how you plan to generate revenue from the therapy you are developing, if you ever receive regulatory approval. This disclosure should be accompanied by appropriate warnings indicating that you may never receive the requisite approvals.
  13. You state, “When injected into scar tissue within the heart wall, myoblasts have shown to be capable of engrafting in the surrounding tissue and differentiating into mature skeletal muscle cells and/or cells which exhibit properties of both skeletal and cardiac muscle cells.” It appears that you may not have enough evidence from your clinical trials to make this statement. Supplementally, please explain to us the basis for this statement.
  14. You state, “Although we believe many of the trials are different from the trials sponsored by us in a number of important respects, it is our view that the trials have advanced the cell therapy industry’s understanding of the potential opportunities and limitations of myoblast-based therapies.” Supplementally, please explain the basis for this view. If this statement is not adequately supported, you should consider deleting it.
  15. Immediately following the business strategy subsection on page 2, please expand the Summary to discuss briefly the risks associated with an investment in the company, its business, etc.

Risk Factors, page 7

“We are a development stage. . . .” page 7

16. Please revise to quantify the losses for each of the last three years, state that you expect to continue to incur significant operating losses in future periods.
17. You state that your lead product candidate is not expected to generate any material revenues until 2008 or 2009. This expectation appears very speculative given your stage of development and regulatory progress to date. Here and

throughout the prospectus, you should temper all statements about expected revenue with appropriate caveats indicating that you may never achieve commercialization of your therapies or regulatory approval.

“Management believes that in connection with. . . .” page 8

18. Please update this risk factor regarding the going concern opinion you will receive and explain the significance of such a qualification.

“We may need substantial additional funding. . . .” page 8

19. You state here that you may need additional funding. It appears that you will need additional funding. Please revise this risk factor and throughout the filing to reflect this fact.
20. Consider creating separate risk factors for the various factors referenced in the bullet list.

If our clinical trials are unsuccessful..., page 10

21. This risk factor is written such that it almost assumes that you obtain regulatory approval. You expand the risk factor to emphasize more emphatically that you may not achieve approval.

“Our cell-based candidates. . . .” page 12

22. You state that you are subject to the risks of failure inherent in the development of product candidates based on new technologies and provide one example of those risks. You should expand this risk factor or create additional risk factors which articulate and explain each of the material risks and not assume that the reader knows what they are.

“Our business involves the use of hazardous materials . . . .” page 15

23. We note that you currently maintain very limited insurance coverage related to your use of hazardous materials. Please indicate if you intend to seek such coverage and approximately when you intend to do so. Also, here and in MD&A, please note and quantify to the extent possible expected increases in expense for coverage for hazardous waste or other forms of insurance coverage going forward, if any.

“Risks Related to Our Intellectual Property” page 20

24. Please disclose who has the obligations to take necessary actions to protect patents under your license and collaboration agreements. If you do not have the obligation to take action, do you have the right to take necessary actions if the other party does not?

“We have licensed. . . .,” page 20

25. You mention the license agreement with Cell Transplants. Please file this agreement as an exhibit with your next amendment and file all material contracts as exhibits to the registration statement consistent with Item 601(b)(10) of Regulation S-K.

Other Risks Related to Our Business, page 26

26. Many of the risk factors in this subsection are generic in that you do not explain with any specificity how they pertain to the company. You should expand each risk factor to explain why it is a risk to the company and describe any past experience which would help explain the risk.

“Our internal control over financial reporting. . . .,” page 28

27. Please expand this risk factor to describe the nature and provide a description of the material weakness you reference. You should also quantify its potential impact, if possible. Also, state what you have done to remedy the material weakness and whether or not it has been remedied fully.

“We do not intend to pay cash dividends . . . .,” page 32

28. Please revise this risk factor to state that because you do not anticipate paying any dividends on the common stock, capital appreciation, if any, of your common stock will be the investor’s sole source of gain.

Special Note Regarding Forward Looking Statements, page 33

29. On page 33, please expand the last sentence of this section to state that the forward-looking statements are also excluded from Section 21E of the Exchange Act.

Use of Proceeds, page 40

30. In addition to the approximate amount, please disclose the timing of the proceeds you plan to use for each of your lead candidates, including where in the development process you expect to be after the expenditure of these proceeds.
31. Please describe which “general corporate purposes” you plan to use the proceeds from this offering for. State an approximate dollar amount for each. You indicate that you may use a portion of your net proceeds for potential acquisitions, collaborations, etc. Please clarify from which currently specified allocation(s) you will take funds for such possible use.

Management’s Discussion and Analysis of Financial Condition and Results of Operations, page 39

Financial Operations Overview, page 40

Research and Development, page 40

32. We note your assertion that you do not track certain cost on a project basis. Please revise your disclosure to clearly indicate the amounts spent towards each specific project such as amounts spent on clinical trials that are identifiable on a project basis.

Stock-Based Compensation, page 41

33. Your disclosure here refers to an independent valuation firm in determining the fair value of your common stock. The reference to an independent valuation firm equates to the use of a valuation expert. Please name the independent valuation firm and provide their consent in the registration statement. In addition please include a more robust discussion of the valuation methodology used in the determination of this stock price. Include whether these valuations are contemporaneous and why management chose the timing of the valuations and did not enlist an independent third party in that valuation.

Liquidity and Capital Resources, page 45

34. We note in your discussion on page 41 where you discuss “sources” of cash that you include the impact of stock based compensation. Please explain to us how this is a “source” of cash. Please note that this discussion is not intended to mimic the information already presented in your statement of cash flows, but it is intended to identify the true activities that result in changes in your cash position.

Commitments and Contingencies, page 48

35. It does not appear that you included any of the minimum royalty payments such as those connected with the William Beaumont Hospital described on page F-13 of your financial statements. Please revise your table to include those amounts or explain to us why you do not feel that they are required to be included.

Business, page 51

36. Please comply with each of comments pertaining to the summary in the forepart and throughout the Business section.

Audited Consolidated Financial Statements – Years Ended December 31, 2005, page F-1 General

37. Please update all of the financial statements included in the filing as required by Rule 3-12(d) of Regulation S-X.

Notes to Consolidated Financial Statements, page F-7

8. Shareholders' Equity, page F-14

Capital Stock, page F-14

38. Please explain to us why it does not appear that you included the effect of the March 2003 stock split on the shares issued prior to that date.

12. Subsequent Events, page F-17

Settlement Agreement, page F-18

39. It appears that portions of this settlement were for "unpaid salary for past services." Please clarify which portions were related to the past services, and how the settlement for those past services was recorded in the current period.

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As appropriate, please amend your registration statement in response to these comments. You may wish to provide us with marked copies of the amendment to expedite our review. Please furnish a cover letter with your amendment that keys your responses to our comments and provides any requested information. Detailed cover letters greatly facilitate our review. Please understand that we may have additional comments after reviewing your amendment and responses to our comments.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes all information required under the Securities Act of 1933 and that they have provided all information investors require

for an informed investment decision. Since the company and its management are in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

Notwithstanding our comments, in the event the company requests acceleration of the effective date of the pending registration statement, it should furnish a letter, at the time of such request, acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

In addition, please be advised that the Division of Enforcement has access to all information you provide to the staff of the Division of Corporation Finance in connection with our review of your filing or in response to our comments on your filing.

We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement. We will act on the request and, pursuant to delegated authority, grant acceleration of the effective date.

We direct your attention to Rules 460 and 461 regarding requesting acceleration of a registration statement. Please allow adequate time after the filing of any amendment for further review before submitting a request for acceleration. Please provide this request at least two business days in advance of the requested effective date.



You may contact James Peklenk at (202) 551-3661 or James Atkinson at (202) 551-3674 if you have questions regarding comments on the financial statements and related matters. Please contact Michael Reedich, Special Counsel at (202) 551-3612, or me at (202) 551-3715 with any other questions.

Sincerely,

Jeffrey Riedler  
Assistant Director

cc: David E. Wells, Esq.  
Hunton & Williams LLP  
1111 Brickell Avenue, Suite 2500  
Miami, FL 33131