# February 12, 2013

## VIA EDGAR

United States Securities and Exchange Commission 100 F Street, NE Mail Stop 4720 Washington, D.C. 20549 Attention: Jeffrey P. Riedler Assistant Director

Re: Heat Biologics, Inc.

Confidential Draft Registration Statement on Form S-1

Submitted December 24, 2012

CIK No. 0001476963

#### Dear Mr. Riedler:

Thank you for your January 18, 2013 letter regarding Heat Biologics, Inc. ("Heat"). In order to assist you in your review of Heat's Form S-1, we hereby submit a letter responding to the comments and Amendment No. 1 to Form S-1 marked to show changes. For your convenience, we have set forth below the staff's numbered comments in their entirety followed by our responses thereto.

#### 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 that we may have comments regarding this material.

Response: All graphic, visual and photographic information that will be included in the prospectus has been included in Amendment No. 1 to the Registration Statement on Form S-1.

2. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

Response: We do not have any written communications that have been presented to potential investors nor do we have any research reports about us that have been published or distributed.

3. We will deliver comments to your confidential treatment request under separate cover. Please be aware that all confidential treatment issues must be resolved before we will consider a request for acceleration of effectiveness for the registration statement.

Response: In light of your comment number 37, regarding disclosure of the university and the inventor, we intend to revise the confidential treatment request to disclose such information.

4. Please amend your filing to identify the lead underwriters or, alternatively, provide us with a detailed and fulsome explanation of why this information cannot be included in the filing. Based upon the facts and circumstances of your response, we may defer further review of the filing until such time as the lead underwriters are identified in the filing. Further, please include the underwriting agreement in your list of exhibits and file a copy of the underwriting agreement as soon as practicable.

Response: We have identified the underwriter on the cover of the prospectus and will file a copy of the underwriting agreement as soon as it is negotiated.

## Prospectus Summary, page 1

#### Overview, page 1

5. Please expand your discussion of the results of your recently completed Phase I clinical trial in lung cancer to state that the trial included 18 patients, indicating the number of whom demonstrated an immune response.

# Response: We have added additional requested disclosure.

6. We note your disclosure that NIH has awarded in excess of \$13 million of funding to fund development of your technology and your clinical programs but that substantially all of such funds have been awarded to the primary inventor of the technology you license. Please expand your disclosure, here and in your Business section, to identify the inventor and more clearly describe the flow of funds from NIH through the primary inventor to your clinical programs. Your disclosure should describe whether any such funds are or will be recognized by you as revenue and the effect on your liquidity. If no funds will flow to the company as revenue or expense reimbursement, please revise your disclosure to so state and expand your disclosure to describe how these grants benefit the company and the development of your technology and product candidates. Please also add appropriate risk factor disclosure highlighting the risks that, if true, the company has little to no control over the direction of the NIH grant funds and other risks associated with the structure of their administration and use. Further, please include a discussion differentiating the treatment of the awards to your primary inventor and the grants awarded directly to the company, as you describe on page 25.

Response: Complied with, we have revised the disclosure.

#### Investment Highlights, page 2

7. In the first bullet point you state "ImPACT has already been shown to activate the immune system..." Please expand your disclosure to more specifically indicate how – pre-clinically or in clinical trials – it has been shown to have such effect.

Response: Complied with, we have added additional disclosure.

# The Offering, page 4

8. You state with respect to your application for listing on the Nasdaq Capital Market that "no assurance can be given that such a listing will be approved." On the cover page, you indicate that listing is a condition to the offering. Please expand your disclosure here and elsewhere in the document, as appropriate, that NASDAQ listing is a condition to the consummation of the offering.

Response: Complied with, we have revised the disclosure on page 4.

## Risk Factors, page 7

9. Please delete the sentence "The risks described below are not the only ones we face." All known material risks should be described.

Response: Complied with, we have deleted the requested sentence.

10. We note your statement on page 30 that "Heat's proprietary technology platform, *ImPACT*, is being applied to develop multiple therapeutic vaccines against a wide range of cancers and infectious diseases." Please add disclosure discussing relevant risks in light of the fact that each of your product candidates rely on the *ImPACT* technology, should results be disappointing or should any adverse effects arise, this may affect all of your product candidates and could significantly affect your product pipeline.

Response: Although ImPACT is being applied to develop vaccines against a wide range of cancers and infectious diseases, we do not believe that disappointing results or adverse effects in treating one disease will affect all of our product candidates. Often, cancer treatments that are effective for the treatment of one type of cancer are not effective for the treatment of other types of cancer as each type of cancer may react differently to the same treatment. Failure in one cancer may be due to the specific antigen expression, cell line, stage of that particular cancer and not reflective of the technology in general. Therefore, we do not believe an additional risk factor is appropriate.

11. While you do not currently have any collaboration or development agreements, such arrangements are common in your industry and may prove to be an attractive financing option in the future. Please add disclosure discussing the relevant risks to your revenues and business that may arise as a result of entering into collaboration or development agreements in the future.

Response: Complied with, we have added a new risk factor.

# "Until the Offering contemplated herein is consummated...," page 9

12. Please update the discussion concerning the Square I Bank loan, including the status of foreclosure proceedings, waiver of default, and amendments to the loan agreement.

Response: Complied with, we have updated the disclosure. The Company is currently in discussion with Square 1 Bank to extend the December 15, 2012 and the bank has not foreclosed on the Company's assets secured by the loan.

## "Certain of our officers may have a conflict of interest.," page 15

13. Please specify the nature of the conflicts of interest that may exist as a result of some of your officers working for the company on a part-time basis.

Response: Complied with, we have added disclosure.

# "We are an 'emerging growth company'...," page 17

14. Please expand your disclosure to describe all of the factors that may cause you to cease to be an "emerging growth company."

Response: Complied with, we have added disclosure.

## "The offering price of the shares has been arbitrarily determined.," page 19

15. The risk factor concerning the arbitrary determination of the offering price appears to contradict the similar discussion under the heading "Determination of Offering Price." If you elect to retain the risk factor, please revise the risk factor to conform the disclosure.

Response: Complied with, we have revised the risk factor.

# Use of Proceeds, page 20

16. Please expand your disclosure to provide an estimate of the amount of proceeds you intend to use for each bulleted item.

Response: Complied with, we have provided the requested disclosure.

# Management's Discussion and Analysis of Financial Condition and Results of Operations, page 22

17. Please include a caption in this section to address the impact that the material weakness over internal controls discussed on page 18 had on the financial reporting processes covered in this registration statement.

Response: Complied with, we have added additional disclosure to the section.

# Overview, page 22

18. Please expand your discussion of the results of your recently completed Phase I clinical trial in lung cancer to state that the trial included 18 patients, indicating the number of whom demonstrated an immune response.

Response: Complied with, we have expanded the discussion.

## Critical Accounting Policies

#### Stock Based Compensation, page 23

19. Please revise your disclosure to include a description of the methods and assumptions used in estimating the fair value of the underlying common stock at each grant or issuance date.

Response: Complied with, we have revised our disclosure to include the requested information.

20. Please revise your disclosure to include a table disclosing, for each issuance date, the number of options granted, exercise price, fair value of the underlying stock and fair value of the instruments granted for the twelve-month period preceding the most recent balance sheet date.

Response: Complied with, we have revised our disclosure to include the requested information.

21. Please revise your disclosure to present the intrinsic value of outstanding vested and unvested options as of the most recent balance sheet date based on the estimated IPO price.

Response: We are unable to revise this disclosure at this time as we do not yet have an estimated IPO price. We will revise our disclosure in future filings as requested.

22. We may have additional comments on your accounting for stock compensation and related disclosure once you have disclosed an estimated offering price. Please provide quantitative and qualitative disclosures explaining the difference between the estimated offering price and the fair value of each equity issuance.

Response: Open. We will provide the requested information at which time an estimated offering price has been determined.

# Results of Operations Operating Expenses, page 24

23. Please revise your disclosures to include the costs incurred during each period presented and to date for each material research project separately.

Response: Complied with, we have added the requested disclosure.

## Current and Future Financing Needs, page 27

24. You state "We have based our estimate on assumptions that may prove to be wrong," however, you do not appear to have included a definitive estimate of funds you will need to operate. Please revise your disclosure to include such an estimate.

Response: Complied with, we have added a definitive estimate of funds.

## Business, page 28 Investment Highlights, page 30

25. Please reconcile your statement that you have "been able to leverage various academic research and manufacturing facilities in order to save capital expenditures that might otherwise have been spent on infrastructure" with your statement on page 31 that you have "efficiently utilized our capital and human resources to...build a modern research facility and vivarium." Please revise your disclosure to include a clear discussion of your investment in research and manufacturing facilities or whether you exclusively rely on third parties, and revise your disclosure to reconcile these two statements.

Response: Complied with, we have removed the reference to "efficiently utilized our capital and human resources to...build a modern research facility and vivarium" as it was mistakenly in the document.

# Strategy, page 30

26. You state in the final bullet point on page 31 that you plan to continue to seek and access external sources of grant funding to support the development of your pipeline programs. Please indicate whether you will seek such grants on your behalf or on behalf of your primary inventor. Further, please expand your disclosure to discuss the efforts of your primary inventor to obtain further grant funding, whether the primary inventor has any obligation to do so pursuant to your license agreements and what role you play in pursuing additional grant funding that may be awarded to your primary inventor.

Response: Complied with, we have expanded the disclosure.

#### ImPACT Technology Platform, page 35

27. Your current description of the ImPACT technology appears to alternate between over-simplification and complex descriptions utilizing undefined scientific terms. Please revise your disclosure to more clearly describe the ImPACT technology.

Response: Complied with. We have added additional disclosure to further clarify the technology.

## Our Product Candidates and Clinical Development Programs, page 37

28. Please reconcile your disclosure that you "are currently in a Phase II clinical trial" with HS-110 with your prior disclosure that you will initiate Phase II in the first quarter of 2013.

Response: Complied with, we have reconciled the disclosure.

# Summary of HS-110 Clinical Trials, page 37

29. Please consider using tabular or graphical depictions of certain of your results to more clearly present the results of the different dosing groups and response groups.

Response: Complied with, we have added additional charts that present the requested disclosure.

30. Please disclose how you defined "clinical benefit" in the context of the HS-110 trial.

Response: Complied with, we have provided a definition of "clinical benefit."

31. Please detail all of the adverse events and the number of patients in which each even occurred. Please consider presenting such information through tabular disclosure.

Response: Complied with. Please see the charts referred to in response 29.

32. Please define "arm 1" of the therapy as used in the final paragraph on page 38.

Response: Complied with, we have defined "arm1".

33. Please delete the quoted "Patient Experience" included on page 39. It is not appropriate to attribute clinical results such as diminished evidence of tumors to non-professional observation.

Response: Complied with, we have deleted the "Patient Experience."

34. Please define or provide context for the parenthetical information included in the description of results in the first three paragraphs on page 38.

Response: Complied with. We have deleted some of the parenthetical information as we do not deem it necessary for an understanding of the results described in the paragraphs referred to.

35. We note the statement at the bottom of page 38 that "it is also important to note that 11 of the 18 patients enrolled on the trial at the time of the interim analysis were on arm 1 of therapy...." We also note the statement in the first paragraph on page 37 under this heading that

the 18 patients were divided into three groups and that each group received a different amount of dosage. If the number of patients were not evenly divided among the three groups, please explain the reason for such action.

Response: Complied with, we have provided additional disclosure.

## Oncology Indications of ImPACT, page 40

36. Please update your estimated timelines throughout this section to reflect estimates as of the date of the registration statement. For example, you estimate bladder cancer cellular vaccines will be completed by the third quarter of 2012, a timeframe which has already passed.

Response: Complied with, all timeframes have been updated.

## License Agreements, page 45

37. Please identify the University with which you have contracted. The identity of the parties to a contract is material information and, therefore, must be disclosed.

Response: Complied with, the name of the University has been disclosed.

38. Please revise your disclosure to include for each agreement described the aggregate potential milestones payable, payments made to date and a range within which the royalty rate falls (within a ten percentage point range).

Response: Please note that we are seeking confidential treatment of the milestone payments and royalty rates and therefore the information requested has been omitted.

## Intellectual Property, page 47

39. Please expand your disclosure to indicate for each family of patents the number of patents and the expiration dates of the material patent(s) in each such family.

Response: Complied with, we have expanded the disclosure.

<u>Management and Board of Directors, page 52</u> <u>Executive Officers and Board of Directors, page 52</u>

40. Please reconcile the offices and titles attributed to Mr. Wolf on the signature block to those indicated in the tabular and narrative disclosure on page 52.

Response: Complied with, the titles have been reconciled.

41. Please indicate clearly which of your officers are part-time employees.

Response: Complied with, we have provided the requested information.

# 2011 Director Compensation, page 57

42. Please update your disclosure to include compensation paid during your fiscal year ended December 31, 2012.

Response: Complied with, we have updated the disclosure.

# Executive Compensation, page 58

43. Please update your disclosure to include compensation paid during your fiscal year ended December 31, 2012.

Response: Complied with, we have updated the disclosure.

## Description of Our Securities, page 59

44. Please disclose the voting thresholds for matters to be voted upon by holders of your common and preferred stock including the specific threshold for election of directors.

Response: Complied with, we have added the disclosure; however please note that upon consummation of this Offering, the outstanding preferred stock will convert to common stock and such thresholds will no longer be relevant.

## Warrants, page 61

45. Please clarify that the piggyback registration rights of the holder of the August 2012 warrant may not exercise such rights with respect to the current offering.

Response: Complied with, additional clarifying language has been added.

# Certain Relationships and Related-Party Transactions, page 65

46. The applicable threshold for reportable related party transactions pursuant to Item 404(d)(1) Regulation S-K is the lesser of \$120,000 or one percent of the average of total assets at year end for the last two completed fiscal years. Please consider the applicable threshold and revise your disclosure accordingly.

Response: Complied with, we have revised the disclosure.

47. For each transaction disclosed, identify the related person and describe the basis on which the person is a related person.

Response: Complied with, we have identified each related party referred to and described the basis of their relationship.

<u>Financial Statements</u> <u>Independent Auditors' Report, page F-2</u>

48. Please file a revised audit report that includes the city and state where issued as required by Rule 2-02(a) of Regulation S-X.

Response: The audit report has been revised to include city and state where issued.

Notes to Consolidated Financial Statements

2. Summary of Significant Accounting Policies
Fair Value of Financial Instruments, page F-10

49. Please disclose the assumptions used in determining the fair value of the warrants using the Monte Carlo simulation.

Response: We have updated our disclosure to include the assumptions used in determining the fair value of the warrants using the Monte Carlo simulation.

#### Revenue Recognition, page F-12

50. You state that grant revenue is recognized as expenses are incurred and submitted to the funding source for reimbursement and the amounts are deemed collectable. Please provide us with an analysis of how the submission to the funding source impacts your ability to recognize revenue. Please cite the authoritative literature used to reach your conclusions.

Response The Company recognizes government grants when there is reasonable assurance that they will comply with the conditions attached to the grants and that the grants will be received. The grants are recognized using an income approach and grant revenue is recognized as the related expenses are incurred. We have updated our disclosure to clarify that the timing of submission to our funding sources does not impact our ability to recognize revenue on these grants.

#### 9. Convertible Notes Payable, page F-15

51. Please provide us an analysis of whether the conversion option for the October 2011 agreement should be a derivative liability.

Response: The conversion option for the note is not a derivative liability as, if the conversion option was a freestanding instrument, it would not qualify as a derivative given the fact that the terms of the convertible note agreement do not require or permit net settlement as the Company's shares are not readily convertible into cash. Accordingly, the note has been classified as a liability without bifurcating the conversion option.

# 13. Stockholders' Deficit Preferred Stock, page F-21

52. Please provide us an analysis of whether the conversion option for all preferred stock issued should be a derivative liability or whether the instruments in their entirety should be classified as liabilities.

Response: The convertible preferred stock is classified as equity as it does not meet the definition of a liability in accordance with ASC 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ("ASC 480-10"). Specifically, the convertible preferred stock is not mandatorily redeemable and does not obligate the Company to buy back its shares in cash or assets. Further, the convertible preferred stock's settlement does not fall within the criteria of ASC 480-10, as the settlement is based on the conversion price or the Company's current stock price. Additionally, the conversion option for the preferred stock is not a derivative liability since the embedded conversion option is clearly and closely related to the host contract, as they are both equity-like instruments. The preferred stock was determined to have more equity-like characteristics than debt-like characteristics as it participates with common shareholders in dividends and has voting rights equal to common shareholders on an as converted basis and is not redeemable.

\* \* \*

We acknowledge that the adequacy and accuracy of the disclosure in our filings is our responsibility. We acknowledge that the staff comments or changes to disclosure do not foreclose the Commission from taking any action with respect to the filings. We acknowledge that the company may not assert staff comments as a defense in any proceedings initiated by the Commission or any person under the federal securities laws of the United States.

If you have any questions or need additional information, please contact the undersigned at (516) 496-2223 or (212) 907-6457.

Sincerely,

/s/ Leslie Marlow

Leslie Marlow

Enclosures

cc: Heat Biologics, Inc.