

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

January 18, 2013

Via E-mail
Jeffrey Wolf
Chief Executive Officer and Chairman
Heat Biologics, Inc.
100 Europa Drive
Chapel Hill, NC 27517

Re: Heat Biologics, Inc.

Confidential Draft Registration Statement on Form S-1

Submitted December 24, 2012

CIK No. 0001476963

Dear Mr. Wolf:

We have reviewed your confidential draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended confidential draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended confidential draft registration statement or filed registration statement, we may have additional comments.

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.
- 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.

- 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.
- 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.

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.
- 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.

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.

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.

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.
- 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.
- 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.

"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.

"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.

"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."

"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

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.

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.

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.

<u>Critical Accounting Policies</u> 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.
- 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.
- 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.
- 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.

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.

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.

Business, page 28

<u>Investment Highlights</u>, 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.

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.

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.

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.

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.
- 30. Please disclose how you defined "clinical benefit" in the context of the HS-110 trial.
- 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.
- 32. Please define "arm 1" of the therapy as used in the final paragraph on page 38.
- 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.
- 34. Please define or provide context for the parenthetical information included in the description of results in the first three paragraphs on page 38.
- 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.

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.

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.

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).

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.

Management and Board of Directors, page 52

Executive Officers and Board of Directors, page 52

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

2011 Director Compensation, page 57

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

Executive Compensation, page 58

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

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.

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.

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.

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

Financial Statements

Independent Auditors' Report, page F-2

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.

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.

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.

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.

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.

General

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy

(http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Vanessa Robertson, Staff Accountant, at (202) 551-3649 or Joel Parker, Accounting Branch Chief, at (202) 551-3651, if you have questions regarding comments on the financial statements and related matters. Please contact Karen Ubell, Staff Attorney, at (202) 551-3873, John Krug, Staff Attorney, at (202) 551-3862 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Jennifer Riegel for

Jeffrey P. Riedler Assistant Director

cc: Via E-mail

Leslie Marlow, Esq. Gracin & Marlow, LLP