

HEAT BIOLOGICS, INC.
Form 8-K
March 21, 2017

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **March 21, 2017**

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

001-35994

26-2844103

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(Commission File Number)

(IRS Employer Identification No.)

801 Capitola Drive

Durham, NC 27713

(Address of principal executive offices and zip code)

(919) 240-7133

(Registrant's telephone number including area code)

N/A

(Former Name and Former Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

- .. Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- .. Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12)
- .. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- .. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On March 21, 2017, Heat Biologics, Inc. (the Company) issued a press release announcing the latest results of its ongoing Phase 2 clinical trial of HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), for the treatment of non-small cell lung cancer (NSCLC). Fifteen patients have completed the HS-110/nivolumab combination treatment to-date and 12 of these 15 patients were evaluable for ELISPOT analysis. Researchers reported a strong correlation between T cell activation, tumor reductions and increased overall survival in these 12 patients. These data reinforce preliminary results seen in the first eight patients as reported last December at the International Association for the Study of Lung Cancer Annual Meeting.

Key findings include:

·
Immune responses to HS-110 were observed in all 5 patients that exhibited tumor reductions.

·
No tumor reductions were observed in patients that did not mount an immune response to HS-110.

·
The timing of immune responses to HS-110 corresponded to the timing of observed clinical responses, and those responses appear to be sustained.

·
To-date, 5 patients have been enrolled in the low tumor infiltrating lymphocytes (TIL) cohort (patients with “cold” tumors). Three of these 5 patients (60%) have experienced significant tumor reduction, which is higher than the 10% response rate of low TIL patients reported for existing data on nivolumab alone.¹

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Researchers also reported that the safety profile continues to be favorable in the HS-110/nivolumab combination, with no evidence of additional toxicities seen as compared to existing data on nivolumab alone.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

¹Teng et al, Cancer Research 75(11) June 1, 2015

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed with this Current Report on Form 8-K:

Exhibit No.	Description
<u>99.1</u>	Press Release of Heat Biologics, Inc. dated March 21, 2017

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 21, 2017

HEAT BIOLOGICS, INC.

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: Chairman, President and Chief
Executive Officer