HEAT BIOLOGICS, INC.
Form 8-K
December 06, 2016

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): **December 6, 2016**

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

001-35994 **26-2844103**

(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 December 6, 2016, Heat Biologics, Inc. (the Company) issued a press release announcing topline response and survival results in its ongoing Phase 1b study evaluating 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. The Company reported that 1-year results from the first eight trial patients showed that the HS-110/nivolumab combination was well-tolerated with a safety profile consistent with single agent nivolumab. There were no additional toxicities seen in HS-110/nivolumab combination compared to existing data on single agent nivolumab alone. HS-110 generated a robust antigen-specific immune response in several patients consistent with the mechanism of action seen in other HS-110 trials. Additionally, the patients who responded best to the combination therapy (immune responders) had longer overall survival and better objective response rate (ORR) than the non-immune responders, even though they had the same baseline immune function. Immune responders in the study saw a 50% ORR while non-immune responders saw a 0% ORR. Moreover, the immune responders had a better median overall survival (OS) than non-immune responders. The 1-year OS is currently 50% for the responders and 25% for the non-responders. Finally, immune responders also saw a better median OS at 12.7 months, than non-immune responders, who saw a median OS of 7.1 months. Researchers concluded that immune response may correlate with clinical efficacy and that HS-110 may have synergistic activity with immune checkpoint inhibitors.

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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

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

Exhibit

Number

Description

99.1

Press Release of Heat Biologics, Inc. dated December 6, 2016

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: December 6, 2016 HEAT BIOLOGICS, INC.

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