HEAT BIOLOGICS, INC.
Form 8-K
March 13, 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 13, 2017**

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 March 13, 2017, Heat Biologics, Inc. (the Company) issued a press release announcing that the Company achieved the efficacy endpoint for its Phase 1b trial 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 (NSCLC) and that the trial met the expansion criteria to advance into a Phase 2. In reviewing the Phase 1b data, the Data Monitoring Committee (the DMC) determined that the Phase 1b safety endpoint was met and that there do not appear to be additional toxicities seen in the HS-110/nivolumab combination compared to existing data on nivolumab alone. Furthermore, 5 out of 15 patients treated with the HS-110/nivolumab combination had 20% or greater tumor reduction. Patients with increased levels of tumor infiltrating lymphocytes (TIL) at 10 weeks appeared to have a durable benefit, with six out of eight of these patients (75%) alive at the one-year follow-up point. The DMC concluded that the positive safety profile, mechanistic evidence and encouraging signs of synergistic efficacy warranted expansion to a Phase 2 trial.

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 No.	Description
99.1	Press Release of Heat Biologics, Inc. dated March 13, 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 13, 2017 HEAT BIOLOGICS, INC.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Heat Biologics, Inc. dated March 13, 2017