HEAT BIOLOGICS, INC.
Form 8-K
December 07, 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): **December 7, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company þ

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. þ

Item 8.01 Other Events.

On December 7, 2017, Heat Biologics, Inc. (the Company) issued a press release announcing that it received written responses from the U.S. Food and Drug Administration (FDA) following the Company s Type C meeting regarding its planned registrational HS-110 clinical trial design for the treatment of non-small cell lung cancer (NSCLC).

The discussion focused on elements of proposed clinical trial designs, both single-arm and controlled, which the FDA agreed would be appropriate to support a registrational trial of HS-110. Clinical endpoints and post-marketing commitments were also discussed in the context of accelerated approval.

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 7, 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: December 7, 2017 HEAT BIOLOGICS, INC.

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