

HEAT BIOLOGICS, INC.
Form 8-K
February 25, 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): **February 25, 2016**

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

001-35994
(Commission File Number)

26-2844103
(IRS Employer Identification No.)

801 Capitola Drive

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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 7.01. Regulation FD Disclosure.

On February 25, 2016, Heat Biologics, Inc. (the Company) issued a press release announcing the matters discussed in Item 8.01 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that Section or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

The Company today announced that it will no longer enroll new patients in its Phase 2 monotherapy trial arm evaluating HS-410 alone for the treatment of non-muscle invasive bladder cancer (NMIBC). The Company added the monotherapy trial arm in response to the intermittent global shortage of standard of care Bacillus Calmette-Guérin (BCG) in early 2015. The shortage has since then been resolved and as such, the Company will no longer enroll new patients in this trial arm based on discussions with the U.S. Food and Drug Administration. The decision does not relate to concerns regarding the safety profile of HS-410. The 16 patients currently enrolled, out of the anticipated 25 patients, can continue receiving HS-410 monotherapy per the study protocol. The Company anticipates reporting topline 6-month data from these 16 patients in the fourth quarter of 2016, contemporaneous with reporting data from the Company's BCG combination cohorts.

This decision does not impact the Company's three additional randomized Phase 2 trial arms evaluating HS-410 in combination with BCG for the treatment of NMIBC. As previously announced, the Company completed enrollment of the 75 patients for these three combination trial arms in October 2015 and continues to expect to report one-year topline efficacy, immune-response and safety data in the fourth quarter of 2016.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

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

Exhibit 99.1

Press Release of Heat Biologics, Inc. dated February 25, 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: February 25, 2016 HEAT BIOLOGICS, INC.

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