

HEAT BIOLOGICS, INC.
Form 8-K
January 26, 2015

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): **January 26, 2015**

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.

Heat Biologics, Inc. (the Company), today issued a press release announcing positive data from two patients in its Phase 1 clinical trial of HS-410 in non-muscle invasive bladder cancer (NMIBC), demonstrating substantially increased tumor infiltrating lymphocytes following treatment. The Company's press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

The information included in this Item 7.01 and in 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 positive data from two patients in the Phase 1 portion of its Phase 1/2 clinical trial of HS-410 in NMIBC. More specifically, analysis of tumor-infiltrating lymphocytes in one patient after surgery and induction BCG (*bacillus Calmette-Guerin*) followed by 6 weeks of HS-410 demonstrated an approximately 70-fold increase in CD8 expression (a marker for CD8+ killer T cells) within the tumor, which was not associated with any increase in CD4 expression (a marker for CD4+ helper T cells). When the patient returned at week 21, the trend continued and an approximate 750-fold increase in CD8 was observed, without any increase in CD4 expression. The Company also reported that with respect to a second patient, a non-specific immune infiltrate was noted on week 7 to be slightly increased as compared to baseline, but which consisted of both CD4+ and CD8+ T cells. The second patient returned with recurrent disease at week 13, when the repeat biopsy showed no further increase in the immune infiltrate. The Company is still evaluating many patients from its Phase 1 clinical trial of HS-410 in NMIBC and continuing its ongoing Phase 2 clinical study.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are being filed as part of this Report.

| Exhibit | Description |
|----------------|--------------------|
|----------------|--------------------|

Number

99.1 Press Release of Heat Biologics, Inc. dated January 26, 2015

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: January 26, 2015 HEAT BIOLOGICS, INC.

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