
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
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))
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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
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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.

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

**Heat Biologics Provides Update on its HS-410 Phase 2 Monotherapy Bladder Cancer Trial Arm**

- *No longer enrolling new patients in monotherapy trial arm due to the current availability of standard of care BCG*
- *No safety concerns related to HS-410; all enrolled patients receiving HS-410 will continue treatment*

DURHAM, NC – February 25, 2016 – [Heat Biologics, Inc.](#) ("Heat") (Nasdaq: HTBX), an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer, announced that the company 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). Heat 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, Heat will no longer enroll new patients in this trial arm based on discussions with the U.S. Food and Drug Administration (FDA). 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. Heat 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 three additional randomized Phase 2 trial arms evaluating HS-410 in combination with BCG for the treatment of NMIBC. As previously announced, Heat 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.

About HS-410 (vesigenurtacel-L)

HS-410 is an investigational product candidate for NMIBC based on Heat's proprietary *ImPACT* immunotherapy platform, designed to generate CD8+ "killer" T cells that attack cancer cells. HS-410 is currently being evaluated in a Phase 2, placebo-controlled NMIBC trial at multiple centers and has been granted U.S. FDA Fast Track Designation for the treatment of NMIBC.



About Heat Biologics, Inc.

Heat Biologics, Inc. (Nasdaq: HTBX) is an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer. Heat's highly specific T cell-stimulating platform technologies, *ImPACT* and *ComPACT*, form the basis of its product candidates. These platforms, in combination with other therapies, such as checkpoint inhibitors, are designed to address three distinct but synergistic mechanisms of action: robust activation of CD8+ "killer" T cells (one of the human immune system's most potent weapons against cancer); reversal of tumor-induced immune suppression; and T cell co-stimulation to further enhance patients' immune response. Currently, Heat is conducting a Phase 2 trial with its HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC) and a Phase 1b trial with its HS-110 (viagenpumatucl-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC). For more information, please visit www.heatbio.com.

Forward Looking Statements

This press release includes forward-looking statements on our current expectations and projections about future events. In some cases, forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based upon current beliefs, expectations and assumptions and include statements regarding the 16 patients continuing to receive HS-410 monotherapy, the anticipated reporting of topline 6-month data from these 16 patients in the fourth quarter of 2016 and the expected reporting of one-year topline efficacy. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's *ImPACT* and *ComPACT* therapies to perform as designed, the ability to enroll patients and complete the clinical trials on time, the other factors described in our annual report on Form 10-K for the year ended December 31, 2015 and Heat's other filings with the SEC. The information in this release is provided only as of the date of this release, and we undertake no obligation to update any forward-looking statements contained in this release based on new information, future events, or otherwise, except as required by law.

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