

HEAT BIOLOGICS, INC.
Form 8-K
December 01, 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): **November 30, 2016**

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

001-35994

26-2844103

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(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 November 30, 2016, Heat Biologics, Inc. (the Company) issued a press release announcing that it presented topline data from its 94-patient Phase 2 trial evaluating HS-410 (vesigenurtacel-L) in combination with standard of care, Bacillus Calmette-Guérin (BCG), or as a monotherapy, for the treatment of non-muscle invasive bladder cancer at the Society of Urology Annual Meeting, in San Antonio, TX. Researchers reported there were encouraging signs of anti-tumor activity as HS-410 generated a robust antigen-specific immune response to multiple tumor-associated peptides in treated patients, while there were no immune responses of this type in the placebo. However, these responses did not translate into clinical outcomes, and there was no statistically significant difference in the primary endpoint (proportion of recurrence-free survival at one year) between the vaccine and placebo arms of the trial. The Company will continue to monitor all patients enrolled in the study for an additional 12 months. At that time the Company will make a final determination on whether to progress its bladder program into a Phase 3 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

Number

Description

99.1

Press Release of Heat Biologics, Inc., dated November 30, 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: December 1, 2016

HEAT BIOLOGICS, INC.

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