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): **March 26, 2018**

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 ☑

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. ☑

Item 8.01 Other Events.

On March 26, 2018, Heat Biologics, Inc. (the "Company") issued a press release reporting 2 year recurrence rate data from the Phase 2 trial evaluating HS-410 (vesigenurtacel-L) in combination with standard of care, Bacillus Calmette-Guérin (BCG), for the treatment of non-muscle invasive bladder cancer. As previously announced, the Company discontinued its HS-410 program in order to focus its resources on current and future checkpoint combination trials, including its HS-110 Phase 2 lung cancer program in combination with Bristol-Myers Squibb's checkpoint inhibitor nivolumab. However, in keeping with clinical trial guidance, the Company continued to monitor all patients enrolled in the study for a 2-year duration.

Within the subgroup of patients who received the low dose of the Company's *ImPACT* HS-410 with standard of care BCG and who demonstrated a positive immune response, 10 out of 10 (100%) remained disease free after a 2-year period. A positive immune response was defined as 2-fold or greater increase from baseline of CD8+ T cells in peripheral blood as measured by ELISPOT analysis.

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 March 26, 2018

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: March 26, 2018

HEAT BIOLOGICS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release of Heat Biologics, Inc. dated March 26, 2018

EXHIBIT 99.1

Heat Biologics Reports Positive Data to Further Support the Mechanism of Action for its Proprietary T-Cell Activation Platform

100% of non-muscle invasive bladder cancer patients who generated an immune response to low dose HS-410 and also received standard of care BCG remain disease free after 2 years

DURHAM, NC – March 26, 2018 – Heat Biologics, Inc. (Nasdaq: HTBX), a biopharmaceutical company developing drugs designed to activate a patient's immune system against cancer, today reported 2 year recurrence rate data from the Phase 2 trial evaluating HS-410 (vesigenurtacel-L) in combination with standard of care, Bacillus Calmette-Guérin (BCG), for the treatment of non-muscle invasive bladder cancer (NMIBC). As previously announced, the Company discontinued its HS-410 program in order to focus its resources on current and future checkpoint combination trials, including its HS-110 Phase 2 lung cancer program in combination with Bristol-Myers Squibb's checkpoint inhibitor nivolumab. However, in keeping with clinical trial guidance, Heat continued to monitor all patients enrolled in the study for a 2-year duration.

Within the subgroup of patients who received the low dose of Heat's *ImPACT* HS-410 with standard of care BCG and who demonstrated a positive immune response, 10 out of 10 (100%) remained disease free after a 2-year period. A positive immune response was defined as 2-fold or greater increase from baseline of CD8+ T cells in peripheral blood as measured by ELISPOT analysis.

Jeff Wolf, Heat's CEO, commented, "We are further encouraged by this latest data in immune responders showing a 100% disease free survival rate over 2 years, in the subgroup of patients that received low-dose HS-410 and BCG. The observed clinical benefit is consistent with our recent data in non-small cell lung cancer where we reported that patients who have robust immune responses as measured by ELISPOT analysis, have improved survival benefit, providing further support for the mechanism of action of our unique gp96-based T-cell Activation Platform. Heat is committed to the development of its therapeutic programs in combination with a PD-1/PD-L1 inhibitor, as we believe this provides us the best opportunity for a sustained, activated CD8+ T-cell response."

Jeff Hutchins, Heat's Chief Scientific Officer, further commented, "We believe the future of immuno-oncology therapy will be built on a multipronged, orchestrated attack: polyclonal T-cell activation, clonal T-cell expansion and checkpoint inhibition. Most importantly, we believe the ability to mount a robust poly T-cell activated immune response has the potential to improve clinical outcomes. We are encouraged by the correlation of clinical benefit and immune responses linked to our gp96-based poly-neoantigen T-cell activation platform in these two different cancer settings."

Heat recently reported positive interim results from its Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced non-small cell lung cancer (NSCLC).

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using of CD8+ "Killer" T-cells. Our T-Cell Activation Platform (TCAP) produces therapies designed to turn "cold" tumors "hot" and be administered in combination with checkpoint therapies and other immuno-modulators to increase their effectiveness. We are currently enrolling patients in our Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®). Pelican Therapeutics, a subsidiary of Heat, is focused on the development of co-stimulatory monoclonal antibody and fusion protein-based therapies designed to activate the immune system. We also have numerous pre-clinical programs at various stages of development. For more information, please visit www.heatbio.com.

Forward Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 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 belief that the development of Heat's therapeutic programs in combination with a PD-1/PD-L1 inhibitor provides Heat the best opportunity for a sustained, activated CD8+ T-cell response, the belief that the future of immuno-oncology therapy will be built on a multipronged, orchestrated attack: polyclonal T-cell activation, clonal T-cell expansion and checkpoint inhibition, the belief that the ability to mount a robust poly T-cell activated immune response has the potential to improve clinical outcomes and the potential benefits of Heat and Pelican's products. These statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements, including the ability of Heat's *ImPACT*® therapy to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, Heat's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Heat's ability to promote or commercialize its product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products, Heat's ability to maintain its license agreements, the continued maintenance and growth of its patent estate, its ability to establish and maintain collaborations, its ability to obtain or maintain the capital or grants necessary to fund its research and development activities, and its ability to retain its key scientists or management personnel, its ability to successfully integrate Pelican, and the other factors described in Heat's most recent annual report on Form 10-K and other filings with the SEC. The information in this release is provided only as of the date of this release and the company undertakes 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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