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 21, 2017**

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))

Item 8.01. Other Events.

On March 21, 2017, Heat Biologics, Inc. (the "Company") issued a press release announcing the latest results of its ongoing Phase 2 clinical trial of HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), for the treatment of non-small cell lung cancer (NSCLC). Fifteen patients have completed the HS-110/nivolumab combination treatment to-date and 12 of these 15 patients were evaluable for ELISPOT analysis. Researchers reported a strong correlation between T cell activation, tumor reductions and increased overall survival in these 12 patients. These data reinforce preliminary results seen in the first eight patients as reported last December at the International Association for the Study of Lung Cancer Annual Meeting.

Key findings include:

- Immune responses to HS-110 were observed in all 5 patients that exhibited tumor reductions.
- No tumor reductions were observed in patients that did not mount an immune response to HS-110.
- The timing of immune responses to HS-110 corresponded to the timing of observed clinical responses, and those responses appear to be sustained.
- To-date, 5 patients have been enrolled in the low tumor infiltrating lymphocytes (TIL) cohort (patients with "cold" tumors). Three of these 5 patients (60%) have experienced significant tumor reduction, which is higher than the 10% response rate of low TIL patients reported for existing data on nivolumab alone.[1]

Researchers also reported that the safety profile continues to be favorable in the HS-110/nivolumab combination, with no evidence of additional toxicities seen as compared to existing data on nivolumab alone.

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.

[1] Teng et al, Cancer Research 75(11) June 1, 2015

Item 9.01 . Financial Statements and Exhibits.

(d) Exhibits.

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

Exhibit No.	Description
99.1	Press Release of Heat Biologics, Inc. dated March 21, 2017

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 21, 2017

HEAT BIOLOGICS, INC.

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

EXHIBIT 99.1

Heat Biologics Reports Positive Interim Phase 2 Lung Cancer Results in Patients Treated with HS-110 in Combination with a Checkpoint Inhibitor

ELISPOT results suggest that HS-110 *plays an integral role in tumor reduction and may enhance efficacy of checkpoint inhibitors in lung cancer patients*

Tumor reduction corresponds to enhanced immune response

DURHAM, NC – March 21, 2017 – Heat Biologics, Inc. ("Heat") (Nasdaq: HTBX), a leader in the development of immunotherapies designed to activate a patient's immune system against cancer, announced the latest results of its ongoing Phase 2 clinical trial of HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), for the treatment of non-small cell lung cancer (NSCLC). Fifteen patients have completed the HS-110/nivolumab combination treatment to-date and 12 of these 15 patients were evaluable for ELISPOT analysis. Researchers reported a strong correlation between T cell activation, tumor reductions and increased overall survival in these 12 patients. These data reinforce preliminary results seen in the first eight patients as reported last December at the International Association for the Study of Lung Cancer Annual Meeting.

Key findings:

- Immune responses to HS-110 were observed in all 5 patients that exhibited tumor reductions.
- No tumor reductions were observed in patients that did not mount an immune response to HS-110.
- The timing of immune responses to HS-110 corresponded to the timing of observed clinical responses, and those responses appear to be sustained.
- To-date, 5 patients have been enrolled in the low tumor infiltrating lymphocytes (TIL) cohort (patients with"cold" tumors). Three of these 5 patients (60%) have experienced significant tumor reduction, which is higher than the 10% response rate of low TIL patients reported for existing data on nivolumab alone.[1]

Researchers reported continued indications that patients are mounting a vaccine-mediated immune response to the vaccine lysate, as well as to peptides derived from cancer-specific antigens in their peripheral blood cells via ELISPOT analysis. ELISPOT analysis is the most widely used method for monitoring cellular immune responses in humans. This suggests that the HS-110 vaccine is making a measurable contribution to the desired cancer-specific immune response.

Of the 15 patients who have completed the HS-110/nivolumab combination treatment to-date, 12 were evaluable for ELISPOT analysis. Six of the 12 evaluable patients met the criteria for a positive ELISPOT response to vaccine lysate, and 5 of these 6 patients experienced tumor reductions and increased overall survival. All 5 patients who exhibited a clinical response also saw an immune response to HS-110. Of the 6 patients who did not respond by ELISPOT analysis, 5 patients saw tumor progression and 1 patient discontinued treatment due to a non-serious adverse event.

These data suggest that the 5 tumor reductions seen thus far in the 15 evaluated patients are the result of synergistic activity between HS-110 and anti-PD-1 therapy. Researchers also reported that the safety profile continues to be favorable in the HS-110/nivolumab combination, with no evidence of additional toxicities seen as compared to existing data on nivolumab alone.

"Checkpoint inhibitors, such as nivolumab, are currently effective in treating approximately 10% of lung cancer patients with low TIL and about 20% of patients overall in the 2nd line setting," said Jeff Hutchins, Ph.D., Heat's Chief Scientific Officer and Senior Vice President of Preclinical Development. "Our results appear to further validate the expected mechanism of action of our approach in combination with checkpoint inhibitors, with a continuing trend towards early and sustained T cell activation in the peripheral blood cells. All patients who mounted a sustained immune response to HS-110 exhibited substantial tumor reductions. We do not see any tumor reduction in patients who did not mount a response to the vaccine. Furthermore, if ELISPOT assay results continue to correlate with clinical results, the combination of HS-110 and nivolumab may become an attractive therapeutic approach for the approximately 80% of patients that do not respond well to nivolumab alone, particularly with the positive safety profile of this combination seen to-date."

[1]Teng et al, Cancer Research 75(11) June 1, 2015

About Heat Biologics, Inc.

Heat Biologics, Inc. (Nasdaq: HTBX) is an immuno-oncology company developing novel therapies that are designed to activate a patient's immune system against cancer utilizing an engineered form of gp96, a protein that activates the immune system when cells die. Heat's highly specific T cell-stimulating therapeutic vaccine platform technologies, *ImPACT* and *ComPACT*, 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 HS-110 (viagenpumatucel-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC) and a Phase 2 trial with HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC).

Heat's wholly-owned subsidiary, Zolovax, Inc., is developing therapeutic and preventative vaccines to treat infectious diseases based on Heat's gp96 vaccine technology, with a current focus on the development of a Zika vaccine in conjunction with the University of Miami.

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 ELISPOT results suggesting that HS-110 plays an integral role in tumor reduction and may enhance efficacy of checkpoint inhibitors in lung cancer patients, continued indication that patients are mounting a vaccine-mediated immune response to the vaccine lysate, as well as peptides derived from cancer-specific immune response, the suggestion that HS-110 vaccine is making a measurable contribution to the desired cancer-specific immune response, the suggestion that the 5 tumor reductions seen thus far in the 15 evaluated patients are the result of synergistic activity between HS-110 and anti-PD-1 therapy, the results appearing to further validate the expected mechanism of action of Heat's approach in combination with checkpoint inhibitors, with a continuing trend towards early and sustained T cell activation in the peripheral blood cells, the combination of HS-110 and nivolumab may become an attractive therapeutic approach for the approximately 80% of patients that do not respond well to nivolumab alone if ELISPOT assay results continue to correlate with clinical results, and the potential of Heat's *ImPACT* and *ComPACT* therapies. 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 to develop its product candidates and prove them safe and efficacious, 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, the company's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to the company'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, the company'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 and the other factors described in the company's annual report

on Form 10-K for the year ended December 31, 2015 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.

Contact:
Jennifer Almond
Investor and Media Relations
919-240-7133
Investorrelations@heatbio.com