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**
(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

EXHIBIT 99.1

Heat Biologics Presents Topline HS-410 Phase 2 Bladder Cancer Results at the Society of Urological Oncology Annual Meeting

DURHAM, NC – November 30, 2016 – Heat Biologics, Inc. (Nasdaq: HTBX), a leader in the development of gp96-based immunotherapies that are designed to activate a patient's immune system to fight cancer, announced that it presented topline data from its 94-patient Phase II 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 Urologic Oncology Annual Meeting in San Antonio, TX.

In the poster, "Top-Line Results from Vesigenurtacel-L (HS-410) in Combination with BCG from a Randomized, Blinded Phase 2 Trial in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC)," researchers reported that 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. To better assess the durability of the positive immunological responses, and in keeping with clinical trial guidance recently issued by International Bladder Cancer Group ("IBCG")[1] recommending a 2-year study duration for NMIBC trials, Heat will continue to monitor all patients enrolled in the study for an additional 12 months. At that time, Heat will make a final determination whether to progress its bladder cancer program into a Phase 3 trial.

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[1] Definitions, End Points, and Clinical Trial Designs for Non–Muscle-Invasive Bladder Cancer: Recommendations from the International Bladder Cancer Group, Journal of Clinical Oncology, 34(16):1935-44, June, 2016

“The ability of HS-410 to prime T-cells suggests a strong signal that the vaccine is having an impact, as well as an opportunity to improve responses, in this challenging disease,” said study principal investigator, Gary Steinberg, M.D., The Bruce and Beth White Family Professor of Surgery and Director of Urologic Oncology at the University of Chicago. “Historically, NMIBC has been very difficult to treat, with BCG being the only approved therapy in the past 40 years. We were surprised to see that all arms of this trial performed much better than historical control, which is a testament to improvements in standard of care, and validates our choice to run a controlled clinical trial. We look forward to continuing to monitor patients in this trial, per IBCG recommendations. and would like to thank the many patients and their families for the commitment to this trial and advancement of the treatment of bladder cancer.”

“We were pleased to see a robust antigen-specific immune response, reinforcing our earlier clinical data,” Jeff Wolf, CEO of Heat Biologics, commented. “Even though we did not achieve our desired clinical outcomes, we are encouraged by the results and believe this, and other combination therapies, have the potential to improve long-term outcomes. In particular, Heat’s *ComPACT* technology, combining a therapeutic vaccine with an immune co-stimulator in a single product, was designed to substantially improve immune response durability. We are actively pursuing new programs to complement our existing platforms, which we expect to announce in early 2017. Moreover, we look forward to examining the additional top-line data that will be reported next week for our combination trial of HS-110 in with Bristol-Myers Squibb’s Opdivo® (nivolumab) in lung cancer.”

“HS-410 stimulated antigen-specific immune responses to multiple tumor-associated peptides,” commented Taylor Schreiber, M.D., Ph.D., Chief Scientific Officer. “The kinetics of these responses indicate efficient priming of CD8+ T cells, consistent with results seen in other Heat Biologics clinical trials. Remaining analyses are in progress to inform future development of other agents and/or combinations aimed at improving immune response durability. Further understanding of the secondary and exploratory endpoints will advise future development steps.”

“We conducted a cost-efficient trial and will continue to gather important data with minimal ongoing costs,” Mr. Wolf added. “We have maintained a solid balance sheet and intend to continue to be very prudent in managing our expenses as we generate additional clinical data and progress our programs and platforms.”

Additionally, Heat will be presenting topline data on its non-small cell lung cancer study of HS-110 in combination with Bristol-Myers Squibb’s Opdivo® (nivolumab) at the International Association for the Study of Lung Cancer Annual Meeting in Vienna, Austria, on December 6th. The presentation, “Viagenpumatucel-L Bolsters Response to Nivolumab Therapy in Advanced Lung Adenocarcinoma: Preliminary Data from the DURGA Trial” will occur on December 6, 2016, 8:56 AM EST (14:56 CET). Following this data release, Heat plans to hold an investor call on December 8th to discuss its overall clinical strategy moving forward.

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*, 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 HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC) and a Phase 1b 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).

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. The Zolovax patent portfolio also includes gp96 vaccines targeting Zika and West Nile virus, Dengue and yellow fever among others.

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 potential of Heat's *ImPACT* and *ComPACT* therapies and continuing to manage our future expenses prudently. 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 our 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.