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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): **October 2, 2014**

**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.**

Heat Biologics, Inc. (the “Company”), today issued a press release announcing that the Company has dosed the ninth and final patient required in the Phase 1 portion of its Phase 1/2 clinical study for Vesigenurtacel-L (HS-410) in patients with high-risk non-muscle invasive bladder cancer. The Company’s press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

The information included in this Item 7.01 and in 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.**

Heat Biologics, Inc. (the “Company”), today announced that it has dosed the ninth and final patient required in the Phase 1 portion of its Phase 1/2 clinical study for Vesigenurtacel-L (HS-410) in patients with high-risk non-muscle invasive bladder cancer. The Company also announced that to date there have been no reported serious adverse events related to its vaccine. The Company recently modified the Phase 1/2 Vesigenurtacel-L study treatment regimen to include a more robust dose-response analysis and the expedited advancement into Phase 2 trials following completed enrollment of a single cohort of Phase 1 data.

**Item 9.01 – Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibits are being filed as part of this Report.

<b>Exhibit Number</b>	<b>Description</b>
<a href="#"><u>99.1</u></a>	Press Release of Heat Biologics, Inc. dated October 2, 2014

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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: October 2, 2014

HEAT BIOLOGICS, INC.

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



**Heat Biologics, Inc. Completes Enrollment of Phase 1 Clinical Trial of Vesigenurtacel-L for the Treatment of Bladder Cancer Required to Advance to Phase 2**

*- Company expects to commence Phase 2 study in the fourth quarter of 2014 -*

**DURHAM, NC – October 2, 2014 – Heat Biologics, Inc. (NASDAQ: HTBX)**, a clinical stage biopharmaceutical company focused on the development of cancer immunotherapies, announced today that it has dosed the ninth and final patient required in the Phase 1 portion of its Phase 1/2 clinical study for Vesigenurtacel-L (HS-410) in patients with high-risk non-muscle invasive bladder cancer. The Company expects to commence the Phase 2 portion of the bladder cancer clinical trial during the fourth quarter of 2014.

Melissa Price, Ph.D., Heat's Vice President of Clinical and Regulatory Affairs commented, "I am pleased we have met our study timeline objectives for the Phase 1 dosing to enable us to advance to Phase 2. Most importantly, there have been no reported serious adverse events related to our vaccine. We are on track to begin Phase 2 a full quarter sooner than originally reported."

Heat recently modified the Phase 1/2 Vesigenurtacel-L study treatment regimen to include a more robust dose-response analysis and the expedited advancement into Phase 2 trials following completed enrollment of a single cohort of Phase 1 data.

"Heat's clinical team and principal investigators are now in a position to quickly progress Vesigenurtacel-L into Phase 2 enrollment," said Jeff Wolf, Chief Executive Officer. "The initiation of the Phase 2 dosing will provide Heat and its stakeholders with much awaited key data on top-line recurrence-free survival for our *ImPACT* bladder cancer vaccine even earlier than we anticipated. We believe this accelerated timeline has the potential to benefit high-risk patients with non-muscle invasive bladder cancer and brings us one step closer to providing a much needed viable treatment option."

Patient enrollment and dosing in the Vesigenurtacel-L Phase 2 study for the treatment of bladder cancer is expected to be completed in the third quarter of 2015. Heat then anticipates reporting top-line recurrence-free survival results in the third quarter of 2016 after the protocol's twelve-month patient observation period ends.

For patients and physicians interested in enrollment information for the Phase 2 portion of the study of Vesigenurtacel-L in patients with high-risk non-muscle invasive bladder cancer, please visit [clinicaltrials.gov](http://clinicaltrials.gov) and use Identifier **NCT02010203**.

**About Bladder Cancer**

According to the American Cancer Society, in 2014, there will be 74,690 new bladder cancer diagnoses and 15,580 deaths from the disease in the U.S. alone. More than 500,000 people in the U.S. have been treated for bladder cancer. Importantly, the U.S. Food and Drug Administration (FDA) has not approved any new drugs to treat bladder cancer in more than 25 years. Heat's Vesigenurtacel-L (HS-410) represents a viable opportunity to address a significant unmet medical need.

**About Vesigenurtacel-L (HS-410)**

Vesigenurtacel-L (HS-410) is an investigational biologic originating from Heat's proprietary Immune Pan Antigen Cytotoxic Therapy (*ImPACT*) based allogeneic cell lines designed to activate a T-cell mediated pan-antigen immune response for the treatment of bladder cancer. *ImPACT* Therapy reprograms live cancer cells from a single tumor source to continually secrete gp96, a chaperone protein found in all human cells. In turn, gp96 chaperones tumor antigens to T-cells to activate a robust, pan-antigen T-cell immune response and direct killer T-cells to attack the patient's cancer.

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#### **About the Vesigenurtacel-L (HS-410) Phase 1/2 Study**

The multi-center Phase 1/2 study will enroll approximately 84 patients with non-muscle invasive bladder cancer and is designed to determine whether vaccination with Vesigenurtacel-L after transurethral resection of bladder tumor (TURBT) extends the time to disease recurrence compared to placebo. The trial will also test the safety and immune response of Vesigenurtacel-L in bladder cancer patients.

#### **About Heat Biologics, Inc.**

Heat Biologics, Inc. ([www.heatbio.com](http://www.heatbio.com)) is a clinical-stage biopharmaceutical company focused on developing its novel, "off-the-shelf" *ImPACT* therapeutic vaccines to combat a wide range of cancers. Our *ImPACT* Therapy is designed to deliver live, genetically-modified, irradiated human cells which are reprogrammed to "pump out" a broad spectrum of cancer-associated antigens together with a potent immune adjuvant called "gp96" to educate and activate a cancer patient's immune system to recognize and kill cancerous cells. Heat's Viagenpumatucel-L (HS-110) will be entering Phase 2 trials against non-small cell lung cancer and its Vesigenurtacel-L (HS-410) is being evaluated in an ongoing Phase 1/2 clinical trial against bladder cancer.

#### **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 expected commencement and completion date of the Phase 2 study, the date of release of top-line results, the potential benefit of the accelerated timeline and the potential for Heat's *ImPACT* Therapy. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability for Heat's *ImPACT* Therapy to perform as designed, and ability to enroll patients as planned, and the other factors described in our annual report on Form 10-K for the year ended December 31, 2013 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.

#### **Heat Biologics, Inc. Contact Information:**

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Source: Heat Biologics, Inc.

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