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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): **December 7, 2017**

**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))

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. ☒

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**Item 8.01 Other Events.**

On December 7, 2017, Heat Biologics, Inc. (the “Company”) issued a press release announcing that it received written responses from the U.S. Food and Drug Administration (FDA) following the Company’s Type C meeting regarding its planned registrational HS-110 clinical trial design for the treatment of non-small cell lung cancer (NSCLC).

The discussion focused on elements of proposed clinical trial designs, both single-arm and controlled, which the FDA agreed would be appropriate to support a registrational trial of HS-110. Clinical endpoints and post-marketing commitments were also discussed in the context of accelerated approval.

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:

<u>Exhibit Number</u>	<u>Description</u>
<a href="#"><u>99.1</u></a>	Press Release of Heat Biologics, Inc. dated December 7, 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: December 7, 2017

HEAT BIOLOGICS, INC.

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



**Heat Biologics Receives FDA Guidance at Type C Meeting for HS-110 Clinical Trial  
in the Treatment of Non-small Cell Lung Cancer**

**DURHAM, NC – December 7, 2017** – Heat Biologics, Inc. ("Heat") (Nasdaq: HTBX), a biopharmaceutical company developing drugs designed to activate a patient's immune system against cancer, received written responses from the U.S. Food and Drug Administration (FDA) following its Type C meeting regarding its planned registrational HS-110 clinical trial design for the treatment of non-small cell lung cancer (NSCLC).

The discussion focused on elements of proposed clinical trial designs, both single-arm and controlled, which the FDA agreed would be appropriate to support a registrational trial of HS-110. Clinical endpoints and post-marketing commitments were also discussed in the context of accelerated approval.

"We are very pleased with the outcome of our recent Type C guidance meeting with the FDA," said George Peoples, M.D., Chief Medical Officer for Heat. "The FDA clearly understands the significant unmet need for more effective second-line treatments for NSCLC. We look forward to incorporating their guidance as we prepare to advance HS-110 into registrational trials."

HS-110 is currently in Phase 2 as a treatment for NSCLC. Trial design details and next steps are expected to be announced following the read-out of the Phase 2 data, anticipated in 2H 2018.

**About Heat Biologics, Inc.**

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer by inducing 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 inhibitor therapies and other immuno-modulators to increase their effectiveness. We are currently enrolling patients in our Phase 2 clinical trial for 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](http://www.heatbio.com).

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### **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 expected announcement of the trial design and next steps, the anticipated timing of the read-out of the Phase 2 data and the potential benefits of our 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, the successful completion of the rights offering 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.

### **Contacts**

*Media and Investor Inquiries*

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