**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): **January 14, 2019**

# 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 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 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 January 14, 2019, Heat Biologics, Inc. (the "Company") issued a press release announcing that it has dosed its first patient in its Phase 2 clinical trial investigating HS-110 in combination with Merck's anti-PD1 checkpoint inhibitor, KEYTRUDA® (pembrolizumab), in patients with advanced non-small cell lung cancer (NSCLC). This expansion of the Company's Phase 2 trial into first-line maintenance treatment with Keytruda follows positive interim results reported earlier this year on previously treated patients receiving HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, OPDIVO® (nivolumab).

**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 January 14, 2019 |

**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: January 14, 2019

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 January 14, 2019 |

**EXHIBIT 99.1**

# Heat Biologics Doses First Patient in New Cohort of its Expanded Phase 2 Trial of HS-110 in Combination with Merck's KEYTRUDA® in Non-Small Cell Lung Cancer Trial

*Phase 2 expansion into first line maintenance therapy follows positive interim results reported in 2018 in combination with Bristol-Myers' Opdivo® (Nivolumab)*

**DURHAM, NC – January 14, 2019** – Heat Biologics, Inc.(NASDAQ: HTBX), a biopharmaceutical company developing therapies designed to activate a patient's immune system against cancer, today announced that it has dosed its first patient in its Phase 2 clinical trial investigating HS-110 in combination with Merck's anti-PD1 checkpoint inhibitor, KEYTRUDA® (pembrolizumab), in patients with advanced non-small cell lung cancer (NSCLC). This expansion of the Company's Phase 2 trial into first-line maintenance treatment with Keytruda follows positive interim results reported last year on previously treated patients receiving HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, Opdivo® (nivolumab). Heat will continue to dose patients with HS-110 in combination with Opdivo® as well.

The Company amended its Phase 2 master protocol to include additional patient cohorts in the front-line maintenance setting for advanced NSCLC. Patients in these cohorts will have received a minimum of 9 weeks of pembrolizumab, with or without chemotherapy, and will begin maintenance treatment receiving HS-110 with pembrolizumab ± pemetrexed. Patients will be evaluated for objective response rate as well as progression-free and overall survival.

Daniel Morgensztern, MD, Associate Professor of Medicine and Director of Thoracic Oncology, Washington University School of Medicine and lead investigator for this trial, commented, "Results from the ongoing Phase 2, multicenter clinical trial combining HS-110 with Bristol-Myers Squibb's checkpoint inhibitor nivolumab (Opdivo®), suggest that HS-110 may enhance the efficacy of checkpoint inhibitors in patients with advanced lung cancer. Expanding this trial to include Merck's anti-PD-1 checkpoint inhibitor pembrolizumab (KEYTRUDA®) is an important next step in evaluating the broad potential of this platform technology."

Jeff Wolf, Heat's CEO, further noted, "The expansion of this trial to include a combination of HS-110 with KEYTRUDA® is in line with our strategy to combine our T-cell activation platform with multiple checkpoint inhibitors. We are very excited to begin dosing patients in this cohort."

New interim data on those patients in this ongoing Phase 2 trial that have been treated with the HS-110 plus nivolumab combination have been selected for oral presentation at the 2019 ASCO-SITC Clinical Immuno-Oncology Symposium on February 28. To learn more about the trial, visit www.heatbio.com. Additional details can also be found at www.clinicaltrials.gov via NCT02439450.

**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. HS-110 is our first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells to attack cancer. Our *ComPACT* technology is the first potential, dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product. 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®) and with Merck's pembrolizumab (Keytruda®). 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, expectation, and assumptions and include statements regarding Heat's ongoing clinical programs, the continued dosing of patients with Opdivo® and the suggestion that HS-110 may enhance the efficacy of checkpoint inhibitors in patients with advanced lung cancer. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's therapies 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, and the other factors described in Heat's filings with the SEC. The information in this release is provided only as of the date of this release, and Heat 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.*

Media and Investor Relations Contact
David Waldman
+1 919 289 4017
investorrelations@heatbio.com