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): **February25, 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.

In connection with the planned oral presentation of Heat Biologic's Inc.'s (the "Company") new HS-110 interim Phase 2 data at the upcoming 2019 ASCO-SITC Clinical Immuno-Oncology Symposium on February 28, 2019, by the principal investigator for the trial, Daniel Morgensztern, MD, Associate Professor of Medicine and Director of Thoracic Oncology, Washington University School of Medicine, an abstract has been posted on the ASCO-SITC website.

The abstract summarizes interim data from the first two cohorts (A & B) of the Company's Phase 2 trial of HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced non-small cell lung cancer (NSCLC). Cohort A is comprised of previously-treated patients who have never received checkpoint inhibitor therapy; Cohort B is comprised of patients whose prior treatment does include checkpoint inhibitor therapy followed by disease progression.

Cohort A results are consistent with those reported in early 2018. With a median follow-up of 14.4 months in this cohort, the median overall survival has not yet been reached and 60% of patients remain alive. Protocol-defined subgroup analysis of patients categorized as 'high' or 'low' TIL (tumor infiltrating lymphocytes), based on levels of CD8+ cells present in the stroma of their tumor tissue at baseline, demonstrate a survival advantage for the 'low TIL' group as compared to the 'high TIL' group (not reached vs 13.8 months). Survival status was independent of patient PD-L1 expression levels on tumor samples from baseline. Objective Response Rate (ORR), Disease Control Rate (DCR) and Progression-Free Survival (PFS) per RECIST 1.1 are 18.6%, 48.8% and 1.9 months, respectively. The landmark 1 year PFS was 23.9% in Cohort A.

The abstract and presentation also contain the first data ever disclosed for Cohort B, patients whose disease progressed while receiving checkpoint inhibitor therapy at any time prior to study entry. Preliminary results suggest that adding HS-110 to nivolumab can restore responsiveness to checkpoint inhibitors with an investigator-assessed ORR of 22%, a DCR of 50%, and a median Progression-Free Survival of 2.2 months.

In both cohorts, combination with HS-110 and nivolumab was well-tolerated with the most common adverse events (AEs) reported as fatigue (31%), cough and diarrhea (19.7% each).

During the presentation, Dr. Morgensztern plans to discuss the interim results of the trial in greater detail along with a subset of correlative assessments and post-hoc analysis that support the mechanism of action of HS-110. Note that because the trial is still enrolling and new data has emerged since abstract submission in November 2018, Dr. Morgensztern's presentation and poster will contain updated results which may vary from the original abstract. The complete abstract is available online at: abstracts.asco.org.

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: February 25, 2019

HEAT BIOLOGICS, INC.

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