

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 19, 2019**

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.)

627 Davis Drive

Morrisville, North Carolina 27560

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0002 par value per share	HTBX	The Nasdaq Capital Market

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 7.01 Regulation FD Disclosure.

Members of the management team of Heat Biologics, Inc. (the “Company”) and certain clinical investigators in its ongoing Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®) presented the information in the presentation poster (the “Poster”) entitled “Viagenpumatucel-L (HS-110) plus nivolumab in previously-treated patients with advanced non-small cell lung cancer (NSCLC)” on November 19, 2019 at the American Association for Cancer Research (AACR) Special Conference on Tumor Immunology and Immunotherapy held in Boston Massachusetts. A copy of the Poster is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

The furnishing of the attached Poster is not an admission as to the materiality of any information therein. The information contained in the Poster is summary information that is intended to be considered in the context of more complete information included in the Company’s filings with the Securities and Exchange Commission (the “SEC”) and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report or the exhibit, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

Item 8.01 Other Events.

On November 19, 2019, members of the management team of the Company and certain clinical investigators in its ongoing Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®) presented the Poster at the American Association for Cancer Research (AACR) Special Conference on Tumor Immunology and Immunotherapy held in Boston, Massachusetts. The Poster provides additional top line data from the Company’s ongoing Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®). The additional data were obtained from Cohort A patients.

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	Poster presentation entitled “Viagenpumatucel-L (HS-110)) plus nivolumab in previously-treated patients with advanced non-small cell lung cancer (NSCLC)



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: November 19, 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	Poster presentation entitled “Viagenpumatucl-L (HS-110) plus nivolumab in previously-treated patients with advanced non-small cell lung cancer (NSCLC)

VIAGENPUMATUCEL-L (HS-110) IN COMBINATION WITH NIVOLUMAB IN PREVIOUSLY-TREATED PATIENTS WITH ADVANCED NON-SMALL LUNG CANCER (NSCLC)

Daniel Margolis¹, Lyubmila Bashenova¹, Salsma N. Wazari¹, Lori McDonnell¹, Afif Hachimi¹, Wael Haddad¹, Mathias Perceat¹, Roger B. Cohen¹

¹Washington University School of Medicine, St. Louis, MO; ²NC San Diego, Moores Cancer Center, San Diego, CA; ³Novartis Biotech, Inc., Durham, NC; ⁴Novartis Oncology Center, Leiden, NL; ⁵Trans Cancer Partners, Cleveland Clinic, Cleveland, OH; ⁶University of Pennsylvania Perelman School of Medicine, Philadelphia, PA

Background

Viagenpumatucel-L (HS-110) is an allogeneic cellular immunotherapy that incorporates a broad range of tumor antigens that are known to be shared among a high proportion of patients with non-small cell lung cancer (NSCLC). This cell vaccine is being given in a 3-dose regimen to induce cellular immunity against the tumor antigen, mediated by Viagenpumatucel-L (HS-110). HS-110 is a single chimeric antigen that can activate MHC and to regulate T cell activation and deliver improved antigen to an MHC for display to MHC, with the most long-lived T cell mediated immune response.¹

The HS-110 "Dose" trial is an exploratory, multi-cohort study protocol evaluating HS-110 in combination with nivolumab (OPDIVO) in the treatment of advanced non-small lung cancer. This was presented by the Sanofi-Genzyme at the 2019 ASCO Annual Meeting. The study was presented by the Sanofi-Genzyme at the 2019 ASCO Annual Meeting. The study was presented by the Sanofi-Genzyme at the 2019 ASCO Annual Meeting.

Mechanism of Action

Study Schema

Patient Characteristics

Characteristic	n (%)
Median age (range)	67 (47-87)
Female:male	20 (24%):52 (64%)
Duration	47 (58%)
ECOG PS 1	32 (40%)
High tumor burden	4 (5%)
Previous treatment	45 (56%)
- Chemotherapy	39 (49%)
- Radiation	3 (4%)
- Immunotherapy	2 (3%)
- Surgery	1 (1%)
- Targeted therapy	1 (1%)
- Other	1 (1%)
- Unknown	1 (1%)

Best Overall Response

Response	n (%)
CR	20 (25%)
PR	20 (25%)
SD	20 (25%)
PD	10 (12.5%)
NE	10 (12.5%)

T Cell Changes by Best Overall Response (BOR)

Best Target Lesion Response

Duration of Clinical Benefit

Overall Survival

Progression-Free Survival

Frequently Reported Adverse Events

Adverse Event	Number of Patients (%)
Any adverse event	40 (50%)
Any event Grade 3	11 (14%)
Hyperkalemia	10 (12.5%)
Diarrhea	10 (12.5%)
Headache	10 (12.5%)
Constipation	10 (12.5%)
Upper respiratory tract infection	10 (12.5%)
Decreased appetite	10 (12.5%)

Table 1: Safety Summary

Table 1 summarizes the safety profile of the combination of Viagenpumatucel-L (HS-110) and nivolumab (OPDIVO) in patients with advanced non-small cell lung cancer. The most common adverse events were any adverse event (50%), any event Grade 3 (14%), hyperkalemia (12.5%), diarrhea (12.5%), headache (12.5%), constipation (12.5%), upper respiratory tract infection (12.5%), and decreased appetite (12.5%).

Conclusions

HS-110 in combination with nivolumab is well tolerated. The effect of HS-110 in combination with nivolumab is not dependent on baseline PD-L1 expression. Best Overall Response of SD or better is associated with an improved duration of clinical benefit, progression-free survival, and overall survival. The occurrence of adverse events, the majority being grade 1 or 2, is associated with improved progression-free survival and overall survival.

References

1. Cohen RB, Margolis D, Bashenova L, et al. Viagenpumatucel-L (HS-110) in combination with nivolumab in patients with advanced non-small cell lung cancer. *Journal of Clinical Oncology*. 2019;37(18):2537-2545.
2. Cohen RB, Margolis D, Bashenova L, et al. Viagenpumatucel-L (HS-110) in combination with nivolumab in patients with advanced non-small cell lung cancer. *Journal of Clinical Oncology*. 2019;37(18):2537-2545.

Acknowledgments

The authors would like to acknowledge the following individuals for their efforts and contributions in producing the manuscript: Daniel Margolis, Lyubmila Bashenova, Salsma N. Wazari, Lori McDonnell, Afif Hachimi, Wael Haddad, Mathias Perceat, Roger B. Cohen, and the patients and their families who participated in this trial to help advance the treatment of non-small cell lung cancer.