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): **May 14, 2020**

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.)*

627 Davis Drive, Suite 400
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 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.

On May 14, 2020, an abstract (the"Abstract") titled "Tumor antigen expression and survival of patients with previously treated advanced non-small cell lung cancer (NSCLC) receiving viagenpumatucel-L (HS-110) plus nivolumab", which had been submitted by Heat Biologics, Inc. (the "Company") to the American Society of Clinical Oncology (ASCO) in connection with its 2020 Annual Meeting was published by ASCO. A copy of the Abstract is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Additionally, the poster associated with this Abstract will be available beginning on May 29, 2020 on the ASCO website.

The furnishing of the attached Abstract and press release is not an admission as to the materiality of any information therein. The information contained in the Abstract is summary information that is intended to be considered in the context of more complete information included in the Company's filings with 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, 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 Information

On May 14, 2020, the Company issued a press release announcing that on May 14, 2020 the Abstract titled "Tumor antigen expression and survival of patients with previously treated advanced non-small cell lung cancer (NSCLC) receiving viagenpumatucel-L (HS-110) plus nivolumab" which had been submitted by the Company to ASCO in connection with its 2020 Annual Meeting was published by ASCO.

The data presented in the Abstract was obtained from the Company's ongoing Phase 2 trial in combination with Bristol-Myers Squibb's (BMS) Opdivo® (nivolumab) for multiple treatment settings in advanced NSCLC.

The data presented included median overall survival (OS), which was 28.7 months with a median follow up of 15.7 months. This study is ongoing and 21 of the 47 patients enrolled (45%) were still alive as of this data-cut.

Exploratory biomarker analysis on cancer testis antigens (CTAs) was performed using patients' tumor tissue at baseline. In this evaluation, improved overall survival (OS) was observed in patients whose tumors have 8 or more overlapping CTAs with the 39 CTAs overexpressed by HS-110. In addition, overexpression of zinc finger protein 492 (ZNF492) was associated with greater OS. ZNF492 is a transcription factor that is expressed in multiple cancers.

The information in the press release shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed with this Current Report on Form 8-K.

Exhibit Number	Exhibit Description
99.1	Abstract titled "Tumor antigen expression and survival of patients with previously treated advanced non-small cell lung cancer (NSCLC) receiving viagenpumatucel-L (HS-110) plus nivolumab"
99.2	Press Release of Heat Biologics, Inc. dated May 14, 2020

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: May 14, 2020

HEAT BIOLOGICS, INC.

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

EXHIBIT 99.1

Tumor antigen expression and survival of patients with previously-treated advanced non-small cell lung cancer (NSCLC) receiving viagenpumatucel-L (HS-110) plus nivolumab

Daniel Morgensztern, Saiama Naheed Waqar, Lyudmila Bazhenova, Lori McDermott, Jeff Hutchins, David H Taylor, Fred L Robinson, Alexa K Dowdell, Brian Piening, Wael A. Harb, Nathan A. Pennell, Roger B. Cohen; Washington University School of Medicine in St. Louis, St. Louis, MO; Washington University School of Medicine, St. Louis, MO; University of California San Diego, San Diego, CA; Heat Biologics, Durham, NC; Heat Biologics, Inc., Durham, NC; Heat Biologics, Morrisville, NC; Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute, Providence Portland Medical Center, Portland, OR; Earle A. Chiles Research Institute at Robert W. Franz Cancer Center, Providence Cancer Institute, Portland, OR; Horizon Oncology Research, LLC, Lafayette, IN; Cleveland Clinic Foundation, Cleveland, OH; University of Pennsylvania Perelman School of Medicine, Philadelphia, PA.

Background:
Viagenpumatucel-L (HS-110) is an allogeneic cellular vaccine derived from a human lung adenocarcinoma cell line transfected with gp96-Ig fusion protein. Gp96-Ig functions as an antigen chaperone for dendritic cell activation and direct CD8+T cell expansion via cross presentation. DURGA is a multi-cohort study evaluating HS-110 plus anti-PD-1 mAbs in patients (pts) with advanced NSCLC. We report on Cohort A, which enrolled previously-treated pts who had not received an anti-PD(L)1 prior to study entry.

Methods:
Primary objectives were safety and objective response rate (ORR). Overall Survival (OS) was a secondary endpoint. Pts received 1 X 10^7 HS-110 cells intradermally every week for 18 wks and nivolumab until tumor progression. To determine cancer testis antigen (CTA) overexpression from baseline pt tumor samples, hybrid-capture RNA-seq libraries were prepared from macrodissected formalin fixed paraffin embedded tumor tissue and sequenced on an Illumina NovaSeq 6000. Gene-level transcripts were quantified using the Salmon software package.

Results:
47 pts were enrolled into Cohort A. ORR and clinical benefit rate (CR + PR + SD) were 21% and 43%, respectively, with a 17.2 month median duration of response. Median OS was 28.7 months (mos), with a median follow up of 15.7 mos. One and 2-year survival were 57% and 36%, respectively. A prespecified exploratory analysis of CTA expression level in baseline pt tumor tissue was performed. 50% of pts shared at least 8 of the 39 total antigens overexpressed by HS110. Although there was no difference in ORR between these groups, mOS was higher in pts with tumors that shared ≥ 8 antigens with HS-110 (not reached (NR) [95%CI: 10.3 mos, NR] vs 6.7 mos [95%CI: 1.4 mos, NR]), p=0.028. Pts whose tumors expressed the ZNF492 antigen also had improved OS (NR [95%CI: 11.6 mos, NR] vs 7.2 mos [95%CI: 1.6 mos, NR]), p=0.03. All pts experienced at least one adverse event (AE), and the most common AEs were fatigue (28%), arthralgia (19%) and cough (17%). There were 2 grade 5 AEs not related to treatment.

Conclusions:
The combination of HS-110 and nivolumab appears safe and well tolerated. OS was improved in pts whose tumors express≥ 8 shared antigens with HS110, as well as in those who specifically expressed ZNF492. Further exploration of antigen expression as a predictor for treatment outcome with HS110 plus nivolumab is ongoing.

Exhibit 99.2

Positive Survival Data from Phase 2 Lung Cancer Trial Accepted for Presentation at 2020 American Society of Clinical Oncology (ASCO) Annual Meeting

Median overall survival (OS) of 28.7 months for HS-110 in combination with nivolumab in previously treated checkpoint inhibitor naïve non-small cell lung cancer (NSCLC) patients

Durham, NC – May 14, 2020 – **Heat Biologics, Inc. ("Heat") (NASDAQ: HTBX)**, a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, including multiple oncology product candidates and a novel COVID-19 vaccine, today announced that it has been selected to deliver a poster presentation at the ASCO Annual Meeting, to be held virtually during May 29 - 31, 2020. The ASCO Annual Meeting is the largest international conference to showcase the latest advancement in oncology. The abstracts published in advance of the ASCO Annual Meeting were made available at 5:00 p.m. Eastern Daylight Time on May 13, 2020 on the ASCO meeting website at: https://meetinglibrary.asco.org/record/184864/abstract

HS-110 is currently in Phase 2 trial in combination with Bristol-Myers Squibb's (BMS) Opdivo® (nivolumab) for multiple treatment settings in advanced non-small cell lung cancer (NSCLC). HS-110 is an "off-the-shelf" allogeneic cell-based therapy designed to activate patients' immune system against multiple tumor antigens to elicit a robust pan-antigen T-cell attack against tumor cells. Heat completed enrollment in this trial in July 2019.

The abstract provides an update on the efficacy data of previously treated, checkpoint inhibitor (CPI) naïve patients with advanced NSCLC. The median overall survival (OS) was 28.7 months with a median follow up of 15.7 months. This study is ongoing and 21 of the 47 patients enrolled (45%) were still alive as of this datacut. Additional subset analysis will also be presented. HS-110 has a good safety profile in over 200 patients and combination of HS-110 and nivolumab appears to be safe and well-tolerated.

Exploratory biomarker analysis on cancer testis antigens (CTAs) was performed using patients' tumor tissue at baseline. In this evaluation, improved overall survival (OS) was observed in patients whose tumors have 8 or more overlapping CTAs with the 39 CTAs overexpressed by HS-110. In addition, overexpression of zinc finger protein 492 (ZNF492) was associated with greater OS. ZNF492 is a transcription factor that is expressed in multiple cancers.

Details of Heat Biologics' ASCO poster presentation:
Abstract Title: Tumor antigen expression and survival of patients with previously treated advanced non-small cell lung cancer (NSCLC) receiving viagenpumatucel-L (HS-110) plus nivolumab
Session: Lung Cancer - Non-Small Cell Metastatic
Abstract #: 9546
Poster#: 312
Date: Friday, May 29, 2020, 8am Eastern Time
Following the presentation, a copy of the poster will be available on Heat Biologics' website at: https://www.heatbio.com/product-pipeline/scientific-publications

Reference:
The Human Protein Atlas - ZNF492: https://www.proteinatlas.org/ENSG00000229676-ZNF492/pathology

About Heat Biologics, Inc.
Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer and other diseases using its proprietary gp96 platform to activate CD8+ "Killer" T-cells. Heat has completed enrollment in its Phase 2 clinical trial for advanced non-small cell lung cancer with its gp96-based HS-110 therapeutic vaccine. HS-110 is the company's first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells. Heat Biologics has also launched a program in collaboration with the University of Miami to develop a vaccine designed to protect against the COVID-19 coronavirus. Heat has numerous other pre-clinical programs at various stages of development. For more information, please visit www.heatbio.com.

Forward Looking Statement
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 such as Heat's gp96 platform activating immune responses against cancer or pathogenic antigens and Heat's developing pipeline. 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, the ability of Heat together with researchers at the University of Miami to develop a proprietary COVID-19 vaccine, 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, its ability to continue to maintain its listing on the Nasdaq Capital Market and its ability to retain its key scientists or management personnel, and the other factors described in Heat's most recent annual report on Form 10-K for the year ended December 31, 2019 filed with the SEC, and other subsequent 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.

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