

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): April 12, 2021

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, 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, if Changed Since Last Report)

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 Stock Market (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 April 12, 2021, Heat Biologics, Inc. (the “Company”) issued a press release announcing a poster presentation at the 2021 American Association for Cancer Research (AACR) Annual Meeting of new preclinical data on PTX-35, demonstrating decreased regulatory T cell (Treg) activity and delayed tumor progression. At the AACR 2021 Annual Meeting, the Company will be presenting a poster presentation entitled “PTX-35, a Potential First-in-class Agonist, Reduced the Suppressive Activity of Regulatory T cells and Enhanced CD4+ T cell Effector Responses in the Presence of Tumor Antigens in a Murine Melanoma Model”.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K 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. The information contained in this Item 7.01 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release attached as Exhibit 99.1 to this Current Report on Form 8-K include “safe harbor” language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are “forward-looking” rather than historical.

The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosures.

Item 8.01. Other Events.

On April 12, 2021, the Company issued a press release announcing new preclinical data on PTX-35, demonstrating decreased regulatory T cell (Treg) activity and delayed tumor progression. In a B16F10 melanoma mouse model, PTX-35, in the presence of tumor antigen supplied by the Company’s HS-110 immunotherapy, resulted in decreased regulatory T cell suppression and enhanced T effector responses. These changes were associated with delayed tumor progression.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

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

Exhibit Number	Exhibit Description
99.1	Heat Biologics, Inc. Press Release



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: April 12, 2021

HEAT BIOLOGICS, INC.

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



Heat Biologics Announces New Preclinical Data on PTX-35, Demonstrating Decreased Regulatory T-cell (Treg) Activity and Delayed Tumor Progression at American Association for Cancer Research (AACR) Annual Meeting 2021

DURHAM, NC – April 12, 2021 – Heat Biologics, Inc. (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 reported that promising new preclinical data of PTX-35 is presented at the AACR Annual Meeting 2021.

PTX-35 is the company's first antibody-based product, currently in a Phase 1 clinical trial for the treatment of patients with solid tumors. PTX-35 is a novel, potential first-in-class antibody modulating TNFRSF25 (death receptor 3), a receptor that is preferentially expressed by antigen-experienced T-cells. In a B16F10 melanoma mouse model, PTX-35 in the presence of tumor antigen supplied by Heat's HS-110 immunotherapy, resulted in decreased regulatory T-cell suppression and enhanced T effector responses. These changes were associated with delayed tumor progression.

Jeff Wolf, Chief Executive Officer of Heat, commented, "PTX-35 is designed to harness the body's natural antigen-specific immune activation. We believe our latest data suggest that PTX-35 can help overcome certain mechanisms of cancer immune evasion. We continue to advance our first-in-human Phase 1 study of PTX-35 in patients with solid tumors and look forward to sharing interim data later this year."

Details of the poster presentation are as follows:

Title: PTX-35, a Potential First-in-class Agonist, Reduced the Suppressive Activity of Regulatory T cells and Enhanced CD4+ T cell Effector Responses in the Presence of Tumor Antigens in a Murine Melanoma Model

Abstract Number: 604

Session: Modifiers of the Tumor Microenvironment

Presenter: Eric Dixon, Director of Discovery Sciences, Heat Biologics

About the AACR Annual Meeting

The 2021 AACR Annual Meeting program covers the latest discoveries across the spectrum of cancer research—from population science and prevention to cancer biology, translational, and clinical studies, as well as survivorship and advocacy—and highlights the work of the best minds in research and medicine from institutions all over the world.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system. Heat's gp96 platform is designed to activate immune responses against cancer or infectious diseases. The Company has multiple product candidates in development leveraging the gp96 platform, including HS-110, which has completed enrollment in its Phase 2 trial, and a COVID-19 vaccine program in preclinical development. In addition, Heat Biologics is also developing a pipeline of proprietary immunomodulatory antibodies and cell-based therapies, including PTX-35 and HS-130 in Phase 1 clinical trials.

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 the latest data suggesting that PTX-35 can help overcome certain mechanisms of cancer immune evasion and sharing interim data later this year. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of PTX-35 to help overcome certain mechanisms of cancer immune evasion, the ability to provide interim data when planned, Heat's vaccine platform to provide protection against COVID-19, 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, especially in light of COVID-19, 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, 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 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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