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 12, 2022**

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(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 January 12, 2022, Heat Biologics, Inc. (the "Company") issued a press release announcing that promising new preclinical data regarding PTX-35 has been accepted for publication in the American Journal of Transplantation. The Company's subsidiary, Pelican Therapeutics, Inc. "Pelican Therapeutics"), is developing PTX-35, a novel, potential first-in-class antibody immunomodulator of TNFRSF25 (death receptor 3), a receptor that is preferentially expressed by antigen-experienced T cells and can be manipulated to expand regulatory T-cell subsets. 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. The following are the PTX-35 key findings:

- A single dose of the preclinical version of PTX-35 (mPTX-35), was able to expand regulatory T cells (Tregs) and significantly improve disease and graft survival outcomes.
- Chemically induced pancreatic failure (a model for type-1 diabetes) could be partially reversed when mice were transplanted with beta-cell islet allografts and treated with mPTX-35.
- Disease protection in preclinical models was correlated with a significant expansion of Tregs and protection of the allograft, resulting in euglycemia and a graft survival benefit.
- Long-term surviving grafts showed a marked increase in Treg infiltration which directly correlated with mPTX-35 agonist activity.

The Company also announced that it expected to file for an End of Phase 2 meeting with the FDA this quarter with the goal of discussing potential Phase 3 registration pathways for HS-110.

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 and 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 includes "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 January 12, 2022, the Company issued a press release announcing that promising new preclinical data regarding PTX-35 has been accepted for publication in the American Journal of Transplantation. Pelican Therapeutics is developing PTX-35, a novel, potential first-in-class antibody immunomodulator of TNFRSF25 (death receptor 3), a receptor that is preferentially expressed by antigen-experienced T cells and can be manipulated to expand regulatory T-cell subsets. 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. The following are the PTX-35 key findings:

- A single dose of the preclinical version of PTX-35 (mPTX-35), was able to expand regulatory T cells (Tregs) and significantly improve disease and graft survival outcomes.
- Chemically induced pancreatic failure (a model for type-1 diabetes) could be partially reversed when mice were transplanted with beta-cell islet allografts and treated with mPTX-35.
- Disease protection in preclinical models was correlated with a significant expansion of Tregs and protection of the allograft, resulting in euglycemia and a graft survival benefit.
- Long-term surviving grafts showed a marked increase in Treg infiltration which directly correlated with mPTX-35 agonist activity.

The Company also announced that it expected to file for an End of Phase 2 meeting with the FDA this quarter with the goal of discussing potential Phase 3 registration pathways for HS-110.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following Exhibit 99.1 is furnished with this Current Report on Form 8-K:

Exhibit Number	Description
99.1	Press release, dated January 12, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

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 12, 2022

HEAT BIOLOGICS, INC.

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

Heat Biologics Announces New PTX-35 Preclinical Data in Organ Transplantation and Provides Update on HS-110

Data demonstrates that PTX-35 may have utility in solid organ transplantation, and to potentially slow or mitigate deleterious immune responses where self-tissue tolerance is impaired

Durham, NC – January 12, 2022 – **Heat Biologics, Inc. ("Heat") (NASDAQ: HTBX)**, a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, today announced promising new preclinical data regarding PTX-35 has been accepted for publication in the American Journal of Transplantation and is available at: https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16940.

Key Findings:

- A single dose of the preclinical version of PTX-35 (mPTX-35), was able to expand regulatory T cells (Tregs) and significantly improve disease and graft survival outcomes.
- Chemically induced pancreatic failure (a model for type-1 diabetes) could be partially reversed when mice were transplanted with beta-cell islet allografts and treated with mPTX-35.
- Disease protection in preclinical models was correlated with a significant expansion of Tregs and protection of the allograft, resulting in euglycemia and a graft survival benefit.
- Long-term surviving grafts showed a marked increase in Treg infiltration which directly correlated with mPTX-35 agonist activity.

PTX-35 is a novel, potential first-in-class antibody immunomodulator of TNFRSF25 (death receptor 3), a receptor that is preferentially expressed by antigen-experienced T cells and can be manipulated to expand regulatory T-cell subsets. 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.

Dr. James Shapiro, Professor in the Department of Surgery and Clinical Islet Transplant Program at the University of Alberta, Edmonton, Canada, commented, "The study demonstrated that a single dose of PTX-35 enabled prolonged graft survival in a mouse model of pancreatic islet allotransplantation. Additionally, PTX-35 could contribute to achieving lasting immunological tolerance in organ transplantation."

Jeff Wolf, Chief Executive Officer of Heat, commented, "We are very encouraged by these results showing pronounced Treg expansion and significantly prolonged graft survival compared to control. PTX-35 has the potential to modulate immunological responses and may facilitate minimization of post-transplant immunosuppression, which supports further clinical evaluation in the context of inflammatory disease. Similar preclinical results have also been previously demonstrated for bone marrow, corneal and cardiac transplantation using these and other TNFRSF25 agonists."

Mr. Wolf further noted, "We are also making significant progress with HS-110 and expect to file for an End of Phase 2 meeting with the FDA this quarter. Our goal for this meeting is to discuss potential Phase 3 registration pathways for HS-110. Although this submission is taking longer than expected, we believe we have prepared a very comprehensive package and look forward to the FDA's feedback."

About Heat Biologics, Inc.
Heat Biologics is a biopharmaceutical company focused on developing first-in-class therapies and vaccines 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 a Phase 2 trial, various infectious disease/biological threat programs in preclinical development and a pipeline of proprietary immunomodulatory antibodies and cell-based therapies, including PTX-35 and HS-130 in Phase 1 clinical trials.

For more information, please visit: www.heatbio.com, and also follow us on Twitter.

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 partially reversing chemically induced pancreatic failure (a model for type-1 diabetes) when mice were transplanted with beta-cell islet allografts and treated with mPTX-35, PTX-35 contributing to achieving lasting immunological tolerance in organ transplantation, the potential of PTX-35 to modulate immunological responses and facilitate minimization or withdrawal of immunosuppression post-transplant, which supports further clinical evaluation in the context of inflammatory disease, expected filing for HS-110 for an End of Phase 2 meeting with the FDA this quarter, and the potential Phase 3 registration pathways for HS-110. 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, Heat's vaccine platform to provide protection against COVID-

19, 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 including a Phase 3 registration pathway for HS-110 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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