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): **July 29, 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(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 July 29, 2020, Heat Biologics, Inc. (the "Company") issued a press release announcing successful pre-clinical testing of the Company's COVID-19 vaccine, which demonstrated *in-vivo* confirmation of vaccine immunogenicity in animal models, including expansion of human-HLA-restricted T-cells against immunodominant epitopes of SARS-CoV-2 Spike protein. Testing demonstrated expansion of antibody-supporting CD4+, and virus killing CD8+ T-cells in the lungs of the animals, a major site for COVID-19 infection. 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 thisCurrent 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 Information

On July 29, 2020, the Company issued a press release announcing successful pre-clinical testing of the Company's COVID-19 vaccine, which demonstrated*in-vivo* confirmation of vaccine immunogenicity in animal models, including expansion of human-HLA-restricted T-cells against immunodominant epitopes of SARS-CoV-2 Spike protein. Testing demonstrated expansion of antibody-supporting CD4+, and virus killing CD8+ T cells in the lungs of the animals, a major site for COVID-19 infection.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is 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: July 29, 2020

HEAT BIOLOGICS, INC.

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

EXHIBIT 99.1

Heat Biologics COVID-19 Vaccine Demonstrates
Immunogenicity Proof-of-Concept in Pre-Clinical Studies

Confirms stimulation of human-HLA-restricted transgenic mouse T-cells against immunodominant epitopes of SARS-CoV-2 Spike protein

Durham, NC – July 29, 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 successful pre-clinical testing of the Company's COVID-19 vaccine, which demonstrated *in-vivo* confirmation of vaccine immunogenicity in animal models, including expansion of human-HLA-restricted T-cells against immunodominant epitopes of SARS-CoV-2 Spike protein. Testing demonstrated expansion of antibody-supporting CD4+, and virus killing CD8+ T-cells in the lungs of the animals, a major site for COVID-19 infection.

"We are pleased to report this significant milestone in the development of our COVID-19 vaccine," said Jeff Wolf, CEO of Heat. "Specifically, our latest pre-clinical studies demonstrated immunogenicity proof-of-concept, illustrating that our vaccine can expand human-HLA-restricted T-cells against immunodominant epitopes of SARS-CoV-2 Spike protein, and validating that the selected vaccine antigen may be appropriate for human testing."

Natasa Strbo MD, DSc, Assistant Professor of Microbiology and Immunology at the University of Miami Miller School of Medicine and co-developer of Heat's gp96 platform, commented, "We are encouraged by the observed T-cell expansion and cytokine secretion in response to Spike protein stimulation in pre-clinical models. Measured cytokines, produced by anti-viral CD4+ T-cells, important for B cell antibody class switching, and CD8+ T-cells, important to clear virus-infected cells, suggests that an optimal immune response is being generated in response to our vaccination. These pre-clinical data imply that our vaccine is prompting a robust and effective immune response to support anti-viral immunity. In addition, stimulation of anti-viral killer CD8+ T-cells in human HLA-A2-positive transgenic mice provides encouraging pre-clinical data to support human trials, as we can expand cells specific for viral antigens presented in the context of the human immune system."

Mr. Wolf continued, "I would like to thank Natasa Strbo and her team at the University of Miami, as well as the team at Heat who are working tirelessly to advance our COVID-19 vaccine platform in breakthrough time. Given this data, we are further encouraged by the outlook for our COVID-19 vaccine, and believe this platform may play an important role as a standalone vaccine or in combination with other antibody-generating vaccines by engaging both the humoral and cellular arms of the immune system to stimulate more robust prophylactic protection."

About Heat Biologics, Inc.
Heat Biologics is a biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system. The company's gp96 platform is designed to activate immune responses against cancer or pathogenic antigens. Multiple product candidates in development leverage the gp96 platform, including HS-110 which has completed enrollment in its Phase 2 trial, HS-130 in Phase 1, and a COVID-19 vaccine program in preclinical development. In addition, Heat is also developing a pipeline of proprietary immunomodulatory antibodies, including PTX-35 which is enrolling in a Phase 1 trial. 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 the vaccine expanding human-HLA-restricted T-cells against immunodominant epitopes of SARS-CoV-2 Spike protein, the selected vaccine antigen being appropriate for human testing, measured cytokines, produced by anti-viral CD4 T-cells, suggesting that an optimal immune response is being generated in response to our vaccination and this platform playing an important role as a standalone vaccine or in combination with other antibody-generating vaccines by engaging both the humoral and cellular arms of the immune system to stimulate more robust prophylactic protection. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including, the ability of the vaccine to expand human-HLA-restricted T-cells against immunodominant epitopes of SARS-CoV-2 Spike protein, the ability to validate the selected vaccine antigen for appropriate for human testing and to generate an optimal immune response, the ability of this platform to play an important role as a standalone vaccine or in combination with other antibody-generating vaccines, 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 an effective 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.

Media and Investor Relations Contact
David Waldman
+1 919 289 4017
investorrelations@heatbio.com