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 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 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 April 29, 2020, Heat Biologics, Inc. (the"Company") issued a press release announcing its strategy and anticipated Q2 2020 milestones for its COVID-19 vaccine program, which anticipated Q2 2020 milestones include (i) completion of development of a cell-based vaccine expressing gp96-Ig, OX40L-Ig and SARS-CoV-2 protein S; (ii) generation of proof of concept data demonstrating vaccine immunogenicity in relevant preclinical models; and (iii) submission of grant applications to fund and accelerate COVID-19 vaccine development. Commencement of preclinical testing of the vaccine is planned to commence this quarter, with the reporting of preliminary data shortly thereafter. The strategy includes a focus on providing prophylactic protection to elderly patients and those with underlying health conditions and driving a cellular immune response via CD8+ T cells, in addition to a humoral immune response.

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

The information in this Item 7.01 and Exhibit 99.1 attached to this Current Report on Form 8-K are being furnished under Item 7.01 of Form 8-K. Such information shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

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 or the press release attached to this Current Report on Form 8-K as Exhibit 99.1, 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 April 29, 2020, the Company announced its strategy and anticipated Q2 2020 milestones for its COVID-19 vaccine program, which anticipated Q2 2020 milestones include (i) completion of development of a cell-based vaccine expressing gp96-Ig, OX40L-Ig and SARS-CoV-2 protein S; (ii) generation of proof of concept data demonstrating vaccine immunogenicity in relevant preclinical models; and (iii) submission of grant applications to fund and accelerate COVID-19 vaccine development. Commencement of preclinical testing of the vaccine is planned to commence this quarter, with the reporting of preliminary data shortly thereafter. The strategy includes a focus on providing prophylactic protection to elderly patients and those with underlying health conditions and driving a cellular immune response via CD8+ T cells, in addition to a humoral immune response.

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	Press Release, issued by Heat Biologics, Inc. on April 29, 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: April 29, 2020

HEAT BIOLOGICS, INC.

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

EXHIBIT 99.1



Heat Biologics Reports Progress on COVID-19 Efforts and Timeline of Anticipated Q2 2020 Milestones

Durham, NC – April 29, 2020 – **Heat Biologics, Inc. ("Heat") (NASDAQ: HTBX)**, a clinical-stage biopharmaceutical company specializing in the development of novel therapeutic and prophylactic vaccines, including one for coronavirus COVID-19 caused by SARS-CoV-2 infection, reported that it continues to advance its COVID-19 vaccine program and provided an outline of its strategy as well as anticipated Q2 2020 milestones for this program.

Heat's gp96 COVID-19 vaccine program is focused on providing prophylactic protection to elderly patients and those with underlying health conditions, the very group of patients with an increased risk of complications and death from COVID-19 infection.

New data suggest that both T-cell (cellular immunity) and antibody (humoral immunity) are required for effective prophylactic protection against COVID-19. Heat's vaccine is being designed to clear virus infected cells by promoting long-term cellular immunity, which is essential for preventing the spread of re-infection in susceptible individuals such as the elderly and other high-risk patients with relevant comorbidities.

Unlike most conventional vaccines that predominantly drive a humoral response, Heat's COVID-19 vaccine platform drives a prominent cellular immune response via CD8+ T cells, in addition to a humoral immune response via a neutralizing IgG antibody. Notably, it was observed that 30% of confirmed COVID-19 patients in China failed to develop high titers of neutralizing antibodies after COVID-19 infection, suggesting a requirement for cellular immunity for recovery. Heat's COVID-19 vaccine targets the Spike or S protein, and expresses gp96 and OX40L, a T cell co-stimulator. OX40L co-stimulation expands CD4+ helper T cells that promote B-cell differentiation and IgG/IgA antibody class switching.

Anticipated Q2 2020 milestones include:

- Completion of development of a cell-based vaccine expressing gp96-Ig, OX40L-Ig and SARS-CoV-2 protein S

- Generation of proof-of-concept data demonstrating vaccine immunogenicity in relevant preclinical models:
    - SARS-CoV-2 protein S specific CD8+ T cells in blood and lungs
    - SARS-CoV-2 protein S specific antibodies in serum
- Submission of grant applications to fund and accelerate COVID-19 vaccine development

Jeff Wolf, Chief Executive Officer of Heat, commented, “We are making progress advancing our COVID-19 vaccine program and remain encouraged by the potential of our platform to provide broad cellular and humoral protection against COVID-19, as well as possible future mutations or other coronaviruses. Specifically, along with our University of Miami collaborators, we are finalizing completion of the vaccine and plan to commence preclinical testing this quarter. These studies will measure the antiviral immune response elicited by SARS-CoV-2 specific antigens in the context of potent immune activators, gp96 and OX40L, in both the blood and lungs of preclinical models. We expect to report our preliminary data shortly thereafter.”

Mr. Wolf continued, “While we are currently funding vaccine development and preclinical studies, we do not expect to use significant corporate resources to advance our COVID-19 vaccine program. We are applying for several large grants to support clinical development of this program and are engaged in collaboration discussions, which we believe may provide attractive and non-dilutive pathways to help accelerate development of our COVID-19 vaccine.”

Heat's gp96 platform has previously undergone rigorous testing in numerous National Institutes of Health (NIH) and U.S. Department of Defense (DOD)-funded mice and primate trials as a vaccine against SIV/HIV, malaria, zika and other infectious diseases. These trials have demonstrated gp96 is a powerful platform with demonstrated antiviral activity in the lungs, as evidenced by a potent immune response and effectiveness in the induction of mucosal immunity in several infectious disease models.

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 continuing to advance its COVID-19 vaccine program, completion of development of a cell-based vaccine expressing gp96-Ig, OX40L-Ig and SARS-CoV-2 protein S during Q2 2020, generation of proof of concept data demonstrating vaccine immunogenicity in relevant preclinical models during Q2 2020, submission of grant applications to fund and accelerate COVID-19 vaccine development during Q2 2020, the potential of the platform to provide broad cellular and humoral protection against COVID-19, as well as possible future mutations or other coronaviruses, plans to commence preclinical testing this quarter and the expected reporting of preliminary data shortly thereafter, and grant funding and collaborations providing attractive and non-dilutive pathways to help accelerate development of our COVID-19 vaccine. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat to complete the development of a cell-based vaccine expressing gp96-Ig, OX40L-Ig and SARS-CoV-2 protein S during Q2 2020, generate proof-of- concept demonstrating vaccine immunogenicity in relevant preclinical models during Q2 2020, submit grant applications to fund and accelerate COVID-19 vaccine development during Q2 2020, commence preclinical testing this quarter and report preliminary data shortly thereafter, the potential of the platform to provide broad cellular and humoral protection against COVID-19, as well as possible future mutations or other coronaviruses, 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, 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