
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): **March 5, 2020**

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)

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 8.01. Other Events.

On March 5, 2020, Heat Biologics, Inc. (the “Company”) issued a press release announcing a strategic collaboration with the University of Miami Miller School of Medicine to support the development of a vaccine leveraging the Company’s proprietary gp96 platform designed to target the *SARS-CoV-2* coronavirus that causes COVID-19.

A copy of the press release is attached as an exhibit to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is being filed as part of this Current Report on Form 8-K.

Exhibit Number	Description
99.1	<u>Press Release of Heat Biologics, Inc. dated March 5, 2020</u>

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: March 5, 2020

HEAT BIOLOGICS, INC.

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

Heat Biologics Announces Research Collaboration with University of Miami to Develop Vaccine Designed to Protect Against COVID-19 Coronavirus

Heat's gp96 vaccine platform activates CD8 T cells, antigen presenting cells and natural killer cells, and induces mucosal immunity which could make it an ideal vaccine for COVID-19

Vaccine designed to induce a multi-epitope specific CD8 T-cell response, which is crucial for protection against potential future mutations of COVID-19

DURHAM, N.C., March 5, 2020 (ACCESSWIRE) -- Heat Biologics, Inc. (Nasdaq:HTBX), a clinical-stage biopharmaceutical company specialized in the development of therapeutic vaccines, announced today a strategic collaboration with the University of Miami Miller School of Medicine to support the development of a vaccine leveraging Heat's proprietary gp96 platform designed to target the *SARS-CoV-2* coronavirus that causes COVID-19.

Clinical and preclinical studies suggest that Heat's gp96-based vaccines may be utilized to target COVID-19. Heat has treated more than 300 patients to date with its gp96-based therapeutic vaccines. Results from these studies together with positive outcomes in NIH and DOD-funded mouse and primate studies against SIV/HIV 1-2, malaria and zika, demonstrate that gp96 vaccines express a broad range of antigens and stimulate a robust systemic immune response, culminating in humoral and cell mediated responses in different organs including the gut, reproductive tract, liver and lungs.

Heat's COVID-19 vaccine will utilize Heat's gp96 platform to generate open docking sites for the insertion of multiple *SARS-CoV-2* antigens. Heat anticipates that its novel approach should activate a potent immune response, without the disadvantages of possible genomic integration of foreign DNA or viral vector instability possible with attenuated viral vaccines. This approach is designed to induce a multi-epitope specific memory CD8 T-cell response that protects against multiple, distinct coronavirus strains across diverse human populations and against potential future mutations of SARS-CoV-2 and other coronavirus.

Heat's COVID-19 program emerged from the same laboratory that originally developed Heat's gp96 platform technology, and will be developed at the University of Miami Miller School of Medicine under the direction of Natasa Strbo, M.D., D.Sc., research assistant professor of microbiology and immunology, who has spent many years advancing the gp96 platform as a vaccine against HIV, malaria, zika and other infectious diseases.

Mucosal immunity and airway memory T-cell responses are crucial in the protection against respiratory viruses such as *SARS-CoV-2*, since these areas are the first to encounter the virus. Importantly, Heat's gp96-based vaccines have demonstrated effectiveness in the induction of mucosal immunity. Dr. Strbo and her team have developed a gp96 vaccine against SIV (the primate equivalent of HIV) that has been shown to induce a dramatic antigen-specific immune response in the mucous membranes. Treated primates (rhesus macaques) were 73 percent less likely to acquire a particularly virulent form of the SIV virus*. These data support broader use of the vaccine platform against other viruses attacking the mucosal tissues, such as COVID-19 (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3594107>).

“T-cell immune responses play a crucial role in protection against coronaviruses and facilitation of coronavirus clearance. It is noteworthy to mention that not antibodies, but only SARS-CoV-specific memory T-cells persisted up to 11 years post-recovery,” said Dr. Strbo. “Therefore, an effective coronavirus vaccine should induce neutralizing antibodies and elicit specific memory CD8 T cell responses. Currently, gp96 is the most efficient agent known to mediate antigen cross-presentation at femto-molar concentrations of antigen. Heat’s gp96 vaccine platform has unique properties that enable it to activate antigen presenting cells, natural killer cells and T cells, which could make it an ideal vaccine for *SARS-CoV-2*.”

Heat’s wholly-owned subsidiary, Zolovax, Inc., will focus on the development of the COVID-19 vaccine. Under the terms of the research collaboration, University of Miami will develop and test one or more vaccine constructs utilizing Heat’s gp-96 vaccine backbone to express antigens associated with COVID-19.

“We are excited about our collaboration with the University of Miami to develop a gp96-based vaccine designed to prevent the spread of COVID-19,” said Jeff Wolf, CEO of Heat. “gp96 is a powerful vaccine platform that has been shown to induce a potent immune response, which may protect against COVID-19 and other highly-virulent infectious diseases. We look forward to advancing this important program”

* Novel vaccination modality provides significant protection against mucosal infection by highly pathogenic SIV, *J Immunol.* 2013 Mar 15; 190(6): 2495–2499.

Additional published studies (Strbo et al 2013 Cutting Edge J Immunol Selinger et al 2014, Vaccari et al Nature Medicine 2016 and 2018) support the feasibility of the gp96-Ig cell secreted-based vaccine platform.

About Heat’s gp96-based therapeutic platform

Heat shock protein gp96 is a chaperone protein found in all human cells. It is a potent immune adjuvant that has the role of “molecular warning system” or more specifically, gp96 has demonstrated a clinical ability to induce immunity against antigens from the cell it came from. gp96 is naturally tethered to the cell and is normally released only during necrosis or cell death.

Heat’s proprietary gp96 vaccine platform reprograms live cells to continually secrete antigens of interest bound to the gp96, thus activating a robust T-cell response against those antigens. Heat’s gp96 platform was developed by Dr. Eckhard Podack at the University of Miami and has undergone rigorous testing in numerous NIH and DOD-funded mice and primate trials as a vaccine against HIV, malaria and other infectious diseases, and has been tested on over 300 patients in numerous NIH and Heat-funded oncology trials.

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 also has numerous pre-clinical programs at various stages of development. For more information, please visit www.heatbio.com.

Forward Looking Statements

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 regarding Heat developing a vaccine designed to protect against COVID-19 coronavirus, Heat's gp96-based vaccines targeting COVID-19, Heat's gp96 platform generating open docking sites for the insertion of multiple SARS-CoV-2 antigens, Heat's gp96 platform activating a potent immune response, without the disadvantages of possible genomic integration of foreign DNA or viral vector instability possible with attenuated viral vaccines, Heat's approach inducing a multi-epitope specific memory CD8 T-cell response that protects against multiple, distinct coronavirus strains across diverse human populations and against potential future mutations of SARS-CoV-2 and other coronavirus, and Heat's gp96 protecting against COVID-19 and other highly-virulent infectious diseases. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's platform to provide protection against COVID-19 coronavirus, and possible future mutations of COVID-19 or other coronaviruses, the ability of the gp96 platform to activate a potent immune response, without the disadvantages of possible genomic integration of foreign DNA or viral vector instability possible with attenuated viral vaccine, the issuance of a patent to Heat for use of Heat's technology platform for treating or preventing infection with the SARS-CoV-2 virus that causes coronavirus disease 2019 (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, 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, 2018 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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