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): **May 11, 2017**

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.)*

801 Capitola Drive
Durham, NC 27713
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 2.02 - Results of Operations and Financial Condition.

On May 11, 2017, Heat Biologics, Inc., a Delaware corporation (the “Registrant") issued a press release that included financial information for the quarter ended March 31, 2017. A copy of the press release is attached as Exhibit 99.1 to this Report on Form 8-K. The information contained in the press release is being furnished to the Securities and Exchange Commission (the “Commission”) and shall not be deemed incorporated by reference into any of the Registrant’s registration statements or other filings with the Commission.

Item 9.01 - Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Heat Biologics, Inc., dated May 11, 2017

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: May 11, 2017

HEAT BIOLOGICS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by Heat Biologics, Inc., dated May 11, 2017

EXHIBIT 99.1

Heat Biologics Provides Business and Clinical Update for the First Quarter of 2017

Heat to double-down on checkpoint combination therapies based on positive interim data of HS-110+PD-1 checkpoint in lung cancer

Acquires Pelican Therapeutics which brings with it a $15.2 million CPRIT grant to fund 70 patient trial, greatly expanding therapeutic reach

DURHAM, NC – May 11, 2017 – Heat Biologics, Inc. ("Heat") (Nasdaq: HTBX), a leader in the development of novel therapies designed to activate a patient's immune system against cancer, today provided a business and clinical update for the first quarter ended March 31, 2017.

During the first quarter, Heat announced a number of major developments. First, it met the safety and efficacy endpoints in its Phase 1b lung cancer trial evaluating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), enabling it to progress to Phase 2 clinical trials. Preliminary data suggests Heat's therapeutic vaccine has the potential to significantly expand the percentage of patients responding to checkpoint inhibitors by increasing T cell activity within the tumor, thereby converting "cold'' tumors into "hot" tumors.

"We are encouraged by these results, showing signs of synergistic efficacy with nivolumab," said Jeff Wolf, Heat's founder and CEO. "Patients with increased levels of tumor infiltrating lymphocytes (TIL) at 10 weeks saw a durable benefit, with 75% (6 out of 8 of these patients) alive at the one-year follow-up point. Additionally, 60% of the patients (3 of the 5 patients) exhibiting low TIL experienced significant tumor reduction, which compares favorably to the 10% response rate of low TIL patients reported for existing data on nivolumab alone."

Researchers reported a strong correlation between T cell activation, tumor reductions and increased overall survival in the 12 of the 15 patients that were evaluable for ELISPOT analysis. Importantly, the timing of immune responses to HS-110 corresponded to the timing of observed clinical responses, and those responses appear to be sustained.

Mr. Wolf continued, "While checkpoint inhibitors have transformed the landscape in the fight against cancer, they are only effective as a monotherapy in a small minority of patients. Our approach has the potential to dramatically increase the response rate in the majority of patients who don't respond to checkpoint therapy alone. As a result of the encouraging data in our checkpoint combination trials and the positive response from within the industry, we are now prioritizing combination therapies, with a particular emphasis on checkpoint inhibitors and T cell co-stimulators. As a result, we are discontinuing programs where we do not see an opportunity to immediately combine with checkpoints, such as our non-muscle invasive bladder cancer program, and will

instead reallocate those resources to fund current and future checkpoint and T cell co-stimulator combination programs."

Heat recently completed the acquisition of Pelican Therapeutics, whose product candidates strengthen its portfolio in the emerging T cell activation space. Pelican's approach has the potential to improve the durability of responses in combination with Heat's vaccine platform, as well as others, by stimulating the production of "memory" CD8+ T cells, as supported by pre-clinical data. This acquisition also brings with it a $15.2 million grant awarded by the Cancer Prevention and Research Institute of Texas (CPRIT) to advance multiple products through preclinical development and at least one program through a 70-patient Phase 1 clinical trial.

"We believe our growing franchise in immuno-oncology and activating cytotoxic T cells places us in a unique position at the core of future combination therapies," Wolf said. "We plan to continue to remain at the forefront in the development of exciting new therapies to activate T cells as part of a broad-based combination approach against cancer."

Heat ended the quarter with over $11 million in cash, and $15 million in non-dilutive grant funding through Pelican.

Recent Developments & First Quarter 2017 Corporate Highlights

- In April 2017, Heat acquired an 80% controlling interest in Pelican Therapeutics, Inc. As of the acquisition date, Pelican is structured as a subsidiary to Heat focused on developing agonists to TNFRSF25, a highly differentiated and potentially "best-in-class" T cell costimulatory receptor. Pelican was the recipient of a highly-competitive $15.2 million New Company Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT), which will enable the Company to advance multiple products through preclinical development and at least one program through a 70-patient Phase 1 clinical trial.

- In April 2017, Heat presented new preclinical data from its collaboration with OncoSec Medical Incorporated at the AACR Annual Meeting. Results suggested that combining *ComPACT* DNA electroporation and cellular vaccination led to increased tumor antigen-specific CD8+ T cells, delayed tumor progression and improved overall survival in preclinical models. The data demonstrated possible synergistic benefits of vaccination plus intratumoral injection.

- In March 2017, Heat reported positive interim results from its Phase 2 clinical trial evaluating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®) for the treatment of non-small cell lung cancer (NSCLC). Fifteen patients had completed the HS-110/nivolumab combination to-date and 12 of these 15 patients were evaluable for ELISPOT analysis. ELISPOT results suggest that HS-110 plays an integral role in tumor reduction and may enhance efficacy of checkpoint inhibitors in lung cancer patients.

- In March 2017, Heat announced that Natasa Strbo, M.D., D.Sc., Research Assistant Professor of Microbiology and Immunology at the University of Miami Miller School of Medicine, received a three-year $981,901 grant from the Florida Department of Health 2016-17 Zika Research Grant Initiative to further develop and test gp96-based Zika vaccine. This vaccine is being developed under a collaboration between the University of Miami and Heat's wholly-owned subsidiary, Zolovax, Inc., which has licensed the intellectual property from the University of Miami.

- In March 2017, Heat announced that it had achieved the safety and efficacy endpoints for its Phase 1b trial evaluating HS-110 in combination with nivolumab for the treatment of NSCLC and that the trial met the expansion criteria to advance into a Phase 2. Five out of 15 patients treated with the HS-110/nivolumab combination had 20% or greater tumor reduction. Patients with increased levels of tumor infiltrating lymphocytes (TIL) at 10 weeks appeared to have a durable benefit, with six out of eight of these patients (75%) alive at the one-year follow-up point.

- In January 2017, Heat announced the appointment of Jeff Hutchins, Ph.D., as its Chief Scientific Officer and Senior Vice President of Preclinical Development. Dr. Hutchins brings over 24 years of research and clinical development experience from both large pharmaceutical and biotechnology companies.

First Quarter 2017 Financial Highlights

- Research and development expenses decreased to approximately $1.9 million in the first quarter of 2017 from $3.7 million in the first quarter of 2016, a decrease of $1.8 million. The decrease is attributable to reductions in clinical trial costs, professional and consulting fees, personnel-related expenses, travel and other costs.

- General and administrative expenses increased to $1.5 million in the first quarter of 2017 from $1.0 million in the first quarter of 2016, an increase of $0.5 million. The increase is attributable to professional services and third-party expenses related to the acquisition of Pelican.

- Net loss for the first quarter of 2017 was $3.2 million compared to a net loss of $4.7 million for the first quarter of 2016.

- Cash and cash equivalents totaled approximately $11.1 million at March 31, 2017 compared to $7.8 million at December 31, 2016. Through the acquisition of Pelican, the Company also has access to a $15.2 million grand from CPRIT, which will enable it to advance multiple products through preclinical development and at least one program through a 70-patient Phase 1 clinical trial.

About Heat Biologics, Inc.
Heat Biologics, Inc. (Nasdaq:HTBX) is an immuno-oncology company developing novel therapies that are designed to activate a patient's immune system against cancer. Heat has generated highly specific T cell-stimulating therapeutic vaccine platform technologies, *ImPACT* and *ComPACT*. These technologies, in combination with other therapies, such as checkpoint inhibitors, are designed to address three distinct but synergistic mechanisms of action: robust activation of CD8+ "killer" T cells (one of the human immune system's most potent weapons against cancer); reversal of tumor-induced immune suppression; and T cell co-stimulation to further enhance patients' immune response. Currently, Heat is conducting a Phase 2 trial with HS-110 (viagenpumatucel-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC).

Most recently, Heat acquired two T cell costimulators through the acquisition of Pelican Therapeutics, a subsidiary to Heat focused on developing agonists to TNFRSF25, a highly differentiated and potentially best-in-class T cell costimulatory receptor. TNFRSF25 has shown great promise due to its preferential specificity for stimulating the production of "memory" CD8+ T cells, the strongest predictive biomarker of clinical benefit from cancer immunotherapy. T cell costimulatory therapy, when combined with checkpoint inhibitors and other treatments, could significantly improve clinical responses for a broader range of patients. Pelican has conducted extensive preclinical studies and completed humanization of its lead monoclonal antibody, PTX-25.

Heat's wholly-owned subsidiary, Zolovax, Inc., is developing therapeutic and preventative vaccines to treat infectious diseases based on Heat's gp96 vaccine technology, with a current focus on the development of a Zika vaccine in conjunction with the University of Miami.

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, expectations and assumptions and include statements regarding preliminary data suggesting that Heat's therapeutic vaccine has the potential to significantly expand the percentage of patients responding to checkpoint inhibitors by increasing T cell activity within the tumor, thereby converting "cold'' tumors into "hot" tumors, Heat's approach having the potential to dramatically increase the response rate in the majority of patients who don't respond to checkpoint inhibitors, TNFRSF25, being a highly differentiated and potentially "best-in-class" T cell costimulatory receptor, T cell costimulatory therapy, when combined with checkpoint inhibitors and other treatments, could significantly improve clinical responses for a broader range of patients, Pelican's approach having the potential to dramatically

improve the durability of responses in combination with Heat's vaccine platform, as well as others, by stimulating the production of "memory" CD8+ T cells, as supported by pre-clinical data, Heat's plan to continue to remain at the forefront in the development of exciting new therapies to activate T cells as part of a broad based combination approach against cancer, Heat's growing franchise in immuno-oncology and activating cytotoxic t-cells placing it in a unique position at the core of future combination therapies, results of the collaboration with OncoSec Medical Incorporated suggesting that the combination of *ComPACT* DNA electroporation and cellular vaccination led to increased tumor antigen-specific CD8+ T cells, delayed tumor progression and improved overall survival in preclinical models and the data demonstrating possible synergistic benefits of vaccination plus intratumoral injection ELISPOT results suggesting that HS-110 plays an integral role in tumor reduction and may enhance efficacy of checkpoint inhibitors in lung cancer patients, and the New Company Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT), enabling Pelican to advance multiple products through preclinical development and at least one program through a 70-patient Phase 1 clinical trial. These statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements, including the ability of Heat's *ImPACT* and *ComPACT* 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, the company's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to the company'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, and its ability to retain its key scientists or management personnel, its ability to successfully integrate Pelican and the other factors described in the company's most recent annual report on Form 10-K and other filings with the SEC. The information in this release is provided only as of the date of this release and the company 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.

Financial Statements

Heat Biologics, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)
(Unaudited)

	Quarter Ended March 31,	
	2017	**2016**
Revenue	$ 24	$ -
Operating expenses:		
Research and development	1,813	3,658
General and administrative	1,527	1,031
Loss from operations	(3,316)	(4,689)
Interest income (expense)	5	(125)
Other income, net	70	80
Net loss	(3,241)	(4,734)
Net loss non-controlling interest	(51)	(175)
Net loss attributable to Heat Biologics, Inc.	**$ (3,190)**	**$ (4,559)**
Net loss per share attributable to Heat Biologics, Inc. - basic and diluted	**$ (0.12)**	**$ (0.50)**
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	**26,957,620**	**9,124,641**

Condensed Consolidated Balance Sheets
(In thousands)
(Unaudited)

	March 31, 2017	**December 31, 2016**
Assets		
Cash and cash equivalents	$ 11,130	$ 7,843
Other assets	888	1,054
Total Assets	**$ 12,018**	**$ 8,897**
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	$ 1,910	$ 2,057
Total Liabilities	1,910	2,057
Common stock	7	5
Additional paid-in-capital	72,442	65,869
Accumulated deficit	(60,195)	(57,005)
Accumulated other comprehensive loss	(139)	(72)
Non-Controlling Interest	(2,007)	(1,957)
Total Liabilities and Stockholders' Equity	**$ 12,018**	**$ 8,897**

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