
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): **November 11, 2017**

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.)

**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 November 13, 2017, Heat Biologics, Inc., a Delaware corporation (the “Company”), issued a press release that included financial information for the quarter ended September 30, 2017. A copy of the press release is attached as Exhibit 99.1 to this Current 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 Company’s registration statements or other filings with the Commission.

Item 8.01 Other Events.

On November 11, 2017, the Company issued a press release that presented updated pre-clinical data evaluating the Company’s Combination Pan-antigen Cytotoxic Therapy (*ComPACT*[™]) platform in combination with a checkpoint inhibitor and T-cell co-stimulators as a potential immunotherapy cocktail approach to treat cancer. Data from the follow-up study build upon previous pre-clinical results utilizing the Company’s *ComPACT* platform, which generated positive synergies with checkpoint inhibitors and the T-cell co-stimulator, OX40.

The press release issued on November 11, 2017 is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
<u>99.1</u>	Press Release issued by Heat Biologics, Inc., dated November 13, 2017
<u>99.2</u>	Press Release issued by Heat Biologics, Inc., dated November 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: November 13, 2017

HEAT BIOLOGICS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
<u>99.1</u>	Press Release issued by Heat Biologics, Inc., dated November 13, 2017
<u>99.2</u>	Press Release issued by Heat Biologics, Inc., dated November 11, 2017



Heat Biologics Reports Third-quarter 2017 Results and Corporate Update

DURHAM, NC – November 13, 2017 – Heat Biologics, Inc. (“Heat”) (Nasdaq: HTBX), a biopharmaceutical company developing drugs designed to activate a patient’s immune system against cancer, reported financial and clinical updates for the third quarter ended September 30, 2017.

“We had a very productive third quarter, as we achieved a number of important milestones,” said Jeff Wolf, CEO of Heat. “We signed a critical manufacturing agreement to further advance our co-stimulatory programs, and we were also granted a Type C meeting with the FDA to review our Phase 2 clinical trial using our HS-110 for the treatment for non-small cell lung cancer.”

Results for the third quarter of 2017 are summarized below.

Third Quarter 2017 Financial Highlights

- Research and development expenses increased eight percent, to approximately \$1.8 million, for the quarter ended September 30, 2017, compared to Q3 2016. The HS-110 program expense increased \$0.4 million primarily due to Chemistry, Manufacturing and Control (CMC) activities, as well as continued patient enrollment for our HS-110 Phase 2, multi-arm trial for non-small cell lung cancer (NSCLC). R&D expenses related to the HS-410 Phase 2 trial decreased \$0.4 million, as currently enrolled patients are now in long-term follow-up for recurrence-free survival. Additional R&D pre-clinical costs were associated with our Zika program, Pelican Therapeutics, Inc. (“Pelican”) T-cell co-stimulatory programs, and laboratory supplies. Unallocated expenses included personnel-related expenses, professional and consulting fees, travel, and other costs. These costs increased approximately \$0.1 million, primarily related to an increase in consultant fees and travel, offset by a decrease in personnel costs.
- General and administrative expenses increased 45 percent, to \$1.2 million, for the quarter ended September 30, 2017, compared to \$0.8 million for the quarter ended September 30, 2016. The \$0.4 million increase was primarily attributable to the increase in personnel costs as we establish Texas operations for our Pelican Therapeutics subsidiary.
- Net loss attributable to Heat for the third quarter of 2017 was \$2.3 million (\$0.06) per basic and diluted share for the third quarter; compared to a net loss of \$1.6 million, or (\$0.08) per basic and diluted share for the quarter ended September 30, 2016.
- Cash and cash equivalents totaled approximately \$4.3 million, as of September 30, 2017. This amount does not include an additional \$6.5 million of CPRIT funds received October 3, 2017.

Third Quarter 2017 Corporate Highlights

- Heat's subsidiary, Pelican Therapeutics, entered into a manufacturing agreement with KBI Biopharma, Inc. to advance its cancer-targeting immunotherapies. Under the agreement, KBI will offer comprehensive development and manufacturing services for cGMP production of Pelican's PTX-35 antibody and PTX-15 fusion protein.
- Heat was granted a Type C meeting with the FDA to discuss its registrational pathway and development plan for its NSCLC trial with HS-110 in combination with Bristol Myers-Squibb's nivolumab (Opdivo®).
- Heat expanded its leadership team with two new hires: Lori McDermott, VP of Clinical Development; and Gary Vinson, VP of CMC.

About Heat Biologics

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer by inducing CD8+ "Killer" T-cells. Our T-Cell Activation Platform (TCAP) produces therapies designed to turn "cold" tumors "hot," and be administered in combination with checkpoint inhibitor therapies and other immuno-modulators to increase their effectiveness. We are currently enrolling patients in our Phase 2 clinical trial for non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®). We also have 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, expectations and assumptions and include statements regarding Heat's advancement of its preclinical programs and the potential benefits to be derived from Heat's and Pelican's product candidates. 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 and Pelican's product candidates 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, and its ability to retain its key scientists or management personnel, its ability to successfully integrate Pelican and the other factors described in Heat'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 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.

Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenue	\$ 471	\$ 220	\$ 906	\$ 220
Operating expenses:				
Research and development	1,824	1,693	5,789	7,127
General and administrative	1,188	821	4,298	2,935
Loss from operations	(3,012)	(2,514)	(10,087)	(10,062)
Interest (expense) income	5	(105)	18	(346)
Other income, net	32	735	109	757
Net loss	(2,504)	(1,664)	(9,054)	(9,431)
Net loss non-controlling interest	(203)	(47)	(344)	(329)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (2,301)</u>	<u>\$ (1,617)</u>	<u>\$ (8,710)</u>	<u>\$ (9,102)</u>
Net loss per share attributable to Heat Biologics, Inc. -basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.08)</u>	<u>\$ (0.27)</u>	<u>\$ (0.59)</u>
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	<u>35,786,606</u>	<u>19,420,026</u>	<u>32,695,360</u>	<u>15,371,267</u>

Condensed Consolidated Balance Sheets
(In thousands)
Unaudited

	September 30, 2017	December 31, 2016
Assets		
Cash and cash equivalents	\$ 4,289	\$ 7,843
Goodwill and In-process R&D	8,055	—
Other assets	2,375	1,054
Total Assets	\$ 14,719	\$ 8,897
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	\$ 3,597	\$ 2,057
Contingent consideration	2,385	—
Deferred tax liability	2,112	—
Total Liabilities	8,094	2,057
Common stock	7	5
Additional paid-in-capital	73,871	65,869
Accumulated deficit	(65,714)	(57,005)
Accumulated other comprehensive loss	(173)	(72)
Non-Controlling Interest	(1,366)	(1,957)
Total Liabilities and Stockholders' Equity	\$ 14,719	\$ 8,897

Contact

For Media and Investor Inquiries

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Heat Biologics Presents Follow-up Data on its *ComPACT*™ T-cell Stimulating Platform at the Society for Immunotherapy of Cancer (SITC) Annual Meeting

Data shows ComPACT therapy improves T-cell priming and enhances rejection of established tumors in pre-clinical models

DURHAM, NC – November 11, 2017 – Heat Biologics, Inc. ("Heat") (Nasdaq: HTBX), a biopharmaceutical company developing drugs designed to activate a patient's immune system against cancer, today presented updated pre-clinical data evaluating its Combination Pan-antigen Cytotoxic Therapy (*ComPACT*™) platform in combination with a checkpoint inhibitor and T-cell co-stimulators as a potential immunotherapy cocktail approach to treat cancer. Data from the follow-up study build upon previous pre-clinical results utilizing Heat's *ComPACT* platform, which generated positive synergies with checkpoint inhibitors and the T-cell co-stimulator, OX40.

The poster presentation, ***Gp96-IG/costimulatory Combination Vaccine Improves T-cell Priming and Enhances Immunity, Memory, and Tumor Elimination***, was presented at the 32nd annual meeting of the Society for Immunotherapy of Cancer (SITC).

The follow-up study was designed to further assess *ComPACT* combined with a checkpoint inhibitor and OX40, but now with the addition of the cell-secreted, T-cell costimulatory, TL1A. *ComPACT* is Heat's next generation, T-cell activation platform (TCAP). It combines T-cell activation and co-stimulation in a single therapy by both delivering the gp96 heat shock protein and a T-cell co-stimulatory fusion proteins in a single compound.

Results in pre-clinical trials show that this combination approach effectively synergizes with antagonist antibody therapies that amplify antigen-specific T-cells; program a memory response; and eliminate tumors. Heat subsidiary Pelican Therapeutics is currently manufacturing a TL1A drug for anticipated human clinical trials that is partially funded through a \$15 million grant provided by the Cancer Prevention Research Institute of Texas (CPRIT).

"Our follow-up study on our *ComPACT* T-cell activation platform provides us with robust data demonstrating a potentially efficacious approach to treating human cancers," said Louis E. Gonzalez, chief scientist at Heat. "The addition of TL1A in combination with OX40 has been found to improve T-cell priming which is an important of any immunotherapy cocktail to treat patients with cancer."

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