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 15, 2018**

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 November 15, 2018, Heat Biologics, Inc., a Delaware corporation (the "Registrant"), issued a press release that included financial information for the quarter ended September 30, 2018. 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 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 November 15, 2018

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 15, 2018

HEAT BIOLOGICS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by Heat Biologics, Inc. dated November 15, 2018

EXHIBIT 99.1

Heat Biologics Reports Third Quarter 2018 Results and Provides Corporate Update

On track to report key clinical milestones beginning in Q4 2018

DURHAM, NC – November 15, 2018 – Heat Biologics, Inc. (Nasdaq: HTBX), a biopharmaceutical company developing therapies designed to activate a patient's immune system against cancer, today reported financial and clinical updates for the third quarter ended September 30, 2018.

Jeff Wolf, Heat's CEO, commented, "We continue to advance our Phase 2 trial investigating our lead candidate HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced non-small cell lung cancer (NSCLC). We intend to announce updates regarding interim Phase 2 data in the fourth quarter of 2018 and plan to complete patient enrollment in Q2 2019. Given the positive interim results we reported earlier this year, which included durable responses to HS-110 in difficult-to-treat low TIL and low PD-L1 patients, we have seen increased interest from within the industry for improving outcomes for those patients least likely to respond to checkpoint inhibitors alone."

"We have completed a Pre-IND Type B meeting with FDA for our next-generation *ComPACT*™ product and plan to file our Phase 1 Investigational New Drug (IND) in the first quarter of 2019. Our *ComPACT*™ therapy combines T-cell activation and co-stimulation within a single treatment, simplifying combination immunotherapy while potentially providing superior immune activation at reduced treatment costs."

"Finally, we are also on track to submit an IND for PTX-35, our novel co-stimulatory antibody designed to harness the body's natural antigen-specific immune activation mechanisms, in the first quarter of 2019. We are encouraged by the preliminary pre-clinical efficacy and safety data which shows a positive toxicity profile across a wide range of doses."

"Importantly, we ended the quarter with a strong cash balance of $21.0 million and expect to receive an additional $6.9 million in CPRIT grant funds for PTX-35 within the next few months. Combined, these funds should provide us with sufficient capital to significantly advance our clinical programs through a number of key milestones, including completion of our Phase 2 trial of HS-110, which holds the potential to drive significant value for shareholders."

Third Quarter 2018 Financial Results

- Recognized $1.8 million of grant revenue for qualified expenditures under the CPRIT grant.
- Research and development expenses increased approximately 144.4% to $4.4 million for the three months ended September 30, 2018 compared to $1.8 million for the three months ended September 30, 2017.
- General and administrative expense increased approximately 33.3% to $1.6 million for the three months ended September 30, 2018 compared to $1.2 million for the three months ended September 30, 2017. The $0.4 million increase consists of professional services/consulting fees associated with our 2018 Annual Meeting of Shareholders as well as an increase in investor relations and new business development fees during the three months ended September 30, 2018.
- Net loss attributable to Heat Biologics was $3.7 million, or ($0.16) per basic and diluted share for the three months ended September 30, 2018 compared to a net loss of $2.3 million, or ($0.64) per basic and diluted share for the three months ended September 30, 2017.
- As of September 30, 2018, the Company had approximately $21.0 million in cash and cash equivalents.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using of 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 inhibitors and other immuno-modulators to increase their effectiveness. HS-110 is our first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient’s own T-cells to attack cancer. Our *ComPACT*™ technology is a dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product. We are currently enrolling patients in our Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb’s nivolumab (Opdivo®). Pelican Therapeutics, a subsidiary of Heat, is focused on the development of co-stimulatory monoclonal antibody and fusion protein-based therapies designed to activate the immune system. 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 the continued advancement of Heat’s Phase 2 trial investigating HS-110 in combination with nivolumab, the completion of enrollment in the Phase 2 trial in Q2 2019, planned announcement of updates regarding interim Phase 2 data in the fourth quarter of 2018, plans to file an IND application for the ComPACT™ trial in the first quarter of 2019, being on track to submit the filing of an IND application for PTX-35 in the first quarter of 2019, the expected receipt of the additional $6.9 million in CPRIT grant funds for PTX-35 within the next few months and Heat’s capital being sufficient to advance our clinical programs through a number of major milestones. 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 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, 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 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.

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(tables follow)

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,	
	2018	2017	2018	2017
Revenue	$ 1,840	$ 471	$ 3,736	$ 906
Operating expenses:				
Research and development	4,404	1,824	10,756	5,789
General and administrative	1,585	1,188	4,727	4,298
Change in fair value of contingent consideration	115	—	666	—
Loss from operations	(4,264)	(2,541)	(12,413)	(9,181)
Interest income	83	5	131	18
Other income, net	32	32	153	109
Net loss before income tax benefit	(4,149)	(2,504)	(12,129)	(9,054)
Income tax benefit	225	—	665	—
Net loss	(3,924)	(2,504)	(11,464)	(9,054)
Net loss non-controlling interest	(265)	(203)	(668)	(344)
Net loss attributable to Heat Biologics, Inc.	**$ (3,659)**	**$ (2,301)**	**$ (10,796)**	**$ (8,710)**
Net loss per share attributable to Heat Biologics, Inc. - basic and diluted	**$ (0.16)**	**$ (0.64)**	**$ (0.75)**	**$ (2.66)**
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	**23,143,952**	**3,578,661**	**14,359,429**	**3,269,536**

Condensed Consolidated Balance Sheets
(In thousands)
Unaudited

	September 30, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 20,962	$ 9,763
Goodwill and In-process R&D	8,055	8,055
Other assets	3,309	2,371
Total Assets	**$ 32,326**	**$ 20,189**
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	$ 5,986	$ 10,497
Contingent consideration	3,275	2,609
Deferred tax liability	637	1,302
Total Liabilities	9,898	14,408
Common stock	5	1
Additional paid-in-capital	104,378	76,382
Accumulated deficit	(79,642)	(68,846)
Accumulated other comprehensive loss	(55)	(166)
Non-Controlling Interest	(2,258)	(1,590)
Total Liabilities and Stockholders' Equity	**$ 32,326**	**$ 20,189**