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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 28, 2019**

**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 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. ☐

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**Item 2.02 Results of Operations and Financial Condition.**

On March 28, 2019, Heat Biologics, Inc., a Delaware corporation (the “Registrant”), issued the attached press release that included financial information for its fiscal year ended December 31, 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	<a href="#">Press Release issued by Heat Biologics, Inc.</a> dated March 28, 2019



## 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 28, 2019

HEAT BIOLOGICS, INC.

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



## EXHIBIT INDEX

Exhibit Number	Description
99.1	<a href="#">Press Release issued by Heat Biologics, Inc.</a> dated March 28, 2019



## Heat Biologics Reports 2018 Results and Provides Corporate Update

*Recently announced interim HS-110 Phase 2 data demonstrating survival benefit in patients with 'cold' tumors (CD8+ TILs < 10% at baseline) who are least likely to respond to checkpoint inhibitors alone*

*Preliminary data suggests the addition of HS-110 to Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor Opdivo® (nivolumab) may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor therapy*

*Company remains on track to complete enrollment of Phase 2 lung cancer trial in Q2 2019 and report additional interim data in Q4 2019*

*Fully funded through completion of HS-110 Phase 2 trial with approximately \$28 million of cash and investments at year end plus an additional \$6.9 million in grant funds expected in Q2 2019*

**DURHAM, NC – March 28, 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 fourth quarter and year ended December 31, 2018.

Jeff Wolf, Heat's CEO, commented, "We are making excellent progress advancing HS-110 and recently reported interim Phase 2 non-small cell lung cancer (NSCLC) data on HS-110 plus nivolumab at the ASCO-SITC Clinical Immuno-Oncology Symposium. Importantly, we observed a survival benefit in patients with low CD8+ "cold" tumors at baseline compared to high CD8+ patients. This Cohort B data was especially encouraging, as all of the enrolled patients had previously experienced disease progression while receiving an immune checkpoint inhibitor. Preliminary data suggest the addition of HS-110 to Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, Opdivo® (nivolumab), may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor therapy. We believe we are the first company to present clinical data in advanced NSCLC with patients whose prior checkpoint inhibitor treatment has failed. The results have generated significant interest within the industry and oncology community."

"We also expanded our Phase 2 trial to dose patients with HS-110 in combination with Merck's anti-PD1 checkpoint inhibitor, KEYTRUDA® (pembrolizumab) with or without ALIMTA® (pemetrexed), in patients receiving front-line maintenance therapy for advanced NSCLC."

"We look forward to filing our Phase 1 Investigational New Drug (IND) for our next-generation therapy (HS-130) in the first half of 2019. HS-130 in combination with HS-110 combines T-cell activation and co-stimulation, potentially providing superior immune activation at reduced treatment costs. Further, we also plan to submit an IND for a CPRIT-funded 70 patient Phase 1 clinical program of PTX-35 in the first half of 2019. PTX-35 is our novel co-stimulatory antibody designed to harness the body's natural antigen-specific T cell immune activation mechanisms. We remain encouraged by the preliminary pre-clinical efficacy and safety data, which show a lack of adverse effects across a wide range of doses."

"We ended 2018 with approximately \$28 million of cash, cash equivalents and short-term investments. We also are on track to receive an additional \$6.9 million in Cancer Prevention Research Institute of Texas (CPRIT) grant funds for PTX-35 in the coming months. As a result, we believe we are well funded beyond completion of our Phase 2 HS-110 trial. As previously disclosed, we have been efficient in our use of funds, which has allowed us to operate under budget, further extending our runway on primarily clinical development programs."

#### **Full Year 2018 Financial Results**

- Recognized \$5.8 million of grant revenue for qualified expenditures under the CPRIT grant.
- Research and development expenses were \$16.2 million for the year ended December 31, 2018 compared to \$8.3 million for the year ended December 31, 2017. The increase was primarily due to the increase enrollment in the Phase 2 portion of our multi-arm NSCLC clinical trial as well as the PTX expense as we continue pre-clinical development of the PTX-35 program.
- General and administrative expenses were \$7.0 million for the year ended December 31, 2018 compared to \$6.4 million for the year ended December 31, 2017.
- Net loss attributable to Heat Biologics was \$15.7 million, or (\$0.90) per basic and diluted share for the year ended December 31, 2018 compared to a net loss of \$11.8 million, or (\$3.08) per basic and diluted share for the year ended December 31, 2017.
- As of December 31, 2018, the Company had approximately \$28 million in cash, cash equivalents and short term investments.

#### **About Heat Biologics, Inc.**

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using 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®) or Merck's anti-PD1 checkpoint inhibitor pembrolizumab (KEYTRUDA®). 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](http://www.heatbio.com).

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## 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 completion of enrollment in the Phase 2 trial in Q2 2019, planned announcement of interim data in the fourth quarter of 2019, the belief that Heat is the first company to present clinical data in advanced NSCLC with patients whose prior checkpoint inhibitor treatment has failed , plans to file a Phase 1 Investigational New Drug (IND) for our next-generation therapy (HS-130) in the first half of 2019 , plans to submit the filing of an IND application for PTX-35 in the first half of 2019, the suggestion that the addition of HS-110 to nivolumab may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor therapy, being on track to receive of an additional \$6.9 million in CPRIT grant funds for PTX-35 within the next few months and Heat’s capital being sufficient beyond completion of its Phase 2 HS-110 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 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.

## Media and Investor Relations Contact

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(tables follow)

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

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Revenue	\$ 5,794	\$ 1,520
Operating expenses:		
Research and development	16,233	8,268
General and administrative	7,025	6,371
Change in fair value of contingent consideration	496	224
Loss from operations	(17,960)	(13,343)
Interest income	266	23
Other income, net	118	101
Net loss before income tax benefit	(17,576)	(13,219)
Income tax benefit	985	809
Net loss	(16,591)	(12,410)
Net loss non-controlling interest	(857)	(568)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (15,734)</u>	<u>\$ (11,842)</u>
Net loss per share attributable to Heat Biologics, Inc.		
- basic and diluted	<u>\$ (0.90)</u>	<u>\$ (3.08)</u>
Weighted-average number of common shares used		
in net loss per share calculation - basic and diluted	<u>17,485,461</u>	<u>3,845,342</u>

**Condensed Consolidated Balance Sheets**  
(In thousands)

	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
Assets		
Cash, cash equivalents and short term investments	\$ 27,724	\$ 9,763
Goodwill and In-process R&D	8,055	8,055
Other assets	1,985	2,371
<b>Total Assets</b>	<u><b>\$ 37,764</b></u>	<u><b>\$ 20,189</b></u>
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	\$ 4,099	\$ 10,497
Contingent consideration	3,105	2,609
Deferred tax liability	317	1,302
Total Liabilities	7,521	14,408
Common stock	7	1
Additional paid-in-capital	114,883	76,382
Accumulated deficit	(84,580)	(68,846)
Accumulated other comprehensive loss	(20)	(166)
Non-Controlling Interest	(47)	(1,590)
<b>Total Liabilities and Stockholders' Equity</b>	<u><b>\$ 37,764</b></u>	<u><b>\$ 20,189</b></u>