

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 15, 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.

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

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

On May 15, 2019, Heat Biologics, Inc., a Delaware corporation (the “Registrant”), issued a press release that included financial information for the quarter ended March 31, 2019. 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.

The following exhibit is filed with this Current Report on Form 8-K:

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Press Release issued by Heat Biologics, Inc.</a> dated May 15, 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: May 15, 2019

HEAT BIOLOGICS, INC.

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

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## EXHIBIT INDEX

Exhibit Number	Description
99.1	<a href="#">Press Release issued by Heat Biologics, Inc.</a> dated May 15, 2019



## Heat Biologics Reports First Quarter 2019 Results and Provides Corporate Update

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

*Anticipates receiving additional \$6.9 million in grant funds after filing PTX-35 IND*

**DURHAM, NC – May 15, 2019** – 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 first quarter ended March 31, 2019.

Jeff Wolf, Heat's CEO, commented, "We are making progress with our Phase 2 clinical trial investigating HS-110 for advanced non-small cell lung cancer (NSCLC) in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, Opdivo® (nivolumab) and Merck's KEYTRUDA® (pembrolizumab). Most notably, we announced positive interim Phase 2 data at the ASCO/SITC Clinical Immuno-Oncology Symposium where we observed a survival benefit in patients with low CD8+ "cold" tumors compared to high CD8+ patients. The Cohort B data was especially encouraging, as the addition of HS-110 to nivolumab may restore anti-tumor activity in patients whose disease has progressed after checkpoint inhibitor therapy."

"We anticipate filing two INDs early this summer: HS-130, the first dual-acting immunotherapy designed to deliver local T-cell activation and co-stimulation, as well as PTX-35, our first-in-class T cell costimulator antibody. We recently presented a poster at the American Association for Cancer Research (AACR) Annual Meeting, in which we reported efficacy in a mouse model, demonstrating that the combination of HS-110 with OX40L co-stimulation has the potential to dramatically enhance anti-tumor immune responses via the activation and expansion of CD8+, tumor antigen-specific, T effector cells. We also remain encouraged by the preliminary pre-clinical efficacy and safety data of PTX-35, which show activity with a favorable safety profile across a wide range of doses."

"We ended the quarter with approximately \$23.5 million of cash, cash equivalents and short-term investments. We expect to receive an additional \$6.9 million in grant funds from Cancer Prevention Research Institute of Texas (CPRIT) after filing our IND for PTX-35."

### First Quarter 2019 Financial Results

- Recognized \$0.7 million of grant revenue for qualified expenditures under the CPRIT grant.
  - Research and development expenses increased to \$3.2 million for the quarter ended March 31, 2019 compared to \$2.9 million for the quarter ended March 31, 2018. The \$0.3 million increase is due to the increased enrollment in the Phase 2 portion of our multi-arm NSCLC clinical trial, stock-based compensation, and the PTX expense as we continue pre-clinical development of the PTX-35 program.
  - General and administrative expenses were approximately \$3.3 million for the quarter ended March 31, 2019 compared to \$1.8 million for the quarter ended March 31, 2018. The \$1.6 million increase is primarily attributable to increased stock-based compensation expense.
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- Net loss attributable to Heat Biologics was approximately \$5.7 million, or (\$0.17) per basic and diluted share for the quarter ended March 31, 2019 compared to a net loss of approximately \$3.3 million, or (\$0.71) per basic and diluted share for the quarter ended March 31, 2018.
- As of March 31, 2019, the Company had approximately \$23.5 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*<sup>™</sup> 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).

#### **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 such as the addition of HS-110 to nivolumab may restore anti-tumor activity in patients whose disease has progressed after checkpoint inhibitor therapy, completion of enrollment in the Phase 2 trial later in the quarter and releasing data later in the year, the anticipated filing of two INDs early this summer, HS-130 being the first potential dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product; the combination of HS-110 with OX40L co-stimulation having the potential to dramatically enhance anti-tumor immune responses, and the expected receipt of an additional \$6.9 million in grant funds from Cancer Prevention Research Institute of Texas (CPRIT) after filing our IND for PTX-35. 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, its ability to retain its key scientists or management personnel, and the other factors described in Heat's Annual Report on Form 10-K and 10-K/A for the year ended December 31, 2018 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.**  
**Consolidated Balance Sheets**

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
	<u>(unaudited)</u>	
<b>Current Assets</b>		
Cash and cash equivalents	\$ 17,896,821	\$ 22,154,251
Short-term investments	5,611,538	5,570,027
Accounts receivable	79,047	28,538
Prepaid expenses and other current assets	818,662	961,317
<b>Total Current Assets</b>	<u>24,406,068</u>	<u>28,714,133</u>
<b>Property and Equipment, net</b>	<u>621,419</u>	<u>643,146</u>
<b>Other Assets</b>		
In-process R&D	5,866,000	5,866,000
Goodwill	2,189,338	2,189,338
Right-of-use asset	463,910	—
Deposits	351,220	351,220
<b>Total Other Assets</b>	<u>8,870,468</u>	<u>8,406,558</u>
<b>Total Assets</b>	<u>\$ 33,897,955</u>	<u>\$ 37,763,837</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 1,618,812	\$ 974,619
Deferred revenue	340,627	1,032,539
Contingent consideration, current portion	1,209,000	1,187,000
Operating lease liability, current portion	166,142	—
Accrued expenses and other liabilities	948,906	1,678,051
<b>Total Current Liabilities</b>	<u>4,283,487</u>	<u>4,872,209</u>
<b>Long Term Liabilities</b>		
Contingent consideration, net of current portion	2,010,515	1,918,225
Deferred tax liability	361,911	316,733
Deferred revenue, net of current portion	200,000	200,000
Operating lease liability, net of current portion	304,997	—
Other long-term liabilities	261,065	213,724
<b>Total Liabilities</b>	<u>7,421,975</u>	<u>7,520,891</u>
<b>Commitments and Contingencies</b>		
<b>Stockholders' Equity</b>		
Common stock, \$.0002 par value; 100,000,000 shares authorized, 34,093,067 and 32,492,144 shares issued and outstanding at March 31, 2019 (unaudited) and December 31, 2018, respectively	6,819	6,499
Additional paid-in capital	116,943,119	114,883,135
Accumulated deficit	(90,295,656)	(84,580,180)
Accumulated other comprehensive loss	(28,093)	(19,904)
<b>Total Stockholders' Equity— Heat Biologics, Inc.</b>	<u>26,626,189</u>	<u>30,289,550</u>
<b>Non-Controlling Interest</b>	<u>(150,209)</u>	<u>(46,604)</u>
<b>Total Stockholders' Equity</b>	<u>26,475,980</u>	<u>30,242,946</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 33,897,955</u>	<u>\$ 37,763,837</u>

**HEAT BIOLOGICS, INC.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(Unaudited)

	Three Months Ended, March 31,	
	2019	2018
Revenue:		
Grant and licensing revenue	\$ 701,062	\$ 752,527
Operating expenses:		
Research and development	3,172,247	2,872,950
General and administrative	3,347,601	1,780,339
Change in fair value of contingent consideration	114,290	11,118
Total operating expenses	<u>6,634,138</u>	<u>4,664,407</u>
Loss from operations	<u>(5,933,076)</u>	<u>(3,911,880)</u>
Interest income	150,852	3,633
Other income, net	8,321	175,020
Total non-operating income, net	<u>159,173</u>	<u>178,653</u>
Net loss before income taxes	(5,773,903)	(3,733,227)
Income tax expense (benefit)	45,178	(205,000)
Net loss	<u>(5,819,081)</u>	<u>(3,528,227)</u>
Net loss – non-controlling interest	(103,605)	(206,461)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (5,715,476)</u>	<u>\$ (3,321,766)</u>
Net loss per share attributable to Heat Biologics, Inc.—basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.71)</u>
Weighted-average number of common shares used in net loss per share attributable to common stockholders—basic and diluted	33,225,164	4,709,553
Other comprehensive loss:		
Net loss	(5,819,081)	(3,528,227)
Unrealized (loss) gain on foreign currency translation	(8,189)	21,325
Total other comprehensive loss	<u>(5,827,270)</u>	<u>(3,506,902)</u>
Comprehensive loss attributable to non-controlling interest	(103,605)	(206,461)
Comprehensive loss	<u>\$ (5,723,665)</u>	<u>\$ (3,300,441)</u>