

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): **August 14, 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))

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

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.

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2019, Heat Biologics, Inc., a Delaware corporation (the “Registrant”) issued a press release that included financial information for its quarter ended June 30, 2019. 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.

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

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued by Heat Biologics, Inc. , dated August 14, 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: August 14, 2019

HEAT BIOLOGICS, INC.

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

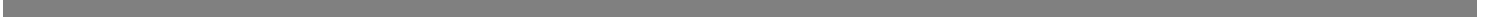


EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued by Heat Biologics, Inc. , dated August 14, 2019



**Heat Biologics Reports Second Quarter 2019 Results
and Provides Corporate Update**

*Completed enrollment of Phase 2 non-small cell lung cancer trial;
on track to report top line data later this year*

Received FDA clearance of IND application for Phase 1 trial of HS-130 in combination with HS-110 for patients with advanced solid tumors refractory to standard of care

DURHAM, NC – August 14, 2019 – Heat Biologics, Inc. (Nasdaq: HTBX), a biopharmaceutical company developing therapeutics designed to activate a patient’s immune system against cancer, today reported financial and clinical updates for the second quarter ended June 30, 2019.

Jeff Wolf, Heat's CEO, commented, “We recently announced that we completed recruitment for 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) or with Merck’s KEYTRUDA® (pembrolizumab) with approximately 120 patients enrolled in the trial. Importantly, we reported promising interim results from the study showing that the addition of HS-110 to nivolumab may restore anti-tumor activity in patients whose disease has progressed after checkpoint inhibitor therapy. Our data showing tumor shrinkage in 35% of patients and disease control in 55% of patients whose disease has progressed after treatment with a checkpoint inhibitor (CPI) supports our mechanistic hypothesis that the broad, T-cell mediated immune response activated by HS-110 may reestablish positive clinical outcomes for patients who have lost the benefit of treatment with a CPI. We are encouraged by the positive results and look forward to reporting additional data later this year.”

“Earlier this week, we announced that the FDA has cleared our Investigational New Drug (IND) application to initiate a Phase 1 clinical trial of HS-130, in combination with HS-110, for patients with advanced solid tumors refractory to standard of care. Up to 30 patients are expected to be enrolled in the trial. HS-130 is the first allogeneic, “off-the-shelf” cell line engineered to express the extracellular domain of OX40 ligand fusion protein (OX40L-Fc), a key costimulator of T cells, with the potential to augment antigen-specific CD8+ T cell response.”

“We ended the quarter with approximately \$19.5 million of cash, cash equivalents and short-term investments. These funds combined with an additional \$6.9 million in grant funds from Cancer Prevention Research Institute of Texas (CPRIT) that we expect to receive after filing our IND for PTX-35 should provide us sufficient capital to fund Heat through our HS-110 data release, as well as other clinical programs.”

Second Quarter 2019 Financial Results

- Recognized \$0.3 million of grant revenue for qualified expenditures under the CPRIT grant.
- Research and development expenses decreased approximately 2% to \$3.4 million for the quarter ended June 30, 2019 compared to \$3.5 million for the quarter ended June 30, 2018. The decrease of approximately \$56,000 is due to the lower PTX-35 expense for 2019, primarily reflecting decreased manufacturing costs, offset by the increased enrollment in the Phase 2 portion of our multi-arm NSCLC clinical trial and stock-based compensation.
- General and administrative expense increased approximately 37% to \$1.9 million for the quarter ended June 30, 2019 compared to \$1.4 million for the quarter ended June 30, 2018. The \$0.5 million increase is primarily attributable to increased personnel costs, including stock-based compensation expense.
- Net loss attributable to Heat Biologics was approximately \$4.8 million, or (\$0.14) per basic and diluted share for the quarter ended June 30, 2019 compared to a net loss of approximately \$3.8 million, or (\$0.26) per basic and diluted share for the quarter ended June 30, 2018.
- As of June 30, 2019, the Company had approximately \$19.5 million in cash, cash equivalents and short investments with an additional \$6.9 million in grant funds from Cancer Prevention Research Institute of Texas (CPRIT) that it expects to receive after filing our IND for PTX-35.

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 therapies 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 the first potential, dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product. We have reached the enrollment targets in our Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®) or with Merck's pembrolizumab (Keytruda®), and expect to report additional results before the end of 2019. 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 such as: *being on track to report additional interim data later this year from the Phase 2 non-small cell lung cancer trial; the addition of HS-110 to nivolumab may restore anti-tumor activity in patients whose disease has progressed after checkpoint inhibitor therapy; the broad, T-cell mediated immune response activated by HS-110 may reestablish positive clinical outcomes for patients who have lost the benefit of treatment with a CPI; the expected size of the Phase 1 clinical trial of Hs-130 in combination with HS-110, for patients with advanced solid tumors refractory to standard of care; the potential of HS-130 to augment antigen-specific CD8+ T cell response; the approximately \$19.5 million of cash, cash equivalents and short-term investments combined with an additional \$6.9 million in grant funds from CPRIT should provide Heat sufficient capital to fund Heat through its HS-110 data release; as well as additional data for our other clinical programs; and the expected receipt of an additional \$6.9 million in grant funds from CPRIT after filing the 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 subsequent 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)

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

	Three Months Ended, June 30,		Six Months Ended, June 30,	
	2019	2018	2019	2018
Revenue:				
Grant and licensing revenue	\$ 342,487	\$ 1,143,177	\$ 1,043,549	\$ 1,895,704
Operating expenses:				
Research and development	3,424,141	3,479,776	6,596,388	6,352,726
General and administrative	1,860,459	1,361,166	5,208,060	3,141,505
Change in fair value of contingent consideration	112,000	539,980	226,290	551,098
Total operating expenses	<u>5,396,600</u>	<u>5,380,922</u>	<u>12,030,738</u>	<u>10,045,329</u>
Loss from operations	<u>(5,054,113)</u>	<u>(4,237,745)</u>	<u>(10,987,189)</u>	<u>(8,149,625)</u>
Interest income	124,793	44,164	275,645	47,797
Other (expense) income, net	(15,585)	(53,224)	(7,264)	121,796
Total non-operating income (expenses), net	<u>109,208</u>	<u>(9,060)</u>	<u>268,381</u>	<u>169,593</u>
Net loss before income taxes	(4,944,905)	(4,246,805)	(10,718,808)	(7,980,032)
Income tax expense (benefit)	—	(235,000)	45,178	(440,000)
Net loss	(4,944,905)	(4,011,805)	(10,763,986)	(7,540,032)
Net loss – non-controlling interest	(174,035)	(196,734)	(277,640)	(403,195)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (4,770,870)</u>	<u>\$ (3,815,071)</u>	<u>\$ (10,486,346)</u>	<u>\$ (7,136,837)</u>
Net loss per share attributable to Heat Biologics, Inc.—basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.26)</u>	<u>\$ (0.32)</u>	<u>\$ (0.72)</u>
Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc.—basic and diluted	33,255,724	14,727,682	33,240,529	9,894,367
Other comprehensive loss:				
Net loss	(4,944,905)	(4,011,805)	(10,763,986)	(7,540,032)
Unrealized gain (loss) on foreign currency translation	16,612	49,946	8,423	71,271
Total other comprehensive loss	<u>(4,928,293)</u>	<u>(3,961,859)</u>	<u>(10,755,563)</u>	<u>(7,468,761)</u>
Comprehensive loss attributable to non-controlling interest	<u>(174,035)</u>	<u>(196,734)</u>	<u>(277,640)</u>	<u>(403,195)</u>
Comprehensive loss	<u>\$ (4,754,258)</u>	<u>\$ (3,765,125)</u>	<u>\$ (10,477,923)</u>	<u>\$ (7,065,566)</u>

HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	June 30, 2019 (unaudited)	December 31, 2018
Current Assets		
Cash and cash equivalents	\$ 13,828,206	\$ 22,154,251
Short-term investments	5,648,609	5,570,027
Accounts receivable	77,382	28,538
Prepaid expenses and other current assets	684,169	961,317
Total Current Assets	<u>20,238,366</u>	<u>28,714,133</u>
Property and Equipment, net	<u>566,593</u>	<u>643,146</u>
Other Assets		
In-process R&D	5,866,000	5,866,000
Goodwill	2,189,338	2,189,338
Right-of-use asset	406,178	—
Deposits	436,283	351,220
Total Other Assets	<u>8,897,799</u>	<u>8,406,558</u>
Total Assets	<u>\$ 29,702,758</u>	<u>\$ 37,763,837</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 1,979,090	\$ 974,619
Deferred revenue	—	1,032,539
Contingent consideration, current portion	1,222,000	1,187,000
Operating lease liability, current portion	129,205	—
Accrued expenses and other liabilities	1,169,609	1,678,051
Total Current Liabilities	<u>4,499,904</u>	<u>4,872,209</u>
Long Term Liabilities		
Contingent consideration	2,109,515	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	282,353	—
Other long-term liabilities	293,582	213,724
Total Liabilities	<u>7,747,265</u>	<u>7,520,891</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock, \$.0002 par value; 100,000,000 shares authorized, 34,066,652 and 32,492,144 shares issued and outstanding at June 30, 2019 (unaudited) and December 31, 2018, respectively	6,822	6,499
Additional paid-in capital	117,350,922	114,883,135
Accumulated deficit	(95,066,526)	(84,580,180)
Accumulated other comprehensive loss	(11,481)	(19,904)
Total Stockholders' Equity— Heat Biologics, Inc.	<u>22,279,737</u>	<u>30,289,550</u>
Non-Controlling Interest	<u>(324,244)</u>	<u>(46,604)</u>
Total Stockholders' Equity	<u>21,955,493</u>	<u>30,242,946</u>
Total Liabilities and Stockholders' Equity	<u>\$ 29,702,758</u>	<u>\$ 37,763,837</u>