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Heat Biologics Reports Third Quarter 2019 Results and Provides Corporate Update

Reported Positive Phase 2 Interim Data in Advanced Non-Small Cell Lung Cancer Patients

MORRISVILLE, NC / ACCESSWIRE / November 15, 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 third quarter ended September 30, 2019.

Jeff Wolf, Heat's CEO, commented, "We remain encouraged by the positive top line data from our Phase 2 trial for HS-110 in advanced non-small cell lung cancer (NSCLC) in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, Opdivo® (nivolumab) and with Merck's anti-PD-1 checkpoint inhibitor Keytruda® (pembrolizumab), which completed enrollment in July 2019. We recently presented a subset of this data in a poster presentation at The Society of Immunotherapy of Cancer's (SITC) 34th Annual Meeting, in which we reported that 61% of patients in our Phase 2 Cohort B achieved disease stabilization per iRECIST, a patient population whose disease had progressed following prior checkpoint inhibitor therapy. Based on this data, we look forward to advancing our clinical trials and intend to aggressively explore all options for the future development of HS-110, including possible collaboration and licensing opportunities."

"We ended the quarter with approximately $15.0 million in cash, cash equivalents and short-term investments. We believe we are well funded to advance our clinical activities though additional major milestones and continue to manage expenses accordingly."

Third Quarter 2019 Financial Results

- Research and development expenses decreased to $3.1 million for the quarter ended September 30, 2019 compared to $4.4 million for the quarter ended September 30, 2018. The decrease of approximately $1.3 million is due to the lower PTX-35 expense for 2019, primarily reflecting decreased manufacturing costs, offset by increased Phase 2 trial expenses, including outsourced clinical trial support services and payments to investigator sites.
- General and administrative expense increased to $2.0 million for the quarter ended September 30, 2019 compared to $1.6 million for the quarter ended September 30, 2018. The $0.4 million increase is primarily attributable to increased personnel costs, including stock-based compensation expense.

- Net loss attributable to Heat Biologics was approximately $6.2 million, or ($0.18) per basic and diluted share for the quarter ended September 30, 2019 compared to a net loss of approximately $3.7 million, or ($0.16) per basic and diluted share for the quarter ended September 30, 2018.
- As of September 30, 2019, the Company had approximately $15.0 million in cash, cash equivalents and short-term 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 an 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 CD8+ "Killer" T-cells. HS-110 is the Company's first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells to attack cancer. Heat has completed enrollment in its 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®). 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. Heat also has 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: looking forward to advancing Heat's clinical trials, the intention to aggressively explore all options for the future development of HS-110, including possible collaboration and licensing opportunities, being well funded to advance Heat's clinical activities through additional major milestones and continuing to manage expenses accordingly, 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.

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(tables follow)

Consolidated Balance Sheets

	September 30, 2019 (unaudited)	December 31, 2018
Current Assets		
Cash and cash equivalents	$ 9,334,421	$ 22,154,251
Short-term investments	5,683,446	5,570,027
Accounts receivable	37,300	28,538
Prepaid expenses and other current assets	734,788	961,317
Total Current Assets	15,789,955	28,714,133
Property and Equipment, net	609,916	643,146
Other Assets		
In-process R&D	5,866,000	5,866,000
Goodwill	1,452,338	2,189,338
Right-of-use asset	347,153	-
Deposits	386,284	351,220
Total Other Assets	8,051,775	8,406,558
Total Assets	$ 24,451,646	$ 37,763,837
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 1,944,333	$ 974,619
Deferred revenue	-	1,032,539
Contingent consideration, current portion	1,477,000	1,187,000
Operating lease liability, current portion	91,068	-
Accrued expenses and other liabilities	1,281,911	1,678,051
Total Current Liabilities	4,794,312	4,872,209
Long Term Liabilities		
Contingent consideration	2,356,515	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	259,222	-
Other long-term liabilities	306,235	213,724
Total Liabilities	8,278,195	7,520,891
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $.0002 par value; 100,000,000 shares authorized, 33,334,124 and 32,492,144 shares issued and outstanding at September 30, 2019 (unaudited) and December 31, 2018, respectively	6,822	6,499
Additional paid-in capital	117,836,082	114,883,135
Accumulated deficit	(101,261,124)	(84,580,180)
Accumulated other comprehensive loss	52,230	(19,904)
Total Stockholders' Equity- Heat Biologics, Inc.	16,634,010	30,289,550
Non-Controlling Interest	(460,559)	(46,604)
Total Stockholders' Equity	16,173,451	30,242,946
Total Liabilities and Stockholders' Equity	$ 24,451,646	$ 37,763,837

Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended, September 30,		Nine months Ended, September 30,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Grant and licensing revenue	$ 6,439	$ 1,840,009	$ 1,049,988	$ 3,735,713
Operating expenses:				
Research and development	3,129,356	4,403,759	9,725,744	10,756,485
General and administrative	1,993,136	1,585,600	7,201,196	4,727,105
Goodwill impairment loss	737,000	-	737,000	-
Change in fair value of contingent consideration	502,000	114,838	728,290	665,936
Total operating expenses	6,361,492	6,104,197	18,392,230	16,149,526
Loss from operations	(6,355,053)	(4,264,188)	(17,342,242)	(12,413,813)
Interest income	97,415	83,509	373,060	131,306
Other (expense) income, net	(73,275)	31,704	(80,539)	153,500
Total non-operating income	24,140	115,213	292,521	284,806
Net loss before income taxes	(6,330,913)	(4,148,975)	(17,049,721)	(12,129,007)
Income tax benefit (expense)	-	225,389	(45,178)	665,080
Net loss	(6,330,913)	(3,923,586)	(17,094,899)	(11,463,927)
Net loss - non-controlling interest	(136,315)	(265,024)	(413,955)	(668,219)
Net loss attributable to Heat Biologics, Inc.	$ (6,194,598)	$ (3,658,562)	$ (16,680,944)	$ (10,795,708)

Net loss per share attributable to Heat Biologics, Inc.-basic and diluted	$ (0.18)	$ (0.16)	$ (0.50)	$ (0.75)
Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc.-basic and diluted	33,650,829	23,143,952	33,255,535	14,359,429
Other comprehensive loss:				
Net loss	$ (6,330,913)	$ (3,923,586)	$ (17,094,899)	$ (11,463,927)
Unrealized gain on foreign currency translation	63,711	39,377	72,134	110,648
Total other comprehensive loss	(6,267,202)	(3,884,209)	(17,022,765)	(11,353,279)
Comprehensive loss attributable to non-controlling interest	(136,315)	(265,024)	(413,955)	(668,219)
Comprehensive loss	$ (6,130,887)	$ (3,619,185)	$ (16,608,810)	$ (10,685,060)

SOURCE: Heat Biologics, Inc.

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https://www.accesswire.com/566707/Heat-Biologics-Reports-Third-Quarter-2019-Results-and-Provides-Corporate-Update