November 10, 2016

Heat Biologics Provides Corporate Update and Reports Third Quarter 2016 Financial Results

Remains on Track to Report Multiple Topline Data Readouts this Quarter

DURHAM, N.C., Nov. 10, 2016 (GLOBE NEWSWIRE) -- Heat Biologics, Inc. (“Heat”) (Nasdaq:HTBX), an immuno-oncology company developing novel therapies that activate a patient’s immune system against cancer, reported its financial results and provided a general business update for the third quarter and nine months ended September 30, 2016.

“We look forward to reporting top-line data in both our bladder and lung cancer trials within the next few weeks,” commented Jeff Wolf, Heat’s Founder and CEO. “Our results come on the heels of encouraging interim study findings from our Phase 1b trial evaluating HS-110 in combination with the Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor, nivolumab. Our data in lung cancer suggest HS-110 may improve response rates for patients with ‘cold tumors’ who typically have lower response rates to checkpoint inhibitor monotherapy. We are also encouraged by our early data in bladder cancer that suggest we are activating a robust antigen-specific immune response.

“Moreover, we are pleased to announce the expansion of our gp96 platform into the infectious disease arena. We recently formed a new subsidiary, Zolovax, which will focus exclusively on developing gp96-based vaccines for Zika and other infectious diseases, such as HIV, West Nile, dengue and yellow fever. Preclinical studies suggest that our gp96 platform may have a role as a broad-based infectious disease vaccine. Importantly, in the case of Zika, the robust mucosal immune response generated by gp96 in ongoing oncology studies may suggest that a gp96 vaccine could also stimulate a Zika-specific immune response in the placenta, thus protecting the fetus from virus transmission.

“During the third quarter, we strengthened our balance sheet and benefitted from the exercise of warrants and substantial pay down of our existing debt. I am pleased to report we ended the quarter with approximately $8.5 million of cash on hand. This year through November 10, 2016, we have generated over $3.1 million in cash from the exercise of our March 23, 2016 warrants. Meanwhile, we continue to carefully manage our expenses as we await important top-line data this quarter.”

Recent Developments & Third Quarter 2016 Corporate Highlights

- In late October, Heat announced that it entered into an agreement with the University of Miami for the license and development of a portfolio of patents leveraging its gp96 platform to target the Zika virus and other infectious diseases including HIV, West Nile, dengue and yellow fever.

- In October, Heat announced that it has advanced its biomarker discovery collaboration with Adaptive Biotechnologies. Adaptive will use its patented immune profiling assay, immunoSEQ™, to enable an in-depth characterization of the immune response to Heat's *ImPACT* and *ComPACT*-based immunotherapies, including HS-410, Heat's Phase 2 product candidate for non-muscle invasive bladder cancer.
- In September, Heat announced that it had resumed enrollment in its Phase 1b trial evaluating HS-110 in combination with nivolumab (Opdivo®), a Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor, for the treatment of non-small cell lung cancer (NSCLC). The decision to resume trial enrollment was based on the encouraging data reported in June, including two clinical responses in "cold tumor" patients. There are currently 15 patients enrolled and the Company expects to report topline 6-month data on the first eight of these patients before year end.
- In July, Heat announced that preclinical findings from its *ComPACT* platform technology were published online in the journal "Cancer Immunology Research." Heat demonstrated that its *ComPACT* technology secreting the co-stimulator OX40L enhanced tumor rejection in two cancer tumor types compared to OX40 agonist antibody treatment. Heat also reported that *ComPACT*-enhanced antigen-specific T cell infiltration into tumors improved memory T cell responses and demonstrated greater specificity than OX40 agonist antibody treatments.

Third Quarter 2016 Financial Highlights

- Research and development (R&D) expenses decreased to approximately $0.6 million in the third quarter of 2016 compared to approximately $0.7 million in the third quarter of 2015, a decrease of approximately $0.1 million. The decrease is primarily attributable to reductions in consultant fees and a decrease in compensation costs attributable to deferral of salary as part of our cost-savings plan.
- Clinical and regulatory expenses decreased to approximately $1.1 million in the third quarter of 2016 compared to approximately $3.7 million in the third quarter of 2015, a decrease of approximately $2.6 million. The decrease is primarily attributable to reductions in clinical trial execution costs.
- General and administrative (G&A) expenses decreased to approximately $0.8 million in the third quarter of 2016 compared to approximately $0.9 million in the third quarter of 2015, a decrease of $0.1 million. The decrease is attributable to a reduction in compensation costs and work force reductions as part of the cost-savings plan.
- Net loss for the third quarter of 2016 was $1.7 million compared to a net loss of $5.4 million for the third quarter of 2015.

Nine Months Ended September 30, 2016 Financial Highlights

- R&D expenses decreased to approximately $1.5 million for the nine months ended September 30, 2016 compared to approximately $1.8 million for the nine months ended September 30, 2015, a decrease of approximately $0.3 million. The decrease is attributable to reductions in patent, license and other professional fees, as well as a decrease in consultant expense and a decrease in compensation costs attributable to deferral in salary as part of our cost-savings initiatives.
- Clinical and regulatory expenses decreased to approximately $5.6 million for the nine months ended September 30, 2016 compared to approximately $9.2 million for the nine months ended September 30, 2015, a decrease of approximately $3.6 million.

The decrease is primarily attributable to reductions in clinical trial execution expenses.

- G&A expenses decreased to approximately $2.9 million for the nine months ended September 30, 2016 compared to approximately $3.1 million for the nine months ended September 30, 2015, a decrease of approximately $0.2 million. The decrease is primarily attributable to a decrease in compensation costs attributable to deferral of salary and work force reductions as part of our cost-savings plan.
- Net loss for the nine months ended September 30, 2016 was $9.4 million compared to a net loss of $14.4 million for the nine months ended September 30, 2015.
- Cash and cash equivalents totaled approximately $8.5 million at September 30, 2016 compared to cash, cash equivalents and short-term investments which totaled approximately $11.6 million at December 31, 2015.

About Heat Biologics, Inc.

Heat Biologics, Inc. (NASDAQ:HTBX) is an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer. Heat's highly specific T cell-stimulating platform technologies, *ImPACT* and *ComPACT*, form the basis of its product candidates. These platforms, in combination with other therapies, such as checkpoint inhibitors, are designed to address three distinct but synergistic mechanisms of action: robust activation of CD8+ "killer" T cells (one of the human immune system's most potent weapons against cancer); reversal of tumor-induced immune suppression; and T cell co-stimulation to further enhance patients' immune response. Currently, Heat is conducting a Phase 2 trial with its HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC) and a Phase 1b trial with its HS-110 (viagenpumatucel-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC). For more information, please visit www.heatbio.com.

Forward Looking Statements

This press release includes forward-looking statements 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 anticipated data readout in the fourth quarter of 2016 for Heat's lead Phase 2 program evaluating HS-410 for the treatment of NMIBC, and its Phase 1b program evaluating HS-110 for the treatment of NSCLC, data in lung cancer suggesting that HS-110 may improve response rates for patients with 'cold tumors', the early data suggesting that we are activating a robust antigen-specific immune response, the suggestion that our gp96 platform may have a role as a broad-based infectious disease vaccine, the suggestion that a gp96 vaccine could also stimulate a Zika-specific immune response in the placenta, thus protecting the fetus from virus transmission, the biomarker identification opportunity with the ImmunoSEQ Assay when used to evaluate the mechanism of action of the *ImPACT* platform, and the potential of Heat's *ImPACT* and *ComPACT* therapies. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's *ImPACT* and *ComPACT* therapies to perform as designed, the ability to enroll patients and complete the clinical trials on time, the other factors described in our annual report on Form 10-K for the year ended December 31, 2015 and our other filings with the SEC. The information in this release is provided only as of the date of this release, and we undertake 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.

Financial Statements

Heat Biologics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	$ 220,233	$ –	$ 220,233	$ –
Operating expenses:				
Research and development	559,177	677,151	1,514,257	1,767,942
Clinical and regulatory	1,133,956	3,718,902	5,613,209	9,261,529
General and administrative	820,574	947,392	2,935,030	3,150,394
Loss from operations	(2,293,474)	(5,343,445)	(9,842,263)	(14,179,865)
Interest expense, net	(105,023)	(88,713)	(346,022)	(207,369)
Other income, net	734,509	4,449	757,044	29,909
Net loss	(1,663,988)	(5,427,709)	(9,431,241)	(14,357,325)
Net loss non-controlling interest	(47,042)	(242,244)	(329,471)	(549,190)
Net loss attributable to Heat Biologics, Inc.	**$ (1,616,946)**	**$ (5,185,465)**	**$ (9,101,770)**	**$ (13,808,135)**
Net loss per share attributable to Heat Biologics, Inc. -basic and diluted	**$ (0.08)**	**$ (0.62)**	**$ (0.59)**	**$ (1.75)**
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	**19,420,026**	**8,408,376**	**15,371,267**	**7,880,637**

Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2016	December 31, 2015
Assets		
Cash, cash equivalents, and short term investments	$ 8,464,635	$ 11,629,598
Other assets	1,327,682	1,565,457
Total Assets	**$ 9,792,317**	**$ 13,195,055**
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	$ 2,170,958	$ 3,977,331
Long term debt, including current portion	2,480,227	6,722,994
Total Liabilities	4,651,185	10,700,325
Common stock	4,124	1,366
Additional paid-in-capital	60,704,297	48,566,451
Accumulated deficit	(53,532,473)	(44,430,703)
Accumulated other comprehensive loss	(149,545)	(86,584)
Non-Controlling Interest	(1,885,271)	(1,555,800)
Total stockholders' equity	5,141,132	2,494,730
Total Liabilities and Stockholders' Equity	**$ 9,792,317**	**$ 13,195,055**

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