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# Heat Biologics Provides Corporate Update and Reports Second Quarter 2016 Financial Results

Announces Proceeds of Approximately \$2.0 Million from Recent Exercise of Warrants

Meets Minimum Bid Price Requirement for Continued Listing on NASDAQ

Funded and On-Track to Achieve Multiple Topline Data Readouts before Year-End

DURHAM, N.C., Aug. 15, 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, provided a general business update and reported its financial results for the second quarter and six months ended June 30, 2016.

"We are pleased to report a number of important scientific, clinical and financial developments at the company," said Jeff Wolf, Heat's Founder and CEO. "First, the preclinical findings demonstrating that our *ComPACT* technology secreting the co-stimulator OX40L significantly enhanced tumor rejection were published in the journal, 'Cancer Immunology Research.' Additionally, we reported encouraging interim study findings from our Phase 1b trial evaluating HS-110 in combination with nivolumab (Opdivo<sup>®</sup>), a Bristol-Myers Squibb anti-PD-1 checkpoint inhibitor, for the treatment of non-small cell lung cancer."

"We remain focused on driving shareholder value and minimizing dilution. We have implemented a number of cost-saving measures to help ensure we achieve important data readouts expected in the fourth quarter with current cash on-hand. Furthermore, I am pleased to report we have generated approximately \$2.0 million in additional cash from the exercise of warrants. Significantly, we have also regained compliance with NASDAQ's minimum closing bid price requirement, which alleviates the immediacy of effecting a reverse stock split."

"Overall, we remain encouraged by the outlook for the business and the growing interest from within the industry to utilize our platform technology with checkpoint inhibitors and other immunotherapies to activate a patient's immune system against cancer. Importantly, our allogeneic cell-based immunotherapy has the potential to offer a broader, off-the-shelf solution that addresses many of the past challenges that have plagued the immuno-oncology market."

**Recent Developments & Second Quarter 2016 Corporate Highlights**

- Heat remains on track to report topline data in the fourth quarter from its Phase 2 trial evaluating HS-410 for the treatment of non-muscle invasive bladder cancer (NMIBC) and its Phase 1b trial evaluating HS-110 in combination with an anti-PD-1 checkpoint inhibitor for the treatment of non-small cell lung cancer (NSCLC).
- 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 significantly 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. Furthermore, the findings also showed that the *ComPACT* platform can be adapted to secrete other costimulatory molecules, including TL1A, 4-1BBL and ICOSL.
- In June, Heat reported interim study findings from its Phase 1b trial evaluating HS-110 in combination with nivolumab for the treatment of NSCLC. The findings suggested that the addition of HS-110 to nivolumab does not alter the nivolumab safety profile to-date. In addition, case studies of three trial patients (one non-responder and two responders) were characterized. While all three patients showed a decrease in immune cell PD-1 expression, which is consistent with nivolumab’s mechanism of action, both responders also showed a decrease in immunosuppressor cells, as well as increases in activated effector T cells in the peripheral blood. Furthermore, the two responders showed an increase in CD8+ T cells in biopsy samples after treatment with HS-110 + nivolumab. These early data appear to suggest that HS-110 in combination with nivolumab may improve response rates for patients with “cold tumors,” who have historically not responded to checkpoint inhibitors alone.
- In June, Heat presented a poster at the ASCO Annual Meeting reviewing the design and endpoints for the ongoing Phase 1b trial of HS-110 in combination with nivolumab.
- In April, Heat presented three posters at the AACR Annual Meeting. In the poster entitled “Phase I/II Study of Patients with NMIBC Treated with Vesigenurtacel-L (HS-410) with or without BCG,” Heat reported that no additional recurrences had been reported to-date, with all patients at least 18 months out from enrollment. In another poster, Heat reported initial preclinical results from its collaboration with OncoSec Medical Incorporated. In the third poster, Heat reported positive preclinical data on its next generation *ComPACT* platform technology.
- In April, Heat implemented cost-saving measures and a focused corporate strategy to achieve important data readouts in the fourth quarter with its current cash on-hand.
- In April, Heat appointed John Prendergast, Ph.D., to its Board of Directors.

## Second Quarter 2016 Financial Highlights

- Research and development (R&D) expenses decreased to approximately \$0.5 million in the second quarter of 2016 compared to approximately \$0.6 million in the second quarter of 2015, a decrease of approximately \$0.1 million. The decrease is primarily attributable to reductions in non-cash stock compensation expense related to equity grants awarded to one of our Scientific Advisory Board members in 2015.
- Clinical and regulatory expenses decreased to approximately \$1.3 million in the second quarter of 2016 compared to approximately \$3.4 million in the second quarter of 2015, a decrease of approximately \$2.1 million. The decrease is primarily attributable to reductions in clinical trial execution costs.
- General and administrative (G&A) expenses increased to approximately \$1.1 million in the second quarter of 2016 compared to approximately \$0.9 million in the second quarter of 2015, an increase of approximately \$0.2 million. The increase is primarily attributable to separation expenses related to the departure of two of our former executive officers, as well as other incremental operating expenses.
- Net loss for the second quarter of 2016 was \$3.0 million compared to a net loss of \$4.9 million for the second quarter of 2015.

### **Six Months Ended June 30, 2016 Financial Highlights**

- R&D expenses decreased to approximately \$1.0 million for the six months ended June 30, 2016 compared to approximately \$1.1 million for the six months ended June 30, 2015, a decrease of approximately \$0.1 million. The decrease is attributable to reductions in patent, license and other professional fees, as well as reductions in compensation costs attributable to deferral in salary as part of our cost-savings initiatives.
- Clinical and regulatory expenses decreased to approximately \$4.5 million for the six months ended June 30, 2016 compared to approximately \$5.5 million for the six months ended June 30, 2015, a decrease of approximately \$1.0 million. The decrease is primarily attributable to reductions in clinical trial execution costs.
- G&A expenses decreased to approximately \$2.1 million for the six months ended June 30, 2016 compared to approximately \$2.2 million for the six months ended June 30, 2015, a decrease of approximately \$0.1 million. The decrease is primarily attributable to reductions in professional services as we bring more services in-house.
- Net loss for the six months ended June 30, 2016 was \$7.8 million compared to a net loss of \$8.9 million for the six months ended June 30, 2015.
- Cash and cash equivalents totaled approximately \$7.1 million at June 30, 2016 compared to cash, cash equivalents and short-term investments totaled approximately \$11.6 million at December 31, 2015. This does not include approximately \$2.0 million raised from the exercise of warrants subsequent to June 30, 2016.

### **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](http://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, Heat's ability to maintain enough cash-on-hand to achieve important data readouts, its Phase 1b program evaluating HS-110 for the treatment of NSCLC 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 Heat's ability to continue to comply with the NASDAQ listing requirements, Heat's ability to raise necessary funds, the ability of Heat's *ImPACT* and *ComPACT* therapies to offer a broader, off-the-shelf solution and 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**

	<b>Heat Biologics, Inc.</b>			
	Condensed Consolidated Statements of Operations			
	(Unaudited)			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 454,907	\$ 587,240	\$ 955,080	\$ 1,090,791
Clinical and regulatory	1,321,418	3,373,758	4,479,253	5,543,231
General and administrative	1,083,298	893,242	2,114,456	2,202,398
Loss from operations	(2,859,623 )	(4,854,240 )	(7,548,789 )	(8,836,420 )
Interest expense, net	(115,978 )	(52,373 )	(240,999 )	(118,677 )

Other (expense) income, net	<u>(57,166 )</u>	<u>3,865</u>	<u>22,535</u>	<u>25,482</u>
Net loss	<u>(3,032,767 )</u>	<u>(4,902,748 )</u>	<u>(7,767,253 )</u>	<u>(8,929,615 )</u>
Net loss non-controlling interest	<u>(107,546 )</u>	<u>(189,277 )</u>	<u>(282,428 )</u>	<u>(306,946 )</u>
Net loss attributable to Heat Biologics, Inc.	<u><b>\$ (2,925,221 )</b></u>	<u><b>\$ (4,713,471 )</b></u>	<u><b>\$ (7,484,825 )</b></u>	<u><b>\$ (8,622,669 )</b></u>
Net loss per share attributable to Heat Biologics, Inc. -basic and diluted	<u><b>\$ (0.17 )</b></u>	<u><b>\$ (0.56 )</b></u>	<u><b>\$ (0.56 )</b></u>	<u><b>\$ (1.13 )</b></u>
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	<u><b>17,524,641</b></u>	<u><b>8,401,159</b></u>	<u><b>13,324,641</b></u>	<u><b>7,612,393</b></u>

Condensed Consolidated Balance Sheets  
(Unaudited)

	<u>June 30, 2016</u>	<u>December 31, 2015</u>
<b>Assets</b>		
Cash, cash equivalents, and short term investments	\$ 7,115,392	\$ 11,629,598
Other assets	<u>1,118,551</u>	<u>1,565,457</u>
<b>Total Assets</b>	<u><b>\$ 8,233,943</b></u>	<u><b>\$ 13,195,055</b></u>
<b>Liabilities and Stockholders' Equity</b>		
Accounts payable and other liabilities	\$ 1,955,045	\$ 3,977,331
Long term debt, including current portion	<u>5,161,357</u>	<u>6,722,994</u>
Total Liabilities	7,116,402	10,700,325
Common stock	3,186	1,366
Additional paid-in-capital	54,981,269	48,566,451
Accumulated deficit	(51,915,528 )	(44,430,703 )
Accumulated other comprehensive loss	(113,158 )	(86,584 )
Non-Controlling Interest	<u>(1,838,228 )</u>	<u>(1,555,800 )</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u><b>\$ 8,233,943</b></u>	<u><b>\$ 13,195,055</b></u>

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Source: Heat Biologics