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Heat Biologics Reports Fiscal Year 2015 Financial Results

Phase 2 Topline Data Expected in the Fourth Quarter of 2016 Evaluating HS-410 in Combination With BCG

DURHAM, N.C., Feb. 18, 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 financial results for the fiscal year ended December 31, 2015.

"2015 proved to be a significant year for Heat as we reported positive Phase 1 data for HS-410 in bladder cancer, as well as initiated a Phase 1b trial evaluating HS-110 in lung cancer in combination with a PD-1 checkpoint inhibitor," stated Jeff Wolf, Heat's Founder and Chief Executive Officer. "We expect to continue the momentum into 2016 with important milestones throughout the year highlighted by topline data for our Phase 2 trial evaluating HS-410 for non-muscle invasive bladder cancer (NMIBC) anticipated in the fourth quarter."

Recent Developments & Fourth Quarter 2015 Corporate Highlights

- On February 10, 2016, Heat announced that the U.S. FDA lifted the partial clinical hold on its HS-410 Phase 2 clinical trial and patient enrollment was resumed after one week; clinical timelines were materially unchanged. The partial clinical hold came after Heat concluded that the cell line on which HS-410 is based had been previously misidentified and immediately notified FDA of this conclusion. The FDA placed Heat's HS-410 Phase 2 clinical trial on partial clinical hold while they reviewed updated documentation. The partial clinical hold did not relate to concerns regarding the safety or efficacy of HS-410.
- In January 2016, Heat reported three-month interim data from the unblinded, monotherapy cohort of the company's ongoing Phase 2 trial of HS-410 for the treatment of high-risk, NMIBC. Images of the bladder taken from patients treated with HS-410 alone (e.g., no Bacillus Calmette-Guérin (BCG)) showed changes that resemble T cell-rich structures, indicating that systemic administration with HS-410 leads to a localized immune response within the bladder that cannot be attributed to standard of care. The interim data further validated HS-410's mechanism of action. One of the treated patients had *carcinoma in situ* (CIS) – the patient population believed to be least responsive to BCG – and that patient experienced complete response. Heat continues to enroll the 25-patient arm and expects to report further monotherapy HS-410 data later this year.
- In November 2015, Heat announced results from its Phase 1 clinical trial, evaluating the safety and immune response of HS-410 after surgery and treatment with standard

of care, BCG, in patients with NMIBC. HS-410 had a positive safety profile with no serious adverse events. HS-410 elicited a broad-based (polyclonal) expansion of patient T cells and a high level of CD8+ tumor-infiltrating lymphocytes (TILs). Additionally, based on tissue samples taken from each patient, HS-410 shared 15 or more tumor antigens with those expressed on the patients' cancer cells.

- In October 2015, Heat completed enrollment of the 75 patients in the company's blinded, randomized, placebo-controlled arms of its Phase 2 clinical trial of HS-410 for the treatment of NMIBC. In these three arms, Heat is evaluating the ability of HS-410 in combination with BCG to prevent cancer recurrence. The company plans to report topline efficacy, immune-response and safety data in the fourth quarter of 2016.

Fiscal Year 2015 Financial Highlights

- Research and development expenses decreased to \$2.6 million in 2015 from \$2.9 million in 2014, a decrease of \$0.3 million. The decrease is attributable to a reduction in pre-manufacturing costs associated with preparing clinical trial material and professional and consulting expenses, offset by increases in compensation costs, lab supplies and other fees.
- Clinical and regulatory expenses increased to \$14.1 million in 2015 from \$5.3 million in 2014, an increase of \$8.8 million. The increase is attributable to increases in clinical trial execution expenses, personnel costs and expenses related to the production of our clinical trial material.
- General and administrative expenses increased to \$4.4 million in 2015 from \$4.0 million in 2014, an increase of \$0.4 million. The increase is attributable to increased personnel and professional service fees.
- Net loss for 2015 was \$20.3 million compared to a net loss of \$11.8 million for 2014.
- Cash, cash equivalents and short-term investments totaled approximately \$11.6 million at December 31, 2015 compared to \$14.4 million at December 31, 2014.

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 (viagenpumatucl-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 expected continued momentum into 2016 with important milestones throughout the year highlighted by topline data for our Phase 2 trial evaluating HS-410 for non-muscle invasive bladder cancer anticipated in the fourth quarter, continued enrollment of the 25-patient monotherapy arm in the Phase 2 trial and expected report of further monotherapy data later this year, 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 Heat's 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

(In thousands, except per share data)

	Year ended December 31,	
	2015	2014
Operating expenses:		
Research and development	\$ 2,595	\$ 2,861
Clinical and regulatory	14,071	5,348
General and administrative	4,356	3,978
Loss from operations	(21,022)	(12,187)
Interest (expense) income	(298)	(32)
Other income (expense)	198	(24)
Net loss attributed to controlling interest	<u>\$ (21,122)</u>	<u>\$ (12,243)</u>
Net loss per share -basic and diluted	<u>\$ (2.53)</u>	<u>\$ (1.83)</u>
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	<u>8,016</u>	<u>6,455</u>

Condensed Consolidated Balance Sheets

(In thousands)

	December 31,	
	2015	2014
Assets		

Cash, cash equivalents, and short term investments	\$ 11,630	\$ 14,413
Other assets	1,588	1,503
Total Assets	\$ 13,218	\$ 15,916
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	\$ 3,977	\$ 2,173
Long term debt, including current portion	6,746	2,711
Total Liabilities	10,723	4,884
Common stock	1	1
Additional paid-in-capital	48,567	35,895
Accumulated deficit	(44,430)	(24,135)
Accumulated other comprehensive loss	(87)	-
Non-Controlling Interest	(1,556)	(729)
Total Liabilities and Stockholders' Equity	\$ 13,218	\$ 15,916

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Source: Heat Biologics