March 31, 2017

Heat Biologics Reports Fiscal Year 2016 Financial Results

DURHAM, N.C., March 31, 2017 (GLOBE NEWSWIRE) -- Heat Biologics, Inc. ("Heat") (Nasdaq:HTBX), a leader in the development of immunotherapies designed to activate a patient's immune system against cancer, reported financial results for the fiscal year ended December 31, 2016.

"2016 was an eventful year, laying the foundation for the major clinical milestones and acquisition that we have announced so far in 2017," said Jeff Wolf, Heat's Founder and CEO. "Most recently, we shared preliminary results from our Phase 2 clinical trial evaluating our vaccine with an anti-PD-1 checkpoint inhibitor. Our findings appear to further validate our vaccine's ability to generate a robust T cell immune response, which may also enhance the efficacy of checkpoint inhibitors for the patients least likely to respond to these therapies. We are encouraged by the data as we advance our clinical programs."

"In March, we also announced our intent to acquire an 80% controlling interest in Pelican Therapeutics, which broadens our current pipeline with the addition of T cell costimulators that have the potential to enhance durability of clinical responses in combination therapies. Importantly, this acquisition includes a $15.2 million grant to fund a 70-patient Phase 1 clinical trial. We are also extending our vaccine platform to target infectious diseases, such as Zika virus, where we believe our platform may be unique in its ability to protect the placenta and prevent transmission of the virus to the fetus."

"Furthermore, we have remained focused on strengthening our balance sheet and extending our cash runway. We ended the fiscal year 2016 with approximately $7.8 million of cash and cash equivalents, and paid down all outstanding debt. This does not reflect the estimated $4.1 million net proceeds recently raised in our latest public offering. We remain diligent in managing our resources and maintaining our lean operations while advancing our immuno-oncology therapies to dramatically improve outcomes for more patients. We look forward to carrying the same momentum through the year."

Recent Developments & Fourth Quarter 2016 Corporate Highlights

- In March 2017, we closed an underwritten public offering of 5,000,000 shares of common stock at a price to the public of $0.80 per share. In addition, the underwriter, Aegis Capital Corp., fully exercised its over-allotment option to acquire an additional 750,000 shares of common stock at a price of $0.80 per share. Total net proceeds were approximately $4.1 million after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.
- In March 2017, we reported positive interim results from our Phase 2 clinical trial evaluating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®) for the treatment of non-small cell lung cancer

(NSCLC). Fifteen patients have completed the HS-110/nivolumab combination to-date and 12 of these 15 patients were evaluable for ELISPOT analysis. ELISPOT results suggest that HS-110 plays an integral role in tumor reduction and may enhance efficacy of checkpoint inhibitors in lung cancer patients.

- In March 2017, we announced that Natasa Strbo, M.D., D.Sc., Research Assistant Professor of Microbiology and Immunology at the University of Miami Miller School of Medicine, received a three-year $981,901 grant from the Florida Department of Health 2016-17 Zika Research Grant Initiative to further develop and test gp96-based Zika vaccine. This vaccine is being developed under a collaboration between the University of Miami and Heat's wholly-owned subsidiary, Zolovax, Inc., which has licensed the intellectual property from the University of Miami.
- In March 2017, we received written notice from Nasdaq notifying us that for the preceding 30 consecutive business days our common stock did not maintain a minimum closing bid price of $1.00. The notice has no immediate effect on the listing or trading of our common stock and the common stock will continue to trade on the Nasdaq Capital Market. We intend to actively monitor the bid price of our common stock and will consider available options to regain compliance with the Nasdaq listing requirements.
- In March 2017, we announced that we had achieved the safety and efficacy endpoints for our Phase 1b trial evaluating HS-110 in combination with nivolumab for the treatment of NSCLC and that the trial met the expansion criteria to advance into a Phase 2. Five out of 15 patients treated with the HS-110/nivolumab combination had 20% or greater tumor reduction. Patients with increased levels of tumor infiltrating lymphocytes (TIL) at 10 weeks appeared to have a durable benefit, with six out of eight of these patients (75%) alive at the one-year follow-up point.
- In March 2017, we entered into a definitive agreement with Pelican Therapeutics, Inc. and certain stockholders of Pelican to acquire an 80% controlling interest in Pelican. Headquartered in Austin, Texas, Pelican is a privately held immuno-oncology company focused on developing agonists to TNFRSF25, a highly differentiated and potentially "best-in-class" T cell costimulatory receptor. Pelican was the recipient of a $15.2 million New Company Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT), which should enable us to advance multiple products through preclinical development and at least one program through a 70-patient Phase 1 clinical trial. The acquisition is contingent upon certain closing conditions and is expected to close by April 30, 2017.
- In March 2017, we announced the acceptance of our abstract titled "Potency of Gp96-Ig/Fc-OX40L cell-based combination vaccine in cancer immunotherapy" at the American Association for Cancer Research (AACR) Annual Meeting being held on April 1-5 in Washington, DC.
- In February 2017, we presented immunological data from our 94-patient Phase 2 trial evaluating HS-410 either alone or in combination with BCG for the treatment of non-muscle invasive bladder cancer (NMIBC). Researchers reported that HS-410, in combination with BCG, continues to be generally well-tolerated, that HS-410 activates CD8+ T cells and that these immune responders appear to have a lower recurrence rate than non-immune responders. These data were an extension on the topline data presented in November 2016 at the Society of Urology Annual Meeting. Researchers reported that there were encouraging signs of anti-tumor activity as HS-410 generated a robust antigen-specific immune response to multiple tumor-associated peptides in treated patients, while there were no immune responses of this type in the placebo.

However, these responses did not translate into clinical outcomes, and there was no statistically significant difference in the primary endpoint between the vaccine and placebo arms of the trial. To better assess the durability of the positive immunological responses, and in keeping with recent clinical trial guidance, we will continue to monitor all patients enrolled in the study for an additional 12 months. At that time, we will make a final determination on whether to progress our bladder program into a Phase 3 trial.

- In January 2017, we announced the appointment of Jeff Hutchins, Ph.D., as our Chief Scientific Officer and Senior Vice President of Preclinical Development. Dr. Hutchins brings over 24 years of research and clinical development experience from both large pharmaceutical and biotechnology companies.
- In December 2016, we made a payment to Pacific Western Bank (formerly known as Square 1 Bank) in the amount of approximately $2.7 million in full satisfaction of the outstanding principal and accrued interest then due on our loan and security agreement. Upon payment, the loan and security agreement was terminated, which positions us with no long-term debt.
- In December 2016, we reported 1-year results from the first eight patients from our Phase 1b trial evaluating HS-110 in combination with nivolumab for the treatment of NSCLC. Data showed that the HS-110/nivolumab combination was well tolerated with a safety profile consistent with single agent nivolumab. There were no additional toxicities seen in the HS-110/nivolumab combination compared to existing data on nivolumab alone. HS-110 generated a robust antigen-specific immune response in several patients consistent with the mechanism of action seen in other HS-110 trials. Additionally, the patients who responded best to the combination therapy ("immune responders") had longer overall survival and better objective response rate than the non-immune responders, even though they had the same baseline immune function. Immune responders in the study saw a 50% objective response rate while non-immune responders saw a 0% objective response rate. Moreover, the immune responders had a better median overall survival than non-immune responders. The 1-year overall survival was 50% for the responders and 25% for the non-responders. Finally, immune responders also saw a better median overall survival at 12.7 months, than non-immune responders, who saw a median overall survival of 7.1 months.

Fiscal Year 2016 Financial Highlights

- Research and development expenses decreased to approximately $9.3 million in 2016 from $16.7 million in 2015, a decrease of $7.4 million. The decrease is attributable to reductions in clinical trial costs, professional and consulting fees, personnel-related expenses, travel and other costs, offset by an increase in manufacturing expenses for *ComPACT* and additional lab supplies.
- General and administrative expenses decreased to $4.1 million in 2016 from $4.3 million in 2015, a decrease of $0.2 million. The decrease is attributable to savings in personnel-related costs and reduced professional fees, offset by an increase in public company expenses including board-related and public relations fees.
- Net loss for 2016 was $13.0 million compared to a net loss of $21.1 million for 2015.
- Cash and cash equivalents totaled approximately $7.8 million at December 31, 2016 compared to cash, cash equivalents and short-term investments of $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 are designed to activate a patient's immune system against cancer utilizing an engineered form of gp96, a protein that robustly activates the immune system. Heat's highly specific T cell-stimulating therapeutic vaccine platform technologies, *ImPACT* and *ComPACT*, 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 HS-110 (viagenpumatucel-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC) and a Phase 2 trial with HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC).

Heat's wholly-owned subsidiary, Zolovax, Inc., is developing therapeutic and preventative vaccines to treat infectious diseases based on Heat's gp96 vaccine technology, with a current focus on the development of a Zika vaccine in conjunction with the University of Miami.

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 regarding Heat's findings appearing to further validate our vaccine's ability to generate a robust T cell immune response, which may also ultimately enhance the efficacy of checkpoint inhibitors for the patients least likely to respond to these therapies, Heat's intent to acquire an 80% controlling interest in Pelican, Heat's vaccine platform being unique in its ability to protect the placenta and prevent transmission of the virus to the fetus, the appearance of a durable benefit of patients with TIL, ELISPOT results suggesting that HS-110 plays an integral role in tumor reduction and may enhance efficacy of checkpoint inhibitors in lung cancer patients, New Company Product Development Award from the Cancer Prevention and Research Institute of Texas (CPRIT), enabling Pelican to advance multiple products through preclinical development and at least one program through a 70-patient Phase 1 clinical trial, the expected closing date of the Pelican acquisition and the potential of Heat's *ImPACT* and *ComPACT* therapies. 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 *ImPACT* and *ComPACT* 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, the company's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to the company'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, the company'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, and its ability to retain its key scientists or management personnel, its ability to consummate the Pelican acquisition and the other factors described in the company's most recent annual report on Form 10-K and other 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.

Financial Statements

Heat Biologics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(unaudited)

	Year ended December 31,	
	2016	2015
Revenue	$ 342	$ -
Operating expenses:		
Research and development	9,331	16,666
General and administrative	4,138	4,356
Loss from operations	(13,127)	(21,022)
Interest (expense) income	(518)	(298)
Other income, net	671	198
Net loss	(12,974)	(21,122)
Net loss non-controlling interest	(401)	(827)
Net loss attributable to Heat Biologics, Inc.	**$ (12,573)**	**$ (20,295)**
Net loss per share attributable to Heat Biologics, Inc. - basic and diluted	**$ (0.71)**	**$ (2.53)**
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	**17,586,210**	**8,015,687**

Condensed Consolidated Balance Sheets
(In thousands)
(unaudited)

	December 31,	
	2016	2015
Assets		
Cash, cash equivalents, and short term investments	$ 7,843	$ 11,630
Other assets	1,054	1,588
Total Assets	**$ 8,897**	**$ 13,218**
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	$ 2,057	$ 3,977
Long term debt, including current portion	-	6,746
Total Liabilities	2,057	10,723
Common stock	5	1

Additional paid-in-capital	65,869	48,567
Accumulated deficit	(57,005)	(44,430)
Accumulated other comprehensive loss	(72)	(87)
Non-Controlling Interest	(1,957)	(1,556)
Total Liabilities and Stockholders' Equity	**$ 8,897**	**$ 13,218**

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Source: Heat Biologics