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Heat Biologics Reports First Quarter 2018 Results and Provides Corporate Update

DURHAM, NC / ACCESSWIRE / May 15, 2018 / [Heat Biologics, Inc.](#) (NASDAQ: HTBX), a biopharmaceutical company developing drugs designed to activate a patient's immune system against cancer, today reported financial and clinical updates for the first quarter ended March 31, 2018.

"We had an eventful first quarter, with a number of positive clinical developments," said Jeff Wolf, CEO of Heat. "Most notably, we announced positive interim results from our Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced non-small cell lung cancer (NSCLC) whose cancers had progressed after treatment with one or more lines of therapy. These data are especially encouraging in patients with low levels of TIL and PD-L1, who are among the most difficult-to-treat patients. Importantly, we believe the data are consistent with the mechanism of action of our T-cell Activation Platform, which has been shown to promote a robust T-cell immune response. We believe the ability of our platform to convert "cold tumors" to "hot tumors" will be an important component in effective immunotherapy combinations against cancer."

"Given the strength of our recent data, we recently completed a capital raise for gross proceeds of \$20.7 million. Consequently, Heat should have sufficient capital to accomplish the following key objectives over the next 5 quarters: 1) complete enrollment in our Phase 2 trial for HS-110 in NSCLC, 2) begin patient enrollment for our *ComPact*™ platform, 3) undertake our Phase I study with our first-in-class T cell costimulator antibody, PTX-35, and 4) report preliminary data for each of these trials."

First Quarter 2018 Corporate Highlights

- On March 26, 2018, the Company reported 2-year recurrence rate data from the Phase 2 trial evaluating HS-410 (vesigenurtacel-L) in combination with standard of care, Bacillus Calmette-Guérin (BCG), for the treatment of non-muscle invasive bladder cancer (NMIBC); achieved 100% (10 out of 10) disease free survival rate over 2 years in the subgroup of patients that generated a positive immune response to low-dose HS-410 and BCG.
- On March 19, 2018, the Company announced the appointment of Anthony Tolcher, M.D., FRCPC, FACP, to the scientific advisory boards of Heat Biologics and its subsidiary, Pelican Therapeutics.
- On March 12, 2018, the Board of Directors adopted a stockholder rights plan intended to ensure that all stockholders of the Company receive fair and equal treatment in the event of an attempted hostile takeover of the Company.
- On February 28, 2018, the Company announced positive interim data from its Phase

2 clinical trial of HS-110 and Nivolumab in NSCLC; reported tumor shrinkage and disease control in a majority of evaluable patients; HS-110 + nivolumab combination showed durable responses in difficult-to-treat low TIL patients and low PD-L1 patients who respond poorly to checkpoint inhibitors.

- On February 20, 2018, the Company reported that the Independent Data Monitoring Committee (DMC) recommended continuing patient enrollment in the ongoing Phase 2 Clinical Trial for HS-110.
- On February 14, 2018, the Company announced its abstract highlighting interim results of its Phase 2 study on HS-110 had been accepted as a scientific poster presentation during the 2018 Keystone Symposia Conference XI: Immunological Memory: Innate, Adaptive and Beyond, February 25 - March 1, 2018 which took place in Austin, TX.

First Quarter 2018 Financial Results

- Recognized \$0.8 million of grant revenue for qualified expenditures under the CPRIT grant.
- Research and development expenses increased to \$2.9 million for the quarter ended March 31, 2018 compared to \$1.8 million for the quarter ended March 31, 2017. The \$1.1 million increase is due to an increase in CMC activity in our HS-110 and PTX-35 programs as well as continued patient enrollment as we progress in our phase 2 HS-110 clinical trial.
- General and administrative expense increased approximately 20% to \$1.8 million for the quarter ended March 31, 2018 compared to \$1.5 million for the quarter ended March 31, 2017. The \$0.3 million increase is primarily attributable to the increase in personnel costs as we establish our Texas operations associated with our Pelican subsidiary.
- Net loss attributable to Heat Biologics was approximately \$3.5 million, or (\$0.75) per basic and diluted share for the quarter ended March 31, 2018 compared to a net loss of approximately \$3.2 million, or (\$1.18) per basic and diluted share for the quarter ended March 31, 2017.
- As of March 31, 2018, the Company had approximately \$9.0 million in cash and cash equivalents. Subsequent to the end of the first quarter, the Company raised approximately \$20.7 million in gross proceeds in a public offering of common shares and warrants.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using of CD8+ "Killer" T-cells. Our T-Cell Activation Platform (TCAP) produces therapies designed to turn "cold" tumors "hot" and be administered in combination with checkpoint therapies and other immunomodulators to increase their effectiveness. HS-110 is our first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells to attack cancer. Our *ComPACT*[™] technology is the first potential, dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product. We are currently enrolling patients in our Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®). 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. We also have 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 regarding the Phase 2 data being consistent with the mechanism of action of our T-cell Activation Platform, the ability of our platform to convert "cold tumors" to "hot tumors" being an important component in effective immunotherapy combinations against cancer, the recent funding providing sufficient capital to accomplish the following key objectives over the next 5 quarters: 1) complete enrollment in our Phase 2 trial for HS-110 in NSCLC, 2) begin patient enrollment for our *ComPact*[™] platform, 3) undertake our Phase I study with our first-in-class T cell costimulator antibody, PTX-35, and 4) report preliminary data for each of these trials. 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*[®] therapy 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, and its ability to retain its key scientists or management personnel, its ability to successfully integrate Pelican, and the other factors described in Heat'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.

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Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
Unaudited

	Quarter ended March 31,	
	2018	2017
Revenue	\$ 752	\$ 24
Operating expenses:		
Research and development	2,873	1,813
General and administrative	1,780	1,527
Change in fair value of contingent consideration	11	-
Loss from operations	<u>(3,912)</u>	<u>(3,316)</u>
Interest income (expense)	4	5
Other income, net	175	70
Net loss	<u>(3,733)</u>	<u>(3,241)</u>
Net loss non-controlling interest	<u>(206)</u>	<u>(51)</u>
Net loss attributable to Heat Biologics, Inc.	<u>\$ (3,527)</u>	<u>\$ (3,190)</u>
Net loss per share attributable to Heat Biologics, Inc. - basic and diluted	<u>\$ 0.75</u>	<u>\$ 1.18</u>
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	<u>4,709,553</u>	<u>2,695,762</u>

Condensed Consolidated Balance Sheets
(In thousands)
Unaudited

	March 31, <u>2018</u>	December 31, <u>2017</u>
Assets		
Cash and cash equivalents	\$ 10,621	\$ 9,763
Goodwill and In-process R&D	8,055	8,055
Other assets	782	2,371
Total Assets	<u>\$ 19,458</u>	<u>\$ 20,189</u>
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	\$ 9,696	\$ 10,497
Contingent consideration	2,620	2,609
Deferred tax liability	1,302	1,302
Total Liabilities	<u>13,618</u>	<u>14,408</u>
Common stock	1	1

Additional paid-in-capital	80,153	76,382
Accumulated deficit	(72,373)	(68,846)
Accumulated other comprehensive loss	(145)	(166)
Non-Controlling Interest	(1,796)	(1,590)
Total Liabilities and Stockholders' Equity	<u>\$ 19,458</u>	<u>\$ 20,189</u>

SOURCE: Heat Biologics, Inc.