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Heat Biologics Reports Fiscal Year 2017 Financial Results

DURHAM, NC / ACCESSWIRE / March 2, 2018/ Heat Biologics, Inc. ("Heat") (NASDAQ: HTBX), a biopharmaceutical company developing drugs designed to activate a patient's immune system against cancer, reported financial results for the fiscal year ended December 31, 2017.

"2017 was a significant year for Heat, as we gained traction on our pipeline developments for both Heat and our subsidiary, Pelican Therapeutics," said Jeff Wolf, CEO of Heat. "Our focus for 2018 will be to continue to generate and report on data to progress HS-110 into registrational trials, advance our PTX-35 into clinical trials, and secure partnerships to enhance our efforts. We look forward to continued progress as we continue to build a leading immunotherapy company."

Fiscal Year 2017 Corporate Highlights

- On December 7, 2017, we received written responses from the FDA following a Type C meeting regarding the planned registrational HS-110 clinical trial design for the treatment of non-small cell lung cancer (NSCLC). The response focused on proposed Phase 3 trial designs, both single-arm and controlled, which the FDA agreed would be appropriate to support a registrational trial of HS-110. Clinical endpoints and post-marketing commitments were also discussed in the context of accelerated approval.
- On October 30, 2017, Heat subsidiary Pelican Therapeutics ("Pelican") received the second tranche in the amount of $6.5 million of its $15.2 million CPRIT grant award. The CPRIT award supports the pre-clinical development, manufacturing and clinical development of a 70-patient Phase 1 clinical trial for PTX-35.
- On September 27, 2017, we announced a manufacturing agreement with KBI Biopharma, Inc. a global biopharmaceutical contract development and manufacturing organization, for cGMP production of Pelican's PTX-35 antibody and PTX-15 fusion protein.
- On May 1, 2017, we announced the completion of the acquisition of an 80 percent controlling interest in Pelican.
- On March 21, 2017, we reported promising interim results for the Phase 1b portion of the trial evaluating HS-110 in combination with Bristol-Myers Squibb's checkpoint inhibitor, nivolumab (Opdivo®), for the treatment of advanced NSCLC.

2018 Additional Development

- On February 27, 2018, at the 2018 Keystone Symposia Conference, Immunological Memory: Innate, Adaptive and Beyond (X1), we presented 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 NSCLC, whose cancers have progressed after treatment with one or more lines of therapy. Data are consistent with HS-110 mechanism-of-action, with tumor shrinkage and disease control demonstrated in a majority of evaluable patients. The HS-110 and nivolumab combination also shows durable responses in both difficult-to-treat, low TIL "cold tumor" patients, as well as low PD-L1 patients who typically do not respond to checkpoint inhibitors.

Fiscal Year 2017 Financial Highlights

- Total operating expenses increased 10.4% to $14.9 million, compared to $13.5 million for the year ended December 31, 2016. For the year ended December 31, 2017, operating expenses are primarily comprised of research and development, general and administrative expenses, as well as change in the fair value of contingent consideration due to the Company's acquisition of 80% controlling interest in Pelican during the year.
- Research and development expenses decreased by 10.8% to $8.3 million for the year ended December 31, 2017, compared to $9.3 million for the year ended December 31, 2016, as we have focused our resources primarily on our NSCLC trial. HS-410 expense decreased $2.3 million due to the current phase of the trial in which patients are in long-term follow-up for recurrence-free survival. HS-130, *ComPACT*™, decreased $0.2 million due to reductions in CMC activities. These decreases were offset by the increased expense of $1.1 million for HS-110 primarily attributable to CMC activities, as well as continued patient enrollment as we advance into Phase 2 of our multi-arm trial. Other programs increased $0.1 million, and include pre-clinical costs associated with our Zika program, T-cell costimulatory programs and laboratory supplies.
- General and administrative expense increased approximately 56.1% to $6.4 million for the year ended December 31, 2017, compared to $4.1 million for the year ended December 31, 2016. The $2.3 million increase is primarily attributable to $1.3 million increase in professional services, consultants and other third-party expenses, as well as approximately $0.6 million in acquisition costs Pelican, and $0.4 million increase in personnel and related expenses, primarily related to the acquisition of Pelican.
- Net loss attributable to Heat Biologics for 2017 was $11.8 million at December 31, 2017, compared to a net loss of $12.6 for 2016.
- Cash and cash equivalents totaled approximately $9.8 million at December 31, 2017, compared to $7.8 million at December 31, 2016.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer by inducing 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 inhibitor therapies and other immuno-modulators to increase their effectiveness. We are currently enrolling patients in our Phase 2 clinical trial for 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 Heat continuing to generate and report on data to progress HS-110 into registrational trials, advance its PTX-35 into clinical trials and secure partnerships to enhance our efforts, Heat's continued progress as it continues to build a leading immunotherapy company and the potential benefits to be derived from Heat's and Pelican's product candidates. 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 and Pelican's product candidates 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 Heat 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,

	2017	2016
Revenue	$ 1,520	$ 342
Operating expenses:		
Research and development	8,268	9,331
General and administrative	6,371	4,138
Change in fair value of contingent consideration	224	-
Loss from operations	(13,343)	(13,127)
Interest income (expense)	22	(519)
Other income, net	101	671
Net loss before income tax benefit	(13,220)	(12,975)
Income tax benefit	810	-
Net loss	(12,410)	(12,975)
Net loss non-controlling interest	(568)	(401)
Net loss attributable to Heat Biologics, Inc.	**$ (11,842)**	**$ (12,574)**
Net loss per share attributable to Heat Biologics, Inc. - basic and diluted	**$ (3.08)**	**$ (7.15)**
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	**3,845,342**	**1,758,621**

Condensed Consolidated Balance Sheets
(In thousands)
Unaudited

	December 31,	
	2017	2016
Assets		
Cash and cash equivalents	$ 9,763	$ 7,843
Goodwill and In-process R&D	8,055	-
Other assets	2,371	1,054
Total Assets	**$ 20,189**	**$ 8,897**
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	$ 10,497	$ 2,057
Contingent consideration	2,609	-
Deferred tax liability	1,302	-
Total Liabilities	14,408	2,057
Common stock	1	1
Additional paid-in-capital	76,382	65,873
Accumulated deficit	(68,846)	(57,005)
Accumulated other comprehensive loss	(166)	(72)
Non-Controlling Interest	(1,590)	(1,957)
Total Liabilities and Stockholders' Equity	**$ 20,189**	**$ 8,897**

Contact

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SOURCE: Heat Biologics, Inc.