

Heat Biologics, Inc. Reports 2013 Fourth Quarter and Full Year Financial Results

Company Advances Two Clinical Development Programs for Lead Product Candidates HS-410 in Bladder and HS-110 Lung Cancer With Innovative and Proprietary ImPACT Cancer Immunotherapy Platform

CHAPEL HILL, NC -- (Marketwired) -- 04/01/14 -- <u>Heat Biologics, Inc.</u> ("Heat Biologics", "Heat" or the "Company") (NASDAQ: HTBX), a clinical stage biopharmaceutical company focused on the development of novel cancer immunotherapies, announced today its financial results for the fourth quarter and full year ended December 31, 2013 and provided a review of the Company's quarterly highlights and recent corporate developments and clinical trial progress for its two lead product candidates, <u>HS-110</u> for the treatment of non-small cell lung cancer (NSCLC) and <u>HS-410</u> for the treatment of bladder cancer.

FOURTH QUARTER 2013 HIGHLIGHTS AND RECENT DEVELOPMENTS

- Submitted revised protocol to FDA for Phase 2 clinical study of HS-110 for treatment of NSCLC and expects to begin patient enrollment in third quarter 2014;
- Reported promising preclinical data on first-head-to-head comparison of Heat's <u>ImPACT</u> immunotherapy in combination with T cell costimulators;
- Appointed oncology immunotherapy expert, Taylor H. Schreiber, M.D., Ph.D., as Vice President of Research and Development;
- Commenced dosing in Phase 1/2 clinical studies of HS-410 for the treatment of bladder cancer and expect to report immune response data in second half 2014;
- Formed a Clinical Advisory Board of preeminent immunotherapy and oncology leaders with Justin Stebbing, M.D., Ph.D., serving as Chairman and Chief Medical Advisor; and
- Appointed oncology biotechnology industry veteran Anil K. Goyal, Ph.D., as Vice President of Business Development.

"We accomplished multiple key milestones in 2013 which we believe were critical in setting the stage for an exciting 2014. Importantly, we assembled a world-class management team and formed a clinical advisory board with leading key opinion leaders in immunotherapy and oncology. This team was highly focused on preparing to commence our HS-410 Phase 1/2 bladder cancer study and worked tirelessly in redesigning the Phase 2 NSCLC protocol in an effort to explore Heat's HS-110 therapeutic vaccine as a single agent, but also its potential in future combination therapy with checkpoint inhibitors, the next generation of oncology treatment," said Jeff Wolf, Chief Executive Officer of Heat Biologics.

"With our two clinical development programs underway, we will continue to work to successfully implement Heat's clinical development and commercialization strategies for our lead product candidates with the ultimate goal to bringing our innovative and proprietary lmPACT Therapy based vaccine product candidates one step closer to approval," Mr. Wolf

concluded.

FOURTH QUARTER AND FULL YEAR ENDED DECEMBER 31, 2013 FINANCIAL SNAPSHOT

As of December 31, 2013, cash, cash equivalents and short term investments totaled \$21.9 million. Based on management's projections, the Company believes that its current cash position will fund operations into the second half of 2015.

For the year ended December 31, 2013, Heat Biologics reported a net loss of (\$6,609,864), and a net loss attributable to common stockholders of (\$9,073,016) or (\$2.42) per share as compared to a net loss of (\$2,471,147) and a net loss attributable to common stockholders of (\$2,420,200), or (\$1.32) per share for the year ended December 31, 2012. The net loss attributable to common stockholders included a non-cash charge of \$2.3 million for beneficial conversion associated with the issuance of preferred stock. The increase in loss was primarily attributable to an increase in operating expenses. Research and development expenses increased to \$2,738,000 for the year ended December 31, 2013 compared to \$903,000 for the year ended December 31, 2012. Clinical and Regulatory expenses increased to \$1,397,000 for the year ended December 31, 2013 compared to \$253,000 for the year ended December 31, 2012. General and Administrative expenses increased to \$2,430,000 for the year ended December 31, 2013 compared to \$1,190,000 for the year ended December 31, 2012.

The components of the increase in expenses are as follows:

The increase in Research and Development spending of \$1,835,000 is due to an increase of \$1,530,000 in pre-manufacturing costs associated with producing Heat's vaccines HS-110 and HS-410 for use in clinical trials. R&D personnel costs, including consultants, increased by \$187,000 primarily due to increased stock-based compensation expense. Patent costs also increased by \$118,000 in a continued effort to expand Heat's robust patent portfolio.

The \$1,144,000 increase in Clinical and Regulatory expense resulted from an increase of approximately \$698,000 in manufacturing and other clinical trial expenditures necessary for the launch of clinical trials for both HS-110 and HS-410. Additionally in preparation to launch the Company's clinical trials, consulting fees increased by \$293,000 and clinical and research personnel costs also increased by \$153,000.

The General and Administrative expense increase of \$1,240,000 was due to several items. Personnel costs increased by \$743,000, including consultants and an increase in non-cash incentive compensation (stock-based compensation expense) of \$321,000. The remaining expense increase was due to miscellaneous expenses such as D&O insurance expense, marketing expenditures related to website enhancement and the initial public offering road show, an increase in travel largely related to fund-raising activities, and costs associated with being a public company during 2013.

About Heat Biologics, Inc.

Heat Biologics, Inc. is a clinical-stage biopharmaceutical company focused on developing its novel, "off-the-shelf" *ImPACT* therapeutic vaccines to combat a wide range of cancers. Our *ImPACT* Therapy is designed to deliver live, genetically-modified, irradiated human cells which are reprogrammed to "pump out" a broad spectrum of cancer-associated antigens

together with a potent immune adjuvant called "gp96" to educate and activate a cancer patient's immune system to recognize and kill cancerous cells. Heat will be entering Phase 2 trials with its HS-110 against non-small cell lung cancer and is conducting Phase 1/2 clinical trials with its HS-410 against bladder cancer. 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 potential for Heat's *ImPACT* Therapy and the expected trial results. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability for Heat's *ImPACT* Therapy to perform as designed and Heat's ability to achieve its development and commercialization strategies. 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.

Heat Biologics, Inc. Contact Information:

Matthew Czajkowski Chief Financial Officer (919) 240-7133 Email Contact

Jenene Thomas
Investor Relations Advisor
Jenene Thomas Communications, LLC
(908) 938-1475
Email Contact

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