

November 14, 2013



# Heat Biologics, Inc. Reports Third Quarter 2013 Financial Results and Provides Clinical Programs Review

CHAPEL HILL, NC -- (Marketwired) -- 11/14/13 -- Heat Biologics, Inc. ("Heat Biologics" or the "Company") (NASDAQ: HTBX), a clinical stage biopharmaceutical company focused on the development of novel cancer immunotherapies announced today the financial results for the third quarter ended September 30, 2013 and provided review of the Company's two lead product candidates, HS-110 and HS-410.

## *THIRD QUARTER HIGHLIGHTS*

- Filed Investigational New Drug application (IND) with the FDA for product candidate HS-410 for bladder cancer and expects to begin patient enrollment in December;
- Refining development strategy of HS-110 based on new preclinical data. Phase 2 protocol to be finalized with patient enrollment expected to begin early in 2014;
- Appointed industry veteran Melissa Price, Ph.D. as Vice President, Clinical and Regulatory Affairs;
- Appointed Louis Bock to Board of Directors bringing significant industry, scientific, operational and business development expertise; and
- Closed initial public offering (IPO) in July 2013 and began trading on the NASDAQ National Market.

"We completed our IPO in the third quarter which has given us access to capital necessary to advance our lead product candidates. Our team is focused on initiating two near-term clinical studies with our lead product candidates HS-110 and HS-410 for lung and bladder cancers, respectively. We are now a step closer to achieving our goal of bringing innovative and proprietary therapeutic vaccine products to the market to improve the lives of cancer patients," said Jeff Wolf, Chief Executive Officer of Heat Biologics.

## *THIRD QUARTER 2013 FINANCIAL SNAPSHOT*

In the third quarter the Company raised approximately \$24.3 million in net proceeds from its initial public offering on July 29, 2013, and the subsequent partial exercise of the underwriters' overallotment option. As of September 30, 2013, cash and cash equivalents totaled \$23.6 million.

For the third quarter ended September 30, 2013, Heat Biologics reported a net loss of (\$2,029,192), and a net loss attributable to common stockholders of (\$2,329,110) or (\$0.48) per share as compared to a net loss of (\$578,939) and a net loss attributable to common stockholders of (\$567,809), or (\$0.31) per share for the third quarter ended September 30, 2012. The increase in the loss was primarily attributable to an increase of approximately \$750,000 in Research and Development expense, an increase of \$178,000 in Clinical and

Regulatory expense and an increase of approximately \$511,000 in General and Administrative expense. The components of the increase in expenses are as follows:

The increase in R&D spending of \$750,000 is primarily related to an increase of \$615,000 in manufacturing costs associated with producing Heat Biologic's vaccines for use in clinical trials for HS-110 and HS-410 and an increase in patent and license fees as part of the Company's continuing effort to maintain and expand its robust patent portfolio.

The \$178,000 increase in Clinical and Regulatory expense was also primarily due to an increase in manufacturing expense for vaccine to be used in our forthcoming clinical trials.

The increase of \$511,000 in General and Administrative expense was due to several items. Non-cash incentive compensation (option expense) increased by approximately \$156,000. The remaining expense of \$355,000 was due to an increase of insurance cost of \$77,000 related to being a public company; an increase of \$59,000 in expenses related to fund raising in connection with the Company's initial public offering and \$92,000 in travel also largely related to fund raising and the initial public offering; \$44,000 in consulting fees primarily associated with recruiting; an increase of \$59,000 in cash compensation expense; and \$24,000 of miscellaneous administrative costs associated with Heat's growth and becoming a public company.

## *CLINICAL PROGRAMS OVERVIEW*

The Company also provided an update on its two current product candidates, HS-110 and HS-410. These two product candidates are based on Heat's proprietary off-the-shelf Immune Pan-Antigen Cytotoxic Therapy ("ImPACT" Therapy). The Company's proprietary ImPACT live cell therapy platform is an engineered version of a naturally occurring heat-shock protein. ImPACT technology transforms allogeneic living cancer cells into powerful machines that continually secrete heat shock protein gp96, the most potent mammalian adjuvant ever described, along with its chaperoned antigens.

### *HS-110 for the treatment of advanced stage IIIB/IV NSCLC*

HS-110 is a biologic product which consists of a lung cancer cell line that has been genetically modified using the Company's ImPACT technology platform to secrete a wide range of lung cancer associated antigens bound to a gp96 adjuvant and is designed to activate a T-cell mediated pan-antigen immune response against the patient's cancer. HS-110 utilizes ImPACT-modified lung cancer cells to stimulate a patient's immune system to activate a robust cytotoxic T-cell response against a wide array of lung cancer antigens.

Based on new preclinical data being generated, the Company is exploring several development pathways for the HS-110 lung cancer program. The Company expects to finalize the Phase 2 protocol and begin enrolling patients early in 2014.

### *HS-410 for the treatment of advanced bladder cancer*

HS-410 is a biologic product which consists of a bladder cancer cell line which has been genetically modified using Heat's ImPACT technology platform to secrete a wide range of bladder cancer antigens bound to a gp96 adjuvant and is designed to activate a T-cell mediated pan-antigen immune response against the patient's bladder cancer.

On October 1, 2013 the Company submitted an IND to the FDA to initiate a Phase 1/2 bladder cancer trial with HS-410. The Company expects to begin enrolling patients in this study by the end of December 2013.

The Phase 1/2 trial is designed to examine safety, tolerability, immune response and preliminary clinical activity of HS-410 in patients with high risk, superficial bladder cancer who have completed surgical resection and 6 weekly intravesical bacillus Calmet-Guerin (BCG) immunotherapy installations. The Company anticipates including approximately 8-10 clinical sites.

#### *About Heat Biologics, Inc.*

Heat Biologics, Inc. ([www.heatbio.com](http://www.heatbio.com)) 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 proprietary ImPACT Therapy is being 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's HS-110, will be entering Phase 2 trials against non-small cell lung cancer and its HS-410 will be entering Phase 1/2 clinical trials against bladder cancer.

#### *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 Heat's continued clinical trials and its goals, and its anticipated enrollment dates and number of sites. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the potential for Heat's ImPACT Therapy and Heat's ability to commence enrollment and complete clinical trials as anticipated. 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.

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