

November 14, 2014



# Heat Biologics, Inc. Reports 2014 Third Quarter Financial Results

## Company Achieves Two Key Development Milestones With Start of Patient Dosing in Phase 2 Bladder and Lung Cancer Clinical Studies

DURHAM, N.C., Nov. 14, 2014 (GLOBE NEWSWIRE) --[Heat Biologics, Inc.](#) ("Heat") (Nasdaq:HTBX), a clinical stage biopharmaceutical company focused on the development of cancer immunotherapies, announced today its financial results for the third quarter ended September 30, 2014 and outlined key highlights of its lead clinical development programs.

### THIRD QUARTER AND RECENT CLINICAL DEVELOPMENT HIGHLIGHTS:

#### *Vesigenurtacel-L (HS-410) for the treatment of bladder cancer*

- Completed enrollment in the Phase 1 portion of the Phase 1/2 clinical trial.
- Initiated patient enrollment and dosing in Phase 2 bladder cancer study in October 2014. This trial is expected to be fully enrolled in the third quarter of 2015; topline one-year recurrence-free survival results are expected to be reported by the third quarter of 2016.

#### *Viagenpumatucl-L (HS-110) for the treatment of non-small cell lung cancer*

- Initiated patient dosing in Phase 2 lung cancer study. Interim immune response from the first 14 patients expected to be reported in the first half of 2015. The protocol of this trial is designed to demonstrate improved overall survival with combination immunotherapy.

### Third Quarter 2014 Financial Highlights

- R&D expenses were relatively flat at \$1.0 million for the third quarter ended September 30, 2014 compared with the third quarter ended September 30, 2013.
- Clinical and regulatory expenses were \$1.3 million for the third quarter ended September 30, 2014, compared with \$0.2 million for the third quarter ended September 30, 2013.
- General and administrative (G&A) expenses were \$0.8 million for the third quarter ended September 30, 2014, compared with \$0.7 million for the third quarter ended September 30, 2013.
- Net loss attributable to common stockholders was \$3.0 million, or \$0.46 per share for the third quarter ended September 30, 2014, compared with a net loss attributable to common stockholders of \$2.3 million, or \$0.48 per share, for the third quarter ended September 30, 2013.
- Cash, cash equivalents and short-term investments were \$15.4 million at September

30, 2014.

"We continue to make excellent progress in advancing our novel drug candidates," stated Jeff Wolf, CEO of Heat Biologics. "We reached important milestones with the initiation of patient dosing in Phase 2 trials for both lung and bladder cancer. Both are areas where we believe our products can address significant unmet medical needs. We note that the start of the bladder trial was achieved a full quarter earlier than anticipated, which should allow us to provide our disease-free survival data ahead of schedule."

### **THIRD QUARTER 2014 FINANCIALS:**

At September 30, 2014, cash and cash equivalents and short-term investments totaled \$15.4 million. Based on Management's projections, the Company's existing cash and short-term investments are anticipated to continue to fund operations for at least the next 12 months.

For the third quarter ended September 30, 2014, Heat Biologics reported a net loss of \$3.1 million and a net loss attributable to common stockholders of \$3.0 million, or \$0.46 per share. This compared with a net loss of \$2.0 million, and a net loss attributable to common stockholders of \$2.3 million, or \$0.48 per share, for the third quarter ended September 30, 2013. The widened loss was primarily attributable to increased R&D, clinical and regulatory and G&A expenses.

R&D spending in the third quarter compared to a year ago was relatively flat at \$1.0 million. Higher compensation costs and costs associated with establishing the Durham, NC facility were offset by lower patent, licensing and pre-manufacturing costs, as well as lower consulting fees.

Clinical and Regulatory expenses were \$1.3 million, compared with \$0.2 million for the quarter ending September 30, 2013, due to increases in clinical trial execution costs, manufacturing and drug handling costs related to the production of vaccines, as well as personnel, travel and facilities costs. The increase was offset primarily by lower consulting costs as well as decreases in various other expenses.

G&A expenses rose 14% to \$0.8 million from \$0.7 million, due primarily to increased costs associated with operating as a public company, increased personnel, franchise tax and travel costs. These increased costs were offset by lower consulting, and miscellaneous administrative costs.

### **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 *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 is conducting a Phase 2 trial of its viagenpumatucel-L ([HS-110](#)) in patients with non-small cell lung cancer as well as a Phase 2 with its vesigenurtacel-L ([HS-410](#)) in patients with non-muscle invasive 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 the expected timing of full enrollment of the Vesigenurtacel-L (HS-410) Phase 2 trial, the expected timing of release of top line results of the Vesigenurtacel-L (HS-410) Phase 2 trial, the expected timing of the reporting of the interim immune response from the first 14 patients of the Viagenpumacel-L (HS-110) Phase 2 clinical trial and the potential for Heat's *ImPACT* Therapy. 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 ability to enroll patients as planned and the other factors described in our annual report on Form 10-K for the year ended December 31, 2013 and our other filings with the SEC. 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.

Condensed Consolidated Statements of Operations

(unaudited)

	Three Months Ended, September 30,		Nine months Ended September 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	1,025,442	992,360	2,425,404	2,121,628
Clinical and regulatory	1,258,566	230,924	3,218,137	747,915
General and administrative	832,101	737,540	2,844,883	1,443,856
Total operating expenses	<u>3,116,109</u>	<u>1,960,824</u>	<u>8,488,424</u>	<u>4,313,399</u>
Loss from operations	(3,116,109)	(1,960,824)	(8,488,424)	(4,313,399)
Total non-operating income (expense)	<u>(11,160)</u>	<u>(68,368)</u>	<u>(20,168)</u>	<u>(178,469)</u>
Net loss	(3,127,269)	(2,029,192)	(8,508,592)	(4,491,868)
Net loss - non-controlling interest	(126,865)	(61,750)	(330,675)	(139,796)
Beneficial conversion charge	—	—	—	(2,300,000)
Preferred stock dividend	—	(361,668)	—	(361,668)
Net loss attributable to common stockholders	<u>(3,000,404)</u>	<u>(2,329,110)</u>	<u>(8,177,917)</u>	<u>(7,013,740)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.46)</u>	<u>\$ (0.48)</u>	<u>\$ (1.27)</u>	<u>\$ (2.45)</u>

Weighted-average number of common shares used in net loss per share attributable to common stockholders—basic and diluted

6,469,272   4,835,582   6,445,129   2,863,310

**HEAT BIOLOGICS, INC.**  
Condensed Consolidated Balance Sheets

	<b>September 30,</b>	<b>December 31,</b>
	<b>2014</b>	<b>2013</b>
	<u>(unaudited)</u>	
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 3,281,984	\$ 4,566,992
Short-term investments	12,115,118	17,297,165
Related party receivable	43,392	24,946
Prepaid expenses and other current assets	<u>648,363</u>	<u>1,066,638</u>
<b>Total Current Assets</b>	16,088,857	22,955,741
<b>Property and Equipment, net</b>	464,348	53,753
<b>Total Other Assets</b>	<u>183,455</u>	<u>10,572</u>
<b>Total Assets</b>	<u>\$ 16,736,660</u>	<u>\$ 23,020,066</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 680,478	\$ 651,917
Accrued expenses and other payables	446,162	503,050
Accrued interest	—	25,364
Current portion of long term debt	<u>130,041</u>	<u>—</u>
<b>Total Current Liabilities</b>	1,256,681	1,180,331
<b>Long Term Liabilities</b>		
Long-term debt, net	1,058,475	—
Stock warrants liability	<u>—</u>	<u>122,590</u>
<b>Total Liabilities</b>	<u>2,315,156</u>	<u>1,302,921</u>
<b>Total Stockholders' Equity— Less Non-Controlling Interest</b>		
	15,026,956	21,991,922
<b>Non-Controlling Interest</b>	<u>(605,452)</u>	<u>(274,777)</u>
<b>Total Stockholders' Equity</b>	<u>14,421,504</u>	<u>21,717,145</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 16,736,660</u>	<u>\$ 23,020,066</u>

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**Source: Heat Biologics**