

March 27, 2015



# Heat Biologics Announces Financial Results for the Year Ended December 31, 2014

DURHAM, N.C., March 27, 2015 (GLOBE NEWSWIRE) --[Heat Biologics, Inc.](#) ("Heat" or the "Company") (Nasdaq:HTBX), a clinical stage biopharmaceutical company focused on the development of cancer immunotherapies, today announced its financial results for the year ended December 31, 2014 and the Company's quarterly highlights and recent corporate developments for its two lead product candidates, [viagenpumatulcel-L \(HS-110\)](#) for the treatment of non-small cell lung cancer (NSCLC) and [vesigenurtacel-L \(HS-410\)](#) for the treatment of non-muscle invasive bladder cancer (NMIBC).

## FOURTH QUARTER 2014 HIGHLIGHTS & RECENT DEVELOPMENTS

- Completed enrollment of Phase 1 clinical trial of HS-410 for the treatment of NMIBC.
  - An immune response analysis of the first 10 patients is expected in the first half of 2015.
- Commenced patient dosing of Phase 2 clinical study of HS-410 for the treatment of NMIBC.
  - The blinded, randomized placebo-controlled study, which includes a monotherapy arm to evaluate HS-410 as a single agent is expected to enroll approximately 100 patients.
  - Heat expects to complete patient enrollment of the first three arms of the Phase 2 study in combination with BCG (Bacillus Calmette–Guérin) in the third quarter of 2015 and report topline results in the second half of 2016.
- Expanded product development team to support development of lead product candidates in oncology.
- Presented positive immunological data on HS-410 in NMIBC at the 7th Annual Phacilitate Immunotherapy Forum.
  - Strong immune response observed in HS-410 treated patient supports the mechanism of action of *ImPACT* therapy.
- Presented positive preclinical data on a novel approach to combination immunotherapy at the Keystone Symposia on "Tumor Immunology - Multidisciplinary Science Driving Combination Therapy."
  - Data support strategy for combination immunotherapy by vaccine and T-cell co-stimulation in a single cell-based product.
- Formed a partnership with the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC) to accelerate Phase 2 enrollment in NMIBC and to initiate planning for

Phase 3 trial.

- Announced a collaboration with OncoSec Medical to evaluate combination of immunotherapy platforms.
  - Heat and OncoSec will jointly evaluate the preclinical efficacy of Heat's proprietary gp96-Ig-based *ImPACT* immunotherapy platform using OncoSec's core technology, ImmunoPulse, an investigational stage intratumoral DNA delivery platform.
- Received US FDA "Fast Track" designation for HS-410 in combination with BCG for the treatment of NMIBC.
- Raised gross proceeds of \$12.3 million in a successful public offering of common stock.

"We accomplished several key clinical and corporate goals over the past year, setting the stage for further progress in 2015," said Jeff Wolf, Heat's CEO. "Our lead clinical programs investigating HS-110 in NSCLC and HS-410 in NMIBC are on track. We have a number of important clinical milestones this year including immune response data from the Phase 1 NMIBC trial, completion of enrollment in the Phase 2 trial in NMIBC and interim immune response data from the ongoing Phase 2 trial in NSCLC."

"We were also pleased with the successful public financing we completed in March of this year," continued Mr. Wolf. "With proceeds from this financing, on top of the December 31st 2014 cash balance, we are starting 2015 in a strong financial position to execute on our development activities."

## **FINANCIAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2014**

Research and development expense for the 2014 Period increased 5% to \$2.9 million compared to \$2.7 million for the 2013 Period. The primary reasons for this change are related to increased patent legal fees of \$286,111 associated with licenses. Salaries and compensation related expense increased by \$252,350 due to hiring over the course of the year. Administrative and allocated expense related to the expansion of the lab during 2014 increased by \$206,417. These increases were offset by \$702,271 in pre-manufacturing costs as we began manufacturing clinical trial batches.

Clinical and regulatory expense for the 2014 Period increased to \$5.3 million compared to \$1.4 million for the 2013 Period. The \$3.9 million increase from the 2013 Period to the 2014 Period was primarily from an increase of \$2.0 million in clinical trial execution, \$1.2 million in payments to investigators, specimen management and other clinical trial expenses, and \$395,851 in drug development and manufacturing related to our clinical trials.

General and administrative expense for the 2014 Period increased to \$4.0 million compared to \$2.4 million for the 2013 Period. The \$1.6 million increase from the 2013 Period to the 2014 Period is primarily attributable to an increase in personnel costs of \$786,595, including non-cash, stock-based compensation of \$277,473.

Total operating expenses for the 2014 period increased to \$12.2 million compared to \$6.6 million for the 2013 period. Operating expenses are primarily comprised of research and development, clinical and regulatory, and general and administrative expenses.

The Company reported a net loss attributable to common stockholders of \$11.8 million, or

(\$1.83) per basic and diluted share for the year ended December 31, 2014. This compares to a net loss of \$9.1 million, or (\$2.42) per basic and diluted share for the year ended December 31, 2013, (the "2013 Period").

As of December 31, 2014, cash, cash equivalents and short-term investments totaled \$14.4 million. On March 16, 2015, the Company closed on a public offering of 1,886,000 shares of common stock, which includes 246,000 shares to cover over-allotments, which the underwriters exercised in full. This offering generated gross proceeds to Heat of approximately \$12.3 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company.

### ***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*<sup>™</sup> therapeutic vaccines to combat a wide range of cancers. Our *ImPACT*<sup>™</sup> 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 [viagenpumatucl-L \(HS-110\)](#) in patients with non-small cell lung cancer as well as a Phase 2 trial 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 successful execution of Heat's business strategy, including with respect to Heat's clinical trials potential for impact of Heat's *ImPACT*<sup>™</sup> Therapy, the timing of the expected immune response analysis from the Phase 1 clinical trial of HS-410 and the expected enrollment, completion and reporting of top-line results from the Phase 2 clinical trial of HS-410 . 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*<sup>™</sup> Therapy to perform as designed, the ability to timely enroll patients and complete the clinical trial on time, the other factors described in our annual report on Form 10-K for the year ended December 31, 2014 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.**

#### **Consolidated Statements of Operations**

(unaudited)

**Years ended,**

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Operating expenses:		
Research and development	\$ 2,861,231	\$ 2,737,688
Clinical and regulatory	5,348,091	1,397,157
General and administrative	3,977,605	2,429,796
Total operating expenses	<u>12,186,927</u>	<u>6,564,641</u>
Loss from operations	<u>(12,186,927)</u>	<u>(6,564,641)</u>
Interest income	40,570	10,068
Other (expense) income	(23,500)	23,828
Interest expense	<u>(73,354)</u>	<u>(79,119)</u>
Total non-operating expense	<u>(56,284)</u>	<u>(45,223)</u>
Net loss	(12,243,211)	(6,609,864)
Net loss - non-controlling interest	(454,394)	(198,516)
Beneficial conversion charge	—	(2,300,000)
Preferred stock dividend	—	<u>(361,668)</u>
Net loss attributable to common stockholders	<u>\$ (11,788,817)</u>	<u>\$ (9,073,016)</u>
Net loss per share attributable to common stockholders - basic and diluted	<u>\$ (1.83)</u>	<u>\$ (2.42)</u>
Weighted number of common shares used in net loss attributable to common stockholders - basic and diluted	<u>6,454,866</u>	<u>3,747,357</u>

**HEAT BIOLOGICS, INC.**  
**Consolidated Balance Sheets**  
(unaudited)

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Current Assets</b>		
Cash and cash equivalents	\$ 3,714,304	\$ 4,566,992
Investments, held to maturity (net)	10,698,982	17,297,165
Prepaid expenses and other current assets	<u>863,227</u>	<u>1,066,638</u>
<b>Total Current Assets</b>	<u>15,276,513</u>	<u>22,930,795</u>
<b>Property and Equipment, net</b>	<u>445,534</u>	<u>53,753</u>
<b>Other Assets</b>		
Restricted cash	101,129	1,252
Deposits	19,798	9,320

Related party receivable	48,642	24,946
Deferred financing costs, net	<u>24,554</u>	<u>—</u>
<b>Total Other Assets</b>	<u>194,123</u>	<u>35,518</u>
<b>Total Assets</b>	<u>\$ 15,916,170</u>	<u>\$ 23,020,066</u>

#### Liabilities and Stockholders' Equity

##### Current Liabilities

Accounts payable	\$ 1,367,426	\$ 651,917
Accrued expenses and other payables	805,968	503,050
Accrued interest	—	25,364
Current portion of long term debt	<u>397,465</u>	<u>—</u>
<b>Total Current Liabilities</b>	<u>2,570,859</u>	<u>1,180,331</u>

##### Long Term Liabilities

Long term debt, net of discount and current portion	2,314,124	—
Stock warrants liability	<u>—</u>	<u>122,590</u>
<b>Total Liabilities</b>	<u>4,884,983</u>	<u>1,302,921</u>

#### Commitments and Contingencies

##### Stockholders' Equity

Common stock, \$.0002 par value; 50,000,000 shares authorized, 6,492,622 and 6,375,426 issued and outstanding at December 31, 2014 and 2013, respectively	982	961
Additional paid in capital	35,894,823	34,337,591
Accumulated deficit	<u>(24,135,447)</u>	<u>(12,346,630)</u>
<b>Total Stockholders' Equity - Less Non-Controlling Interest</b>	11,760,358	21,991,922
<b>Non-Controlling Interest</b>	<u>(729,171)</u>	<u>(274,777)</u>
<b>Total Stockholders' Equity</b>	<u>11,031,187</u>	<u>21,717,145</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 15,916,170</u>	<u>\$ 23,020,066</u>

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