
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **October 30, 2015**

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

001-35994

(Commission File Number)

26-2844103

(IRS Employer Identification No.)

**801 Capitola Drive
Durham, NC 27713**

(Address of principal executive offices and zip code)

(919) 240-7133

(Registrant's telephone number including area code)

N/A

(Former Name and Former Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-
-
-
-

Item 2.02 – Results of Operations and Financial Condition.

On October 30, 2015, Heat Biologics, Inc., a Delaware corporation, (the “Registrant”) issued the attached press release that included financial information for the quarter ended September 30, 2015. A copy of the press release is attached as Exhibit 99.1 to this Report on Form 8-K. The information contained in the press release is being furnished to the Commission and shall not be deemed incorporated by reference into any of the Registrant’s registration statements or other filings with the Commission.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits.

Exhibit 99.1 Press Release issued by Heat Biologics, Inc., dated October 30, 2015.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: October 30, 2015

HEAT BIOLOGICS, INC.

By: /s/ Jeff Wolf
Name: Jeff Wolf
Title: Chairman, President and
Chief Executive Officer

EXHIBIT INDEX

**Exhibit
Number**

Description

[99.1](#)

Press Release issued by Heat Biologics, Inc., dated October 30, 2015.



Heat Biologics Releases Third Quarter 2015 Financial Results

DURHAM, NC – October 30, 2015 – Heat Biologics, Inc. (“Heat”) (Nasdaq:HTBX), an immuno-oncology company developing novel therapies to activate a patient’s immune system against cancer, released its financial results for the third quarter ended September 30, 2015.

“During the third quarter, we continued to advance our programs while demonstrating our ability to quickly shift to accommodate the rapidly evolving immunotherapy space,” said Jeff Wolf, Founder and CEO of Heat Biologics. “We treated the first patient in a new trial in non-small cell lung cancer combining our HS-110 with Opdivo[®], a Bristol Myers-Squibb PD-1 checkpoint inhibitor.¹ This trial represents the first checkpoint inhibitor/vaccine combination in non-small cell lung cancer, as well as an important paradigm for future checkpoint combinations, since published data indicates our vaccines may be synergistic with checkpoint inhibitors. Additionally, we recently completed enrollment in the randomized portion of our Phase 2 trial with our HS-410 therapy in non-muscle invasive bladder cancer and we expect to announce Phase 1 results this quarter.”

Third Quarter 2015 Corporate Highlights & Recent Developments

- In October, Heat completed enrollment of the 75 patients in the company’s blinded, randomized, placebo-controlled arms of its Phase 2 clinical trial of HS-410 (vesigenurtacel-L) for the treatment of high-risk, non-muscle invasive bladder cancer (NMIBC). In these three arms, Heat is evaluating the ability of HS-410 in combination with standard of care, Bacillus Calmette-Guérin (BCG), to prevent cancer recurrence. Heat continues to enroll an additional 25 patients to evaluate HS-410 as a monotherapy in an unblinded, open-label arm. The company expects to report topline efficacy, immune-response and safety data in the fourth quarter of 2016.
- In September, Heat reported further findings from its preclinical research conducted with *ComPACT* in a poster at the CRI-CIMT-EATI-AACR Inaugural International Cancer Immunotherapy Conference. Heat’s next generation combination immunotherapy platform, *ComPACT*, combines a pan-antigen T cell priming vaccine and T cell co-stimulator in a single product, producing the first potential dual-acting immunotherapy. Heat expects to announce its selection of the first product candidate based on the *ComPACT* platform in the first quarter of 2016.
- In September, Heat announced the dosing of its first patient in a Phase 1b clinical trial investigating the combination of HS-110 (viagenpumatuacel-L) and a PD-1 checkpoint inhibitor in patients with non-small cell lung cancer (NSCLC). Primary and second endpoints include safety and tolerability, immune response, overall response rate and progression-free survival. Topline data is expected in the fourth quarter of 2016.

Third Quarter 2015 Financial Highlights

- Research and development expenses totaled \$0.7 million for the third quarter of 2015 compared to \$1.0 million for the third quarter of 2014, a decrease of \$0.3 million. The decrease is attributable to a reduction in pre-manufacturing costs associated with preparing to produce HS-410 and HS-110 for use in our clinical trials, offset by increases in compensation costs, lab supplies and other fees.





- Clinical and regulatory expenses totaled \$3.7 million for the third quarter of 2015 compared to \$1.3 million for the third quarter of 2014, an increase of \$2.4 million. The increase is attributable to increases in clinical trial execution costs, investigator payments and expenses related to the production of HS-410 and HS-110 for our clinical trials.
- General and administrative expenses totaled \$0.9 million for the third quarter of 2015 compared to \$0.8 million for the third quarter of 2014, an increase of \$0.1 million. The increase is attributable to increased employee and professional service fees.
- Net loss was \$5.4 million for the third quarter of 2015, compared to \$3.1 million for the third quarter of 2014.
- Cash, cash equivalents and short-term investments totaled approximately \$15.0 million at September 30, 2015, compared to \$14.4 million at December 31, 2014.

Year to Date 2015 Financial Highlights

- Research and development expenses totaled \$1.8 million for the nine months ended September 30, 2015 compared to \$2.4 million for the nine months ended September 30, 2014, a decrease of \$0.6 million. The decrease is attributable to a reduction in pre-manufacturing costs associated with preparing to produce HS-410 and HS-110 for use in our clinical trials, offset by increases in compensation costs, lab supplies and other fees.
- Clinical and regulatory expenses totaled \$9.3 million for the nine months ended September 30, 2015 compared to \$3.2 million for the nine months ended September 30, 2014, an increase of \$6.1 million. The increase is attributable to increases in clinical trial execution costs, investigator payments and expenses related to the production of HS-410 and HS-110 for our clinical trials.
- General and administrative expenses totaled \$3.2 million for the nine months ended September 30, 2015 compared to \$2.8 million for the nine months ended September 30, 2014, an increase of \$0.4 million. The increase is attributable to increased employee and professional service fees.
- Net loss was \$14.4 million for the nine months ended September 30, 2015, compared to \$8.5 million for the nine months ended September 30, 2014.

About Heat Biologics, Inc.

Heat Biologics, Inc. (Nasdaq: HTBX) is an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer. Heat's highly specific T cell-stimulating platform technologies, *ImPACT*[™] and *ComPACT*, form the basis of its product candidates.ⁱⁱ These platforms, in combination with other therapies, such as checkpoint inhibitors, are designed to address three distinct but synergistic mechanisms of action: robust activation of CD8+ "killer" T cells (one of the human immune system's most potent weapons against cancer); reversal of tumor-induced immune suppression; and T cell co-stimulation to further enhance patients' immune response.

Currently, Heat is conducting a Phase 2 trial with its HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC) and a Phase 1b trial with its HS-110 (viagenpumatu cel-L) in combination with a PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC).



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 expected timing of the release of data, the expected announcing of its first product candidate based on *ComPACT*, the timing of the reporting of topline efficacy, immune-response and safety results from Heat's Phase 2 clinical trial of HS-410, the expected timing of the results from the Phase 1 trial evaluating HS-410, the expected timing of topline data from the Phase 1b clinical trial of HS-110 and the potential of Heat's *ImPACT* and *ComPACT* therapy. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's *ImPACT* and *ComPACT* therapies to perform as designed, the ability to enroll patients and complete the clinical trials on time, the other factors described in our annual report on Form 10-K for the year ended December 31, 2014 and Heat's 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.



Financial Statements

HEAT BIOLOGICS, INC.

Consolidated Balance Sheets (Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	\$ 8,210,938	\$ 3,714,304
Investments, held to maturity (net)	6,742,987	10,698,982
Prepaid expenses and other current assets	986,264	863,227
Total Current Assets	<u>15,940,189</u>	<u>15,276,513</u>
Property and Equipment, net	<u>467,999</u>	<u>445,534</u>
Other Assets		
Restricted cash	101,146	101,129
Deposits	69,798	19,798
Related party receivable	58,017	48,642
Deferred financing costs, net	25,379	24,554
Total Other Assets	<u>254,340</u>	<u>194,123</u>
Total Assets	<u>\$ 16,662,528</u>	<u>\$ 15,916,170</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 936,361	\$ 1,367,426
Accrued expenses and other payables	2,074,174	805,968
Current portion of long term debt	2,053,859	397,465
Total Current Liabilities	<u>5,064,394</u>	<u>2,570,859</u>
Long Term Liabilities		
Long term debt, net of discount and current portion	2,831,787	2,314,124
Other long term liabilities	12,228	—
Total Liabilities	<u>7,908,409</u>	<u>4,884,983</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock, \$.0002 par value; 50,000,000 shares authorized, 8,415,434 and 6,492,622 shares issued and outstanding at September 30, 2015 (unaudited) and December 31, 2014, respectively	1,365	982
Additional paid in capital	48,038,935	35,894,823
Accumulated deficit	(37,943,582)	(24,135,447)
Accumulated other comprehensive loss	(64,238)	—
Total Stockholders' Equity— Less Non-Controlling Interest	<u>10,032,480</u>	<u>11,760,358</u>
Non-Controlling Interest	<u>(1,278,361)</u>	<u>(729,171)</u>
Total Stockholders' Equity	<u>8,754,119</u>	<u>11,031,187</u>
Total Liabilities and Stockholders' Equity	<u>\$ 16,662,528</u>	<u>\$ 15,916,170</u>



HEAT BIOLOGICS, INC.

Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended, September 30,		Nine Months Ended, September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 677,151	\$ 1,025,442	\$ 1,767,942	\$ 2,425,404
Clinical and regulatory	3,718,902	1,258,566	9,261,529	3,218,137
General and administrative	947,392	832,101	3,150,394	2,844,883
Total operating expenses	<u>5,343,445</u>	<u>3,116,109</u>	<u>14,179,865</u>	<u>8,488,424</u>
Loss from operations	<u>(5,343,445)</u>	<u>(3,116,109)</u>	<u>(14,179,865)</u>	<u>(8,488,424)</u>
Non-operating (expenses) income				
Interest income	20,121	9,740	49,970	27,261
Other income (expense)	4,449	(12,762)	29,909	(39,291)
Interest expense	(108,834)	(8,138)	(257,339)	(8,138)
Total non-operating (expenses) income	<u>(84,264)</u>	<u>(11,160)</u>	<u>(177,460)</u>	<u>(20,168)</u>
Net loss	<u>(5,427,709)</u>	<u>(3,127,269)</u>	<u>(14,357,325)</u>	<u>(8,508,592)</u>
Net loss – non-controlling interest	<u>(242,244)</u>	<u>(126,865)</u>	<u>(549,190)</u>	<u>(330,675)</u>
Net loss attributable to Heat Biologics, Inc.	<u>\$ (5,185,465)</u>	<u>\$ (3,000,404)</u>	<u>\$ (13,808,135)</u>	<u>\$ (8,177,917)</u>
Net loss per share attributable to Heat Biologics, Inc.—basic and diluted	<u>\$ (0.62)</u>	<u>\$ (0.46)</u>	<u>\$ (1.75)</u>	<u>\$ (1.27)</u>
Weighted-average number of common shares used in net loss per share attributable to common stockholders—basic and diluted	8,408,376	6,469,272	7,880,637	6,445,129
Other comprehensive loss:				
Net loss	(5,427,709)	(3,127,269)	(14,357,325)	(8,508,592)
Unrealized loss on foreign currency translation	<u>(27,244)</u>	<u>—</u>	<u>(64,238)</u>	<u>—</u>
Total other comprehensive loss	<u>(5,454,953)</u>	<u>(3,127,269)</u>	<u>(14,421,563)</u>	<u>(8,508,592)</u>
Comprehensive loss attributable to non-controlling interest	<u>(242,244)</u>	<u>(126,865)</u>	<u>(549,190)</u>	<u>(330,675)</u>
Comprehensive loss	<u>\$ (5,212,709)</u>	<u>\$ (3,000,404)</u>	<u>\$ (13,872,373)</u>	<u>\$ (8,177,917)</u>



HEAT BIOLOGICS, INC.

Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Cash Flows from Operating Activities		
Net loss	\$ (14,357,325)	\$ (8,508,592)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	84,373	41,850
Amortization of debt issuance costs	75,818	13,848
Amortization of bond premium	102,618	137,897
Re-measurement of fair value of stock warrants liability	—	7,263
Stock-based compensation	1,046,086	722,358
Increase (decrease) in cash arising from changes in assets and liabilities:		
Related party receivable	(9,375)	(18,446)
Prepaid expenses, and other current assets, and restricted cash	(157,440)	318,275
Deposits	(50,000)	(10,478)
Accounts payable	(385,161)	28,561
Accrued expenses and other payables	1,260,355	(56,888)
Other long term liabilities	12,228	—
Accrued interest	—	(25,364)
Net Cash Used in Operating Activities	<u>(12,377,823)</u>	<u>(7,349,716)</u>
Cash Flows from Investing Activities		
Proceeds from maturities of short term investments	14,943,468	13,827,773
Purchases of short term investments	(11,090,091)	(8,783,623)
Purchases of property and equipment	(106,838)	(452,444)
Net Cash Provided by Investing Activities	<u>3,746,539</u>	<u>4,591,706</u>
Cash Flows from Financing Activities		
Proceeds from March 2015 public offering, net of underwriting discounts	11,400,870	—
Proceeds from the exercise of stock options	—	37,719
Proceeds from issuance of long term debt	2,242,575	1,435,283
Payments on long term debt	(145,161)	—
Stock issuance costs	(302,461)	—
Net Cash Provided by Financing Activities	<u>13,195,823</u>	<u>1,473,002</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(67,905)</u>	<u>—</u>
Net Increase in Cash and Cash Equivalents	4,496,634	(1,285,008)
Cash and Cash Equivalents – Beginning of Period	3,714,304	4,566,992
Cash and Cash Equivalents – End of Period	<u>\$ 8,210,938</u>	<u>\$ 3,281,984</u>
Supplemental Disclosure for Cash Flow Information		
Interest paid	<u>\$ 257,339</u>	<u>\$ 8,138</u>
Cashless exercise of stock warrants	<u>\$ —</u>	<u>\$ 452,874</u>



CONTACT:

Heat Biologics, Inc.

Jennifer Almond

Investor and Media Relations

919-240-7133

investorrelations@heatbio.com

i OPDIVO is a registered trademark of Bristol-Myers Squibb Company

ii *ImPACT* is a registered trademark of Heat Biologics, Inc.