
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): **February 18, 2016**

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 February 18, 2016, Heat Biologics, Inc., a Delaware corporation, (the “Registrant”) issued the attached press release that included financial information for its fiscal year ended December 31, 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 February 18, 2016.

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: February 18, 2016

HEAT BIOLOGICS, INC.

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

EXHIBIT INDEX

**Exhibit
Number**

Description

99.1

Press Release, dated February 18, 2016*

*Filed herewith.



Heat Biologics Reports Fiscal Year 2015 Financial Results

· *Phase 2 topline data expected in the fourth quarter of 2016 evaluating HS-410 in combination with BCG*

DURHAM, NC – February 18, 2016 – Heat Biologics, Inc. (“Heat”) (Nasdaq: HTBX), an immuno-oncology company developing novel therapies that activate a patient’s immune system against cancer, reported financial results for the fiscal year ended December 31, 2015.

“2015 proved to be a significant year for Heat as we reported positive Phase 1 data for HS-410 in bladder cancer, as well as initiated a Phase 1b trial evaluating HS-110 in lung cancer in combination with a PD-1 checkpoint inhibitor,” stated Jeff Wolf, Heat’s Founder and Chief Executive Officer. “We expect to continue the momentum into 2016 with important milestones throughout the year highlighted by topline data for our Phase 2 trial evaluating HS-410 for non-muscle invasive bladder cancer (NMIBC) anticipated in the fourth quarter.”

Recent Developments & Fourth Quarter 2015 Corporate Highlights

- On February 10, 2016, Heat announced that the U.S. FDA lifted the partial clinical hold on its HS-410 Phase 2 clinical trial and patient enrollment was resumed after one week; clinical timelines were materially unchanged. The partial clinical hold came after Heat concluded that the cell line on which HS-410 is based had been previously misidentified and immediately notified FDA of this conclusion. The FDA placed Heat’s HS-410 Phase 2 clinical trial on partial clinical hold while they reviewed updated documentation. The partial clinical hold did not relate to concerns regarding the safety or efficacy of HS-410.
 - In January 2016, Heat reported three-month interim data from the unblinded, monotherapy cohort of the company’s ongoing Phase 2 trial of HS-410 for the treatment of high-risk, NMIBC. Images of the bladder taken from patients treated with HS-410 alone (e.g., no Bacillus Calmette-Guérin (BCG)) showed changes that resemble T cell-rich structures, indicating that systemic administration with HS-410 leads to a localized immune response within the bladder that cannot be attributed to standard of care. The interim data further validated HS-410’s mechanism of action. One of the treated patients had *carcinoma in situ* (CIS) – the patient population believed to be least responsive to BCG – and that patient experienced complete response. Heat continues to enroll the 25-patient arm and expects to report further monotherapy HS-410 data later this year.
-



- In November 2015, Heat announced results from its Phase 1 clinical trial, evaluating the safety and immune response of HS-410 after surgery and treatment with standard of care, BCG, in patients with NMIBC. HS-410 had a positive safety profile with no serious adverse events. HS-410 elicited a broad-based (polyclonal) expansion of patient T cells and a high level of CD8+ tumor-infiltrating lymphocytes (TILs). Additionally, based on tissue samples taken from each patient, HS-410 shared 15 or more tumor antigens with those expressed on the patients' cancer cells.
- In October 2015, 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 for the treatment of NMIBC. In these three arms, Heat is evaluating the ability of HS-410 in combination with BCG to prevent cancer recurrence. The company plans to report topline efficacy, immune-response and safety data in the fourth quarter of 2016.

Fiscal Year 2015 Financial Highlights

- Research and development expenses decreased to \$2.6 million in 2015 from \$2.9 million in 2014, a decrease of \$0.3 million. The decrease is attributable to a reduction in pre-manufacturing costs associated with preparing clinical trial material and professional and consulting expenses, offset by increases in compensation costs, lab supplies and other fees.
 - Clinical and regulatory expenses increased to \$14.1 million in 2015 from \$5.3 million in 2014, an increase of \$8.8 million. The increase is attributable to increases in clinical trial execution expenses, personnel costs and expenses related to the production of our clinical trial material.
 - General and administrative expenses increased to \$4.4 million in 2015 from \$4.0 million in 2014, an increase of \$0.4 million. The increase is attributable to increased personnel and professional service fees.
 - Net loss for 2015 was \$20.3 million compared to a net loss of \$11.8 million for 2014.
 - Cash, cash equivalents and short-term investments totaled approximately \$11.6 million at December 31, 2015 compared to \$14.4 million at December 31, 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. 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 an anti-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 continued momentum into 2016 with important milestones throughout the year highlighted by topline data for our Phase 2 trial evaluating HS-410 for non-muscle invasive bladder cancer anticipated in the fourth quarter, continued enrollment of the 25-patient monotherapy arm in the Phase 2 trial and expected report of further monotherapy data later this year, and the potential of Heat's *ImPACT* and *ComPACT* therapies. 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, 2015 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.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)

	Year ended December 31,	
	2015	2014
Operating expenses:		
Research and development	\$ 2,595	\$ 2,861
Clinical and regulatory	14,071	5,348
General and administrative	4,356	3,978
Loss from operations	(21,022)	(12,187)
Interest (expense) income	(298)	(32)
Other income (expense)	198	(24)
Net loss attributed to controlling interest	<u>\$ (21,122)</u>	<u>\$ (12,243)</u>
Net loss per share -basic and diluted	<u>\$ (2.53)</u>	<u>\$ (1.83)</u>
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	<u>8,016</u>	<u>6,455</u>

Condensed Consolidated Balance Sheets
(In thousands)

	December 31,	
	2015	2014
Assets		
Cash, cash equivalents, and short term investments	\$ 11,630	\$ 14,413
Other assets	1,588	1,503
Total Assets	<u>\$ 13,218</u>	<u>\$ 15,916</u>
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	\$ 3,977	\$ 2,173
Long term debt, including current portion	6,746	2,711
Total Liabilities	10,723	4,884
Common stock	1	1
Additional paid-in-capital	48,567	35,895
Accumulated deficit	(44,430)	(24,135)
Accumulated other comprehensive loss	(87)	-
Non-Controlling Interest	(1,556)	(729)
Total Liabilities and Stockholders' Equity	<u>\$ 13,218</u>	<u>\$ 15,916</u>

CONTACT:

Heat Biologics, Inc.

Jennifer Almond

Investor and Media Relations

919-240-7133

investorrelations@heatbio.com