
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): **November 15, 2019**

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.)

627 Davis Drive

Morrisville, North Carolina 27560

(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))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|--------------------------------------------|-------------------|-------------------------------------------|
| Common Stock, \$0.0002 par value per share | HTBX | The Nasdaq Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 15, 2019, Heat Biologics, Inc., a Delaware corporation (the “Registrant”), issued a press release that included financial information for its quarter ended September 30, 2019. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in the press release is being furnished to the Securities and Exchange Commission (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 Number | Description |
|-------------------|----------------------------------------------------------------------------------------|
| 99.1 | Press Release issued by Heat Biologics, Inc. , dated November 15, 2019 |



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: November 15, 2019

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 issued by Heat Biologics, Inc. , dated November 15, 2019 |



Heat Biologics Reports Third Quarter 2019 Results and Provides Corporate Update

Reported positive Phase 2 interim data in advanced non-small cell lung cancer patients

MORRISVILLE, NC – November 15, 2019 – Heat Biologics, Inc. (Nasdaq: HTBX), a biopharmaceutical company developing therapeutics designed to activate a patient's immune system against cancer, today reported financial and clinical updates for the third quarter ended September 30, 2019.

Jeff Wolf, Heat's CEO, commented, "We remain encouraged by the positive top line data from our Phase 2 trial for HS-110 in advanced non-small cell lung cancer (NSCLC) in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, Opdivo® (nivolumab) and with Merck's anti-PD-1 checkpoint inhibitor Keytruda® (pembrolizumab), which completed enrollment in July 2019. We recently presented a subset of this data in a poster presentation at The Society of Immunotherapy of Cancer's (SITC) 34th Annual Meeting, in which we reported that 61% of patients in our Phase 2 Cohort B achieved disease stabilization per iRECIST, a patient population whose disease had progressed following prior checkpoint inhibitor therapy. Based on this data, we look forward to advancing our clinical trials and intend to aggressively explore all options for the future development of HS-110, including possible collaboration and licensing opportunities."

"We ended the quarter with approximately \$15.0 million in cash, cash equivalents and short-term investments. We believe we are well funded to advance our clinical activities through additional major milestones and continue to manage expenses accordingly."

Third Quarter 2019 Financial Results

- Research and development expenses decreased to \$3.1 million for the quarter ended September 30, 2019 compared to \$4.4 million for the quarter ended September 30, 2018. The decrease of approximately \$1.3 million is due to the lower PTX-35 expense for 2019, primarily reflecting decreased manufacturing costs, offset by increased Phase 2 trial expenses, including outsourced clinical trial support services and payments to investigator sites.
- General and administrative expense increased to \$2.0 million for the quarter ended September 30, 2019 compared to \$1.6 million for the quarter ended September 30, 2018. The \$0.4 million increase is primarily attributable to increased personnel costs, including stock-based compensation expense.
- Net loss attributable to Heat Biologics was approximately \$6.2 million, or (\$0.18) per basic and diluted share for the quarter ended September 30, 2019 compared to a net loss of approximately \$3.7 million, or (\$0.16) per basic and diluted share for the quarter ended September 30, 2018.
- As of September 30, 2019, the Company had approximately \$15.0 million in cash, cash equivalents and short-term investments with an additional \$6.9 million in grant funds from Cancer Prevention Research Institute of Texas (CPRIT) that it expects to receive after filing an IND for PTX-35.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using CD8+ "Killer" T-cells. HS-110 is the Company's first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells to attack cancer. Heat has completed enrollment in its Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®) or with Merck's pembrolizumab (Keytruda®). Pelican Therapeutics, a subsidiary of Heat, is focused on the development of co-stimulatory monoclonal antibody and fusion protein-based therapies designed to activate the immune system. Heat also has numerous pre-clinical programs at various stages of development. For more information, please visit www.heatbio.com.

Forward Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 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 such as: looking forward to advancing Heat's clinical trials, the intention to aggressively explore all options for the future development of HS-110, including possible collaboration and licensing opportunities, being well funded to advance Heat's clinical activities through additional major milestones and continuing to manage expenses accordingly, and the expected receipt of an additional \$6.9 million in grant funds from CPRIT after filing the IND for PTX-35. These statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements, including the ability of Heat's therapies to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, Heat's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Heat's ability to promote or commercialize its product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products, Heat's ability to maintain its license agreements, the continued maintenance and growth of its patent estate, its ability to establish and maintain collaborations, its ability to obtain or maintain the capital or grants necessary to fund its research and development activities, its ability to retain its key scientists or management personnel, and the other factors described in Heat's Annual Report on Form 10-K and 10-K/A for the year ended December 31, 2018 and other subsequent filings with the SEC. The information in this release is provided only as of the date of this release and the company undertakes 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.

Media and Investor Relations Contact

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(tables follow)

HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

| | September 30, 2019 (unaudited) | December 31, 2018 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|
| Current Assets | | |
| Cash and cash equivalents | \$ 9,334,421 | \$ 22,154,251 |
| Short-term investments | 5,683,446 | 5,570,027 |
| Accounts receivable | 37,300 | 28,538 |
| Prepaid expenses and other current assets | 734,788 | 961,317 |
| Total Current Assets | <u>15,789,955</u> | <u>28,714,133</u> |
| Property and Equipment, net | <u>609,916</u> | <u>643,146</u> |
| Other Assets | | |
| In-process R&D | 5,866,000 | 5,866,000 |
| Goodwill | 1,452,338 | 2,189,338 |
| Right-of-use asset | 347,153 | — |
| Deposits | 386,284 | 351,220 |
| Total Other Assets | <u>8,051,775</u> | <u>8,406,558</u> |
| Total Assets | <u>\$ 24,451,646</u> | <u>\$ 37,763,837</u> |
| Liabilities and Stockholders' Equity | | |
| Current Liabilities | | |
| Accounts payable | \$ 1,944,333 | \$ 974,619 |
| Deferred revenue | — | 1,032,539 |
| Contingent consideration, current portion | 1,477,000 | 1,187,000 |
| Operating lease liability, current portion | 91,068 | — |
| Accrued expenses and other liabilities | 1,281,911 | 1,678,051 |
| Total Current Liabilities | <u>4,794,312</u> | <u>4,872,209</u> |
| Long Term Liabilities | | |
| Contingent consideration | 2,356,515 | 1,918,225 |
| Deferred tax liability | 361,911 | 316,733 |
| Deferred revenue, net of current portion | 200,000 | 200,000 |
| Operating lease liability, net of current portion | 259,222 | — |
| Other long-term liabilities | 306,235 | 213,724 |
| Total Liabilities | <u>8,278,195</u> | <u>7,520,891</u> |
| Commitments and Contingencies | | |
| Stockholders' Equity | | |
| Common stock, \$.0002 par value; 100,000,000 shares authorized, 33,334,124 and 32,492,144 shares issued and outstanding at September 30, 2019 (unaudited) and December 31, 2018, respectively | 6,822 | 6,499 |
| Additional paid-in capital | 117,836,082 | 114,883,135 |
| Accumulated deficit | (101,261,124) | (84,580,180) |
| Accumulated other comprehensive loss | 52,230 | (19,904) |
| Total Stockholders' Equity— Heat Biologics, Inc. | <u>16,634,010</u> | <u>30,289,550</u> |
| Non-Controlling Interest | <u>(460,559)</u> | <u>(46,604)</u> |
| Total Stockholders' Equity | <u>16,173,451</u> | <u>30,242,946</u> |
| Total Liabilities and Stockholders' Equity | <u>\$ 24,451,646</u> | <u>\$ 37,763,837</u> |

HEAT BIOLOGICS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

| | Three Months Ended, September 30, | | Nine months Ended, September 30, | |
|----------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-----------------------|-------------------------------------|------------------------|
| | 2019 | 2018 | 2019 | 2018 |
| Revenue: | | | | |
| Grant and licensing revenue | \$ 6,439 | \$ 1,840,009 | \$ 1,049,988 | \$ 3,735,713 |
| Operating expenses: | | | | |
| Research and development | 3,129,356 | 4,403,759 | 9,725,744 | 10,756,485 |
| General and administrative | 1,993,136 | 1,585,600 | 7,201,196 | 4,727,105 |
| Goodwill impairment loss | 737,000 | — | 737,000 | — |
| Change in fair value of contingent consideration | 502,000 | 114,838 | 728,290 | 665,936 |
| Total operating expenses | 6,361,492 | 6,104,197 | 18,392,230 | 16,149,526 |
| Loss from operations | (6,355,053) | (4,264,188) | (17,342,242) | (12,413,813) |
| Interest income | 97,415 | 83,509 | 373,060 | 131,306 |
| Other (expense) income, net | (73,275) | 31,704 | (80,539) | 153,500 |
| Total non-operating income | 24,140 | 115,213 | 292,521 | 284,806 |
| Net loss before income taxes | (6,330,913) | (4,148,975) | (17,049,721) | (12,129,007) |
| Income tax benefit (expense) | — | 225,389 | (45,178) | 665,080 |
| Net loss | (6,330,913) | (3,923,586) | (17,094,899) | (11,463,927) |
| Net loss – non-controlling interest | (136,315) | (265,024) | (413,955) | (668,219) |
| Net loss attributable to Heat Biologics, Inc. | <u>\$ (6,194,598)</u> | <u>\$ (3,658,562)</u> | <u>\$ (16,680,944)</u> | <u>\$ (10,795,708)</u> |
| Net loss per share attributable to Heat Biologics, Inc.—basic and diluted | <u>\$ (0.18)</u> | <u>\$ (0.16)</u> | <u>\$ (0.50)</u> | <u>\$ (0.75)</u> |
| Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc.—basic and diluted | 33,650,829 | 23,143,952 | 33,255,535 | 14,359,429 |
| Other comprehensive loss: | | | | |
| Net loss | \$ (6,330,913) | \$ (3,923,586) | \$ (17,094,899) | \$ (11,463,927) |
| Unrealized gain on foreign currency translation | 63,711 | 39,377 | 72,134 | 110,648 |
| Total other comprehensive loss | (6,267,202) | (3,884,209) | (17,022,765) | (11,353,279) |
| Comprehensive loss attributable to non-controlling interest | (136,315) | (265,024) | (413,955) | (668,219) |
| Comprehensive loss | <u>\$ (6,130,887)</u> | <u>\$ (3,619,185)</u> | <u>\$ (16,608,810)</u> | <u>\$ (10,685,060)</u> |