
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): **August 14, 2018**

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 August 14, 2018, Heat Biologics, Inc., a Delaware corporation (the “Registrant”), issued a press release that included financial information for the quarter ended June 30, 2018. 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 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 5.08 Shareholder Director Nominations.

As previously announced, on July 20, 2018 the Company stated that it would be scheduling a new date for the 2018 Annual Meeting of Stockholders (the “2018 Annual Meeting”) and that notice by a stockholder of any qualified stockholder proposal or qualified stockholder nominations must be received by the Company at its principal executive offices at 801 Capitola Drive, Suite 12, Durham, North Carolina 27713, and directed to the attention of the Corporate Secretary, by August 1, 2018 in order to be considered for inclusion in the Company’s proxy statement and form of proxy for the 2018 Annual Meeting. On August 13, 2018, the Board of Directors approved October 2, 2018 as the date of our 2018 Annual Meeting of Stockholders to be held at 1:00 p.m. and determined to further extend to August 20, 2018 the date by which notice by a stockholder of any qualified stockholder proposal or qualified stockholder nominations must be received by the Company at its principal executive offices at 801 Capitola Drive, Suite 12, Durham, North Carolina 27713, and directed to the attention of the Corporate Secretary, in order to be considered for inclusion in the Company’s proxy statement and form of proxy for the 2018 Annual Meeting. Such stockholder proposals or nominations must conform to the rules and regulations promulgated by the Commission. Any such notice received after the close of business on August 20, 2018 will be considered untimely and not properly brought before the 2018 Annual Meeting.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Heat Biologics, Inc. dated August 14, 2018

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: August 14, 2018

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 August 14, 2018



Heat Biologics Reports Second Quarter 2018 Results and Provides Corporate Update

Completed a capital raise of \$20.7 million in the second quarter of 2018

On track to report key clinical milestones beginning in Q4 2018

DURHAM, NC – August 14, 2018 – Heat Biologics, Inc. (Nasdaq: HTBX), a biopharmaceutical company developing drugs designed to activate a patient's immune system against cancer, today reported financial and clinical updates for the second quarter ended June 30, 2018.

Jeff Wolf, Heat's CEO, commented, "Earlier this year we reported positive interim results from our Phase 2 trial investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced non-small cell lung cancer (NSCLC). Since then, we have continued to execute on our clinical plan and remain on track to report additional interim Phase 2 data in the fourth quarter of 2018 and to complete trial enrollment in Q2 2019."

"In addition to our Phase 2 HS-110 program, we look forward to filing our Investigational New Drug (IND) application to initiate a Phase 1 clinical trial for our *ComPACT*™ trial in the fourth quarter of 2018. Our *ComPACT*™ therapy combines T-cell activators and co-stimulators within a single treatment, simplifying combination immunotherapy while providing superior immune activation and reduced treatment costs."

"Finally, we look forward to filing our second Investigational New Drug (IND) application to initiate a Phase 1 clinical trial for PTX-35, a novel co-stimulatory monoclonal antibody, in the first quarter of 2019. Each of our therapies is designed to enhance the response rate for patients least likely to respond to checkpoint inhibitors through a combination treatment that enhances the immune defense mechanisms."

"Importantly, we completed a capital raise of \$20.7 million in the second quarter of 2018. In addition, we have subsequently generated an additional \$4.8 million through the exercise of warrants. These funds, combined with the additional \$6.9 million in CPRIT grant funds for PTX-35, which we expect to receive in the third quarter of this year, should provide us sufficient capital to advance our clinical programs and achieve a number of major milestones through the end of 2019."

Second Quarter 2018 Corporate Highlights

- On April 18, 2018, Heat Biologics released guidance regarding major upcoming milestones through Q3, 2019.
- On May 7, 2018, Heat Biologics announced the closing of \$20.7 million public offering.

Second Quarter 2018 Financial Results

- Recognized \$1.1 million of grant revenue for qualified expenditures under the CPRIT grant.
- Research and development expenses increased approximately 59.1% to \$3.5 million for the quarter ended June 30, 2018 compared to \$2.2 million for the quarter ended June 30, 2017. The \$1.3 million increase is due in part to PTX expenses, as the Company began pre-clinical development of PTX-35 and PTX-15 against TNFRSF25 for testing in patients.
- General and administrative expense decreased approximately 12.5% to \$1.4 million for the quarter ended June 30, 2018 compared to \$1.6 million for the quarter ended June 30, 2017. The \$0.2 million decrease is primarily attributable to the acquisition costs of the Pelican subsidiary during the three months ended June 30, 2017.
- Net loss attributable to Heat Biologics was approximately \$4.1 million, or (\$0.27) per basic and diluted share for the quarter ended June 30, 2018 compared to a net loss of approximately \$3.2 million, or (\$0.91) per basic and diluted share for the quarter ended June 30, 2017.
- As of June 30, 2018, the Company had approximately \$24.7 million in cash and cash equivalents.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using of CD8+ "Killer" T-cells. Our T-Cell Activation Platform (TCAP) produces therapies designed to turn "cold" tumors "hot" and be administered in combination with checkpoint therapies and other immunomodulators to increase their effectiveness. HS-110 is our first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells to attack cancer. Our *ComPACT*[™] technology is the first potential, dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product. We are currently enrolling patients in our Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®). 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. We also have 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 regarding the reporting of additional interim Phase 2 data in the fourth quarter of 2018 and the completion of trial enrollment in Q2 2019, the filing of an Investigational New Drug (IND) application to initiate a Phase 1 clinical trial for our ComPACT™ trial in the fourth quarter of 2018, , the filing of an Investigational New Drug (IND) application to initiate a Phase 1 clinical trial for PTX-35 in the first quarter of 2019, receipt of the additional \$6.9 million in CPRIT grant funds for PTX-35 in the third quarter of this year and

Heat’s capital being sufficient to advance our clinical programs through a number of major milestones through the end of 2019. 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 *ImPACT*® therapy 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, and its ability to retain its key scientists or management personnel, its ability to successfully integrate Pelican, and the other factors described in Heat’s most recent annual report on Form 10-K and other 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.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
Unaudited

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenue	\$ 1,143	\$ 411	\$ 1,896	\$ 435
Operating expenses:				
Research and development	3,480	2,152	6,353	3,965
General and administrative	1,361	1,582	3,142	3,109
Change in fair value of contingent consideration	540	-	551	-
Loss from operations	(4,238)	(3,323)	(8,150)	(6,639)
Interest income	44	6	48	12
Other income, net	(53)	8	122	77
Net loss	(4,247)	(3,309)	(7,980)	(6,550)
Net loss non-controlling interest	(197)	(90)	(403)	(141)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (4,050)</u>	<u>\$ (3,219)</u>	<u>\$ (7,577)</u>	<u>\$ (6,409)</u>
Net loss per share attributable to Heat Biologics, Inc.				
- basic and diluted	<u>\$ (0.27)</u>	<u>\$ (0.91)</u>	<u>\$ (0.77)</u>	<u>\$ (2.06)</u>
Weighted-average number of common shares used				
in net loss per share calculation - basic and diluted	<u>14,727,682</u>	<u>3,524,483</u>	<u>9,894,367</u>	<u>3,112,412</u>

Condensed Consolidated Balance Sheets
(In thousands)
Unaudited

	<u>June 30,</u>	<u>December 31,</u>
	<u>2018</u>	<u>2017</u>
Assets		
Cash and cash equivalents	\$ 24,661	\$ 9,763
Goodwill and In-process R&D	8,055	8,055
Other assets	4,748	2,371
Total Assets	<u>\$ 37,464</u>	<u>\$ 20,189</u>
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	\$ 7,555	\$ 10,497
Contingent consideration	3,160	2,609
Deferred tax liability	1,302	1,302
Total Liabilities	12,017	14,408
Common stock	5	1
Additional paid-in-capital	103,953	76,382
Accumulated deficit	(76,423)	(68,846)
Accumulated other comprehensive loss	(95)	(166)
Non-Controlling Interest	(1,993)	(1,590)
Total Liabilities and Stockholders' Equity	<u>\$ 37,464</u>	<u>\$ 20,189</u>