

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 9, 2020**

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, Suite 400
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 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 Stock Market, LLC (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 9, 2020, Heat Biologics, Inc., a Delaware corporation (the “Registrant”), issued the attached press release that included financial information for its quarter ended September 30, 2020. 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
<u>99.1</u>	<u>Press Release issued by Heat Biologics, Inc. November 9, 2020.</u>

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 9, 2020

HEAT BIOLOGICS, INC.

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

Heat Biologics Provides Third Quarter 2020 Business Update

Continued progress on oncology and COVID-19 Vaccine Programs

Over \$117 million in cash and short-term investments

Durham, NC – November 9, 2020 – Heat Biologics, Inc. (“Heat”) (NASDAQ: HTBX), a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, including multiple oncology product candidates and a novel COVID-19 vaccine, today provided financial, clinical and operational updates for the third quarter ended September 30, 2020.

Jeff Wolf, Chief Executive Officer of Heat, commented, "We continue to make progress on both our oncology and COVID-19 vaccine programs. We presented data for HS-110 in combination with Nivolumab in our Phase 2 lung cancer trial at the 2020 American Society of Clinical Oncology Annual Meeting demonstrating a strong survival benefit in a cohort of previously treated checkpoint inhibitor naïve patients with advanced non-small cell lung cancer (NSCLC). We are actively pursuing a variety of strategies to maximize value for the program."

"At the same time, we continue to advance PTX-35, our potential first-in-class T-cell co-stimulatory antibody, through clinical development. Earlier this year, we initiated the first clinical trial site for PTX-35 in multiple solid tumors and began dosing patients in the Phase 1 clinical trial. PTX-35 is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. This study is expected to enroll up to 30 patients with advanced solid tumors refractory to standard of care."

"Importantly, we announced preclinical data for our gp96-based COVID-19 vaccine. The data, generated at the University of Miami Miller School of Medicine and published in bioRxiv, shows robust T-cell mediated immune response directed against the spike protein of SARS-CoV-2. Our gp96-based COVID-19 vaccine induced the expansion of both "killer" CD8+ T-cells that destroy virus infected cells, as well as "helper" CD4+ T-cells that assist in producing highly specific antibodies. As a result, we believe our vaccine has the potential to be used as either a standalone vaccine, or in combination with other antibody-focused vaccine approaches to enhance prophylactic protection. These results highlight the potential utility and versatility of our vaccine platform to address SARS-CoV-2, relevant mutations and other pathogens of interest."

"We continue to strengthen our IP portfolio and were recently awarded an additional U.S. patent covering Heat's gp96 platform in combination with a T cell costimulatory agonist in a single therapy. We believe the combination of our gp96 platform in a single therapy holds enormous promise in the prevention and treatment of cancer and infectious diseases, such as COVID-19."

"Finally, we have maintained a solid balance sheet with over \$117 million of cash and short-term investments as of September 30, 2020. We believe this capital will provide us significant runway to achieve a number of important clinical milestones that we believe will drive value for shareholders in the months and years ahead," concluded Mr. Wolf.

Third Quarter 2020 Financial Results

- Recognized \$0.8 million of grant revenue for qualified expenditures under the CPRIT and NIH grants. No grant revenue was recognized under the respective grants for the three months ended September 30, 2019. The increase in grant revenue in the current-year period primarily reflects the expected timing of completion of deliveries under the current phase of the contracts. As of September 30, 2020, we had deferred revenue of \$1.2 million for CPRIT proceeds received but for which the costs had not been incurred or the conditions of the award had not been met.
 - Research and development expenses was \$3.2 million and \$3.1 million for the three months ended September 30, 2020 and 2019, respectively.
 - General and administrative expense was \$6.6 million and \$2.0 million for the three months ended September 30, 2020 and 2019. General and administrative expenses primarily consist of personnel costs, including stock-based compensation expense, and consulting expenses to manage the business.
 - Net loss attributable to Heat Biologics was approximately \$8.9 million, or (\$0.06) per basic and diluted share for the quarter ended September 30, 2020 compared to a net loss of approximately \$6.2 million, or (\$0.18) per basic and diluted share for the quarter ended September 30, 2019.
 - As of September 30, 2020, the Company had approximately \$117.3 million in cash, cash equivalents and short investments.
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About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system. The company's gp96 platform is designed to activate immune responses against cancer or pathogenic antigens. The Company has multiple product candidates in development leveraging the gp96 platform, including HS-110, which has completed enrollment in its Phase 2 trial, HS-130 in Phase 1, and a COVID-19 vaccine program in preclinical development. In addition, Heat is also developing a pipeline of proprietary immunomodulatory antibodies, including PTX-35 which is enrolling in a Phase 1 trial.

For more information, please visit: www.heatbio.com, and also follow us on Twitter.

Forward Looking Statement

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, expectation, and assumptions and include statements such as PTX-35 being the potential first-in-class T- cell costimulatory antibody, the expected enrollment of the Phase 1 PTX-35 study, the potential of Heat's COVID-19 vaccine to be used as either a standalone vaccine or in combination with other antibody-focused vaccine approaches to enhance prophylactic protection, the combination of Heat's gp96 platform in a single therapy holding enormous promise in the prevention and treatment of cancer and infectious diseases, such as COVID-19 and Heat's capital providing a significant runway to achieve a number of important clinical milestones that will drive value for shareholders in the months and years ahead. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's vaccine platform to provide protection against COVID-19, 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, especially in light of COVID-19, 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 continue to maintain its listing on the Nasdaq Capital Market and its ability to retain its key scientists or management personnel, and the other factors described in Heat's most recent annual report on Form 10-K filed with the SEC, and other subsequent filings with the SEC. The information in this release is provided only as of the date of this release, and Heat 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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HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	September 30,	December 31,
	2020	2019
	(unaudited)	
Current Assets		
Cash and cash equivalents	\$ 24,808,083	\$ 9,039,887
Short-term investments	92,501,019	5,713,922
Accounts receivable	212,141	34,986
Prepaid expenses and other current assets	1,620,504	420,328
Total Current Assets	119,141,747	15,209,123
Property and Equipment, net	720,396	559,410
Other Assets		
In-process R&D	5,866,000	5,866,000
Goodwill	1,452,338	1,452,338
Operating lease right-of-use asset	2,123,414	2,287,500
Finance lease right-of-use asset	276,918	187,573
Deposits	129,505	394,637
Total Other Assets	9,848,175	10,188,048
Total Assets	\$ 129,710,318	\$ 25,956,581
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 753,872	\$ 1,503,342
Deferred revenue, current portion	1,166,481	3,410,319
Contingent consideration, current portion	—	1,124,970
Contingent consideration, related party - current portion	—	454,364
Operating lease liability, current portion	271,703	216,832
Finance lease liability, current portion	106,409	49,104
Accrued expenses and other liabilities	1,503,899	1,676,467
Total Current Liabilities	3,802,364	8,435,398
Long Term Liabilities		
Other long-term liabilities	26,331	—
Derivative warrant liability	60,915	—
Deferred tax liability	361,911	361,911
Deferred revenue, net of current portion	240,000	200,000
Operating lease liability, net of current portion	1,374,141	1,519,574
Financing lease liability, net of current portion	187,881	142,667
Contingent consideration, net of current portion	2,131,830	1,653,197
Contingent consideration, related party - net of current portion	626,685	485,984
Total Liabilities	8,812,058	12,798,731
Commitments and Contingencies (Note 13)		
Stockholders' Equity		
Common stock, \$.0002 par value; 250,000,000 shares authorized, 157,021,194 and 33,785,999 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	31,402	6,757
Additional paid-in capital	245,740,939	118,173,843
Accumulated deficit	(124,195,893)	(104,597,748)
Accumulated other comprehensive loss	(35,910)	(11,250)
Total Stockholders' Equity - Heat Biologics, Inc.	121,540,538	13,571,602
Non-Controlling Interest	(642,278)	(413,752)
Total Stockholders' Equity	120,898,260	13,157,850
Total Liabilities and Stockholders' Equity	\$ 129,710,318	\$ 25,956,581

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Grant and contract revenue	\$ 849,732	\$ 6,439	\$ 2,344,777	\$ 1,049,988
Operating expenses:				
Research and development	3,172,663	3,129,356	8,745,966	9,725,744
General and administrative	6,579,193	1,993,136	11,651,415	7,201,196
Goodwill impairment loss	—	737,000	—	737,000
Change in fair value of contingent consideration	229,000	502,000	1,045,000	728,290
Total operating expenses	<u>9,980,856</u>	<u>6,361,492</u>	<u>21,442,381</u>	<u>18,392,230</u>
Loss from operations	<u>(9,131,124)</u>	<u>(6,355,053)</u>	<u>(19,097,604)</u>	<u>(17,342,242)</u>
Change in fair value of warrant liability	(37,230)	—	(1,039,303)	—
Investor relations expense	—	—	(66,767)	—
Interest income	140,614	97,415	249,404	373,060
Other income (expense), net	111,307	(73,275)	127,599	(80,539)
Total non-operating income (loss)	<u>214,691</u>	<u>24,140</u>	<u>(729,067)</u>	<u>292,521</u>
Net loss before income taxes	(8,916,433)	(6,330,913)	(19,826,671)	(17,049,721)
Income tax expense	—	—	—	(45,178)
Net loss	<u>(8,916,433)</u>	<u>(6,330,913)</u>	<u>(19,826,671)</u>	<u>(17,094,899)</u>
Net loss - non-controlling interest	(64,824)	(136,315)	(228,526)	(413,955)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (8,851,609)</u>	<u>\$ (6,194,598)</u>	<u>\$ (19,598,145)</u>	<u>\$ (16,680,944)</u>
Net loss per share attributable to Heat Biologics, Inc.-				
Net loss per share attributable to Heat Biologics, Inc.-basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.18)</u>	<u>\$ (0.20)</u>	<u>\$ (0.50)</u>
Weighted-average number of common shares used in net loss per share attributable to common stockholders-				
Weighted-average number of common shares used in net loss per share attributable to Heat Biologics, Inc.—basic and diluted	143,728,870	33,650,829	96,481,271	33,255,535
Comprehensive loss:				
Net loss	\$ (8,916,433)	\$ (6,330,913)	\$ (19,826,671)	\$ (17,094,899)
Unrealized (loss) gain on foreign currency translation	(63,954)	63,711	(24,660)	72,134
Total comprehensive loss	<u>(8,980,387)</u>	<u>(6,267,202)</u>	<u>(19,851,331)</u>	<u>(17,022,765)</u>
Comprehensive loss attributable to non-controlling interest	(64,824)	(136,315)	(228,526)	(413,955)
Comprehensive loss - Heat Biologics, Inc.	<u>\$ (8,915,563)</u>	<u>\$ (6,130,887)</u>	<u>\$ (19,622,805)</u>	<u>\$ (16,608,810)</u>