

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 7, 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 (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 August 7, 2020, Heat Biologics, Inc., a Delaware corporation (the “Registrant”), issued the attached press release that included financial information for its quarter ended June 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. August 7, 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: August 7, 2020

HEAT BIOLOGICS, INC.

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



Heat Biologics Provides Second Quarter 2020 Business Update

Progress on COVID-19 Vaccine Program

*Reports over \$100 million in cash and
short-term investments as of August 6, 2020*

Durham, NC – August 7, 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 second quarter ended June 30, 2020.

Jeff Wolf, Chief Executive Officer of Heat Biologics, commented, “This quarter we achieved significant milestones in advancing our unique COVID-19 vaccine program, which we are developing in collaboration with researchers at University of Miami. Specifically, our latest pre-clinical studies demonstrated immunogenicity proof-of-concept, validating that the selected vaccine antigen may be appropriate for human testing. Preclinical testing demonstrated expansion of antibody-supporting CD4+, and virus killing CD8+ T-cells in the lungs of the animals, a major site for COVID-19 infection. We believe this platform may play an important role as a standalone vaccine or in combination with other antibody-generating vaccines to provide broad cellular T-cell and humoral protection against COVID-19, particularly for elderly patients and those with underlying health conditions who have an increased risk of complications and death from COVID-19.”

“Additionally, we established a partnership with Waisman Biomanufacturing to manufacture our COVID-19 vaccine for anticipated Phase 1 trials in humans. We believe that the unique capabilities and previous expertise gained working with Waisman on our cancer programs, HS-110 and HS-130 that are based upon the same gp96 platform, will help shorten the development timeline for our COVID-19 vaccine.”

“We recently presented our latest data for HS-110 in combination with Nivolumab in our Phase 2 lung cancer trial at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting. Importantly, this data demonstrated a strong survival benefit in a cohort of previously treated checkpoint inhibitor (CPI) naïve patients with advanced non-small cell lung cancer (NSCLC) and further reinforced the potential utility of HS-110 in combination with a checkpoint inhibitor as a frontline treatment for NSCLC.”

“We also continue to accelerate PTX-35, our potential first-in-class T-cell co-stimulatory antibody, through clinical development. Specifically, we announced patient enrollment in our first-in-human clinical trial in multiple solid tumors following FDA clearance of our Investigational New Drug (IND) application. This study is expected to enroll up to 30 patients with advanced solid tumors refractory to standard of care.”

“We have continued to strengthen our balance sheet, and now have over \$100 million in cash and short-term investments as of August 6, 2020, which should provide us with the resources to significantly advance our clinical programs,” concluded Mr. Wolf.

Second Quarter 2020 Financial Results

- Recognized \$0.6 million of grant revenue for qualified expenditures under the CPRIT grant compared to \$0.3 million for the quarter ended June 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 contract. As of June 30, 2020, we had deferred revenue of \$1.9 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 decreased approximately 17.6% to \$2.8 million for the three months ended June 30, 2020 compared to \$3.4 million for the quarter ended June 30, 2019.
 - General and administrative expense was \$1.8 million and \$1.9 million for the quarters ending June 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 \$4.5 million, or (\$0.05) per basic and diluted share for the quarter ended June 30, 2020 compared to a net loss of approximately \$4.8 million, or (\$0.14) per basic and diluted share for the quarter ended June 30, 2019.
 - As of June 30, 2020, the Company had approximately \$47 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 the platform playing an important role as a standalone vaccine or in combination with other antibody-generating vaccines to provide broad cellular T-cell and humoral protection against COVID-19, particularly for elderly patients and those with underlying health conditions that have an increased risk of complications and death from COVID-19, the unique capabilities and previous expertise gained working with Waisman on HS-130 helping shorten the clinical timeline for our potentially life-saving COVID-19 vaccine, the potential utility of HS-110 in combination with a checkpoint inhibitor as a frontline treatment for NSCLC, the continued acceleration of PTX-35, our potential first-in-class T-cell co-stimulatory antibody, through clinical development, the enrollment in the PTX-35 clinical trial of up to 30 patients with advanced solid tumors refractory to standard of care and having sufficient capital to significantly advance our clinical programs. 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.

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HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	<u>June 30,</u> <u>2020</u> (unaudited)	<u>December 31,</u> <u>2019</u>
Current Assets		
Cash and cash equivalents	\$ 20,668,241	\$ 9,039,887
Short-term investments	26,312,039	5,713,922
Accounts receivable	26,967	34,986
Prepaid expenses and other current assets	593,924	420,328
Total Current Assets	<u>47,601,171</u>	<u>15,209,123</u>
Property and Equipment, net	<u>669,401</u>	<u>559,410</u>
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	2,134,573	2,287,500
Finance lease right-of-use asset	306,643	187,573
Deposits	122,905	394,637
Total Other Assets	<u>9,882,459</u>	<u>10,188,048</u>
Total Assets	<u><u>\$ 58,153,031</u></u>	<u><u>\$ 25,956,581</u></u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 779,642	\$ 1,503,342
Deferred revenue, current portion	1,915,924	3,410,319
Contingent consideration, current portion	1,531,636	1,124,970
Contingent consideration, related party - current portion	454,364	454,364
Operating lease liability, current portion	228,776	216,832
Finance lease liability, current portion	104,828	49,104
Accrued expenses and other liabilities	1,202,705	1,676,467
Total Current Liabilities	<u>6,217,875</u>	<u>8,435,398</u>
Long Term Liabilities		
Other long-term liabilities	22,847	—
Derivative warrant liability	47,939	—
Deferred tax liability	361,911	361,911
Deferred revenue, net of current portion	200,000	200,000
Operating lease liability, net of current portion	1,402,962	1,519,574
Financing lease liability, net of current portion	215,112	142,667
Contingent consideration, net of current portion	1,969,538	1,653,197
Contingent consideration, related party - net of current portion	578,977	485,984
Total Liabilities	<u>11,017,161</u>	<u>12,798,731</u>
Stockholders' Equity		
Common stock, \$.0002 par value; 250,000,000 shares authorized, 110,023,783 and 33,785,999 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	22,006	6,757
Additional paid-in capital	163,007,558	118,173,843
Accumulated deficit	(115,344,284)	(104,597,748)
Accumulated other comprehensive income (loss)	28,044	(11,250)
Total Stockholders' Equity - Heat Biologics, Inc.	<u>47,713,324</u>	<u>13,571,602</u>
Non-Controlling Interest	<u>(577,454)</u>	<u>(413,752)</u>
Total Stockholders' Equity	<u>47,135,870</u>	<u>13,157,850</u>
Total Liabilities and Stockholders' Equity	<u><u>\$ 58,153,031</u></u>	<u><u>\$ 25,956,581</u></u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
Grant and licensing revenue	\$ 593,165	\$ 342,487	\$ 1,495,045	\$ 1,043,549
Operating expenses:				
Research and development	2,790,797	3,424,141	5,573,303	6,596,388
General and administrative	1,801,674	1,860,459	5,072,222	5,208,060
Change in fair value of contingent consideration	843,000	112,000	816,000	226,290
Total operating expenses	<u>5,435,471</u>	<u>5,396,600</u>	<u>11,461,525</u>	<u>12,030,738</u>
Loss from operations	<u>(4,842,306)</u>	<u>(5,054,113)</u>	<u>(9,966,480)</u>	<u>(10,987,189)</u>
Change in fair value of warrant liability	(24,363)	—	(1,002,073)	—
Investor relations expense	—	—	(66,767)	—
Interest income	56,080	124,793	108,790	275,645
Other income (expense), net	273,771	(15,585)	16,292	(7,264)
Total non-operating income (loss)	<u>305,488</u>	<u>109,208</u>	<u>(943,758)</u>	<u>268,381</u>
Net loss before income taxes	(4,536,818)	(4,944,905)	(10,910,238)	(10,718,808)
Income tax expense	—	—	—	(45,178)
Net loss	<u>(4,536,818)</u>	<u>(4,944,905)</u>	<u>(10,910,238)</u>	<u>(10,763,986)</u>
Net loss - non-controlling interest	(82,388)	(174,035)	(163,702)	(277,640)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (4,454,430)</u>	<u>\$ (4,770,870)</u>	<u>\$ (10,746,536)</u>	<u>\$ (10,486,346)</u>
Net loss per share attributable to Heat Biologics, Inc.-				
Net loss per share attributable to Heat Biologics, Inc.-basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.14)</u>	<u>\$ (0.15)</u>	<u>\$ (0.32)</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	87,930,846	33,255,724	72,606,461	33,240,529
Comprehensive loss:				
Net loss	\$ (4,536,818)	\$ (4,944,905)	\$ (10,910,238)	\$ (10,763,986)
Unrealized (loss) gain on foreign currency translation	(179,510)	16,612	39,294	8,423
Total comprehensive loss	<u>(4,716,328)</u>	<u>(4,928,293)</u>	<u>(10,870,944)</u>	<u>(10,755,563)</u>
Comprehensive loss attributable to non-controlling interest	(82,388)	(174,035)	(163,702)	(277,640)
Comprehensive loss - Heat Biologics, Inc.	<u>\$ (4,633,940)</u>	<u>\$ (4,754,258)</u>	<u>\$ (10,707,242)</u>	<u>\$ (10,477,923)</u>