

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 10, 2021**

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 10, 2021, Heat Biologics, Inc., a Delaware corporation (the “Registrant”), issued the attached press release that included financial information for its quarter ended September 30, 2021. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in this Item 2.02 and 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 10, 2021.</u>
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

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 10, 2021

HEAT BIOLOGICS, INC.

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



Heat Biologics Provides Third Quarter 2021 Business Update

Durham, NC – November 10, 2021 – Heat Biologics, Inc. (“Heat”) (NASDAQ: HTBX), today provided strategic, financial, and operational updates for the third quarter ended September 30, 2021.

Jeff Wolf, Chief Executive Officer of Heat, commented, “Our clinical and preclinical programs are progressing well. In September, we expanded dosing in our Phase 1 clinical trial of monoclonal antibody PTX-35 in patients with solid tumors, and are planning a clinical development pathway to utilize PTX-35 in the context of inflammatory disease. We are also preparing for an end of Phase 2 meeting with the FDA for HS-110 to discuss potential Phase 3 registration pathways.”

“Additionally, we recently announced our new biosecurity/biodefense initiative, which leverages our gp96 platform against known or unknown future biological threats. In the short time since launching this program, we have filed patents to protect our proprietary technology and have established collaborations with leading institutions to advance our research. At the same time, we’ve assembled a knowledgeable and experienced biothreat advisory board that is well-versed on our biothreat platform. We plan to provide further updates on our biodefense efforts in the near future.”

“Our strategic vision is to become a fully integrated, immune system-focused biopharmaceutical company, and we continue to evolve in that direction. In August we announced the groundbreaking of our new wholly-owned Scorpion biomanufacturing and bioanalytic subsidiary, which is designed to support our internal manufacturing needs as we advance our programs as well as to offer much-needed biomanufacturing/bioanalytic services to other biotech and pharmaceutical clients. Our ultimate goal is to reduce development costs, accelerate development timelines, and ensure the highest levels of quality by controlling the entire process internally. Overall, we have maintained a solid balance sheet and are well positioned to execute on a number of key milestones that we believe will drive significant value for shareholders.”

Third Quarter 2021 Financial Results

- Recognized \$0.5 million of grant revenue for qualified expenditures under the CPRIT grant for the quarter ended September 30, 2021 compared to \$0.8 million for the quarter ended September 30, 2020. The decrease 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, 2021, we had a grant receivable balance of \$0.9 million for CPRIT proceeds not yet received but for which the costs had been incurred or the conditions of the award had been met. We continue our efforts to secure future non-dilutive grant funding to subsidize ongoing research and development costs.
 - Research and development expense was \$4.4 million and \$3.2 million for the three months ended September 30, 2021 and 2020, respectively.
 - General and administrative expense was \$3.4 million and \$6.6 million for the three months ended September 30, 2021 and 2020. The decrease was primarily due to a decrease in stock-based compensation expense of \$3.9 million.
 - Net loss attributable to Heat Biologics was approximately \$7.4 million, or (\$0.30) per basic and diluted share for the quarter ended September 30, 2021 compared to a net loss of approximately of \$8.9 million, or (\$0.43) per basic and diluted share for the quarter ended September 30, 2020.
 - As of September 30, 2021, the Company had approximately \$108.9 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. Heat's gp96 platform is designed to activate immune responses against cancer or infectious diseases. The Company has multiple product candidates in development leveraging the gp96 platform, including HS-110, which has completed enrollment in a Phase 2 trial, various infectious disease/biological threat programs in preclinical development and a pipeline of proprietary immunomodulatory antibodies and cell-based therapies, including PTX-35 and HS-130 in Phase 1 clinical trials.

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 regarding, plans for a clinical development pathway for PTX-35 in inflammatory disease, the vision to become a fully integrated immune system-focused biopharmaceutical company, providing further updates on our biodefense efforts in the near future, reducing development costs, accelerating development timelines, and ensuring the highest levels of quality control at Scorpion by overseeing the entire process internally and being well positioned to execute on a number of key upcoming milestones and driving significant value for shareholders. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including Heat's ability to advance a clinical development pathway for PTX-35 in inflammatory disease, Heat's ability to implement Heat's vision to become a fully integrated immune system-focused biopharmaceutical company, Heat's ability to leverage its gp96 platform for its new biosecurity/biodefense initiative, Heat's ability to reduce development costs, accelerate development timelines and ensure the highest levels of quality control, Heat's ability to provide further near-term updates on its biodefense efforts, execute on key upcoming milestones and drive shareholder value, Heat's ability to augment its clinical programs and enhance and expand its therapeutic pipeline, 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 and its cash and short-term investments providing significant runway to fund Heat's current clinical programs and further expand Heat's therapeutic portfolio, 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 annual report on Form 10-K for the year ended December 31, 2020 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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(tables follow)

HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	September 30, 2021	December 31, 2020
	(unaudited)	
Current Assets		
Cash and cash equivalents	\$ 7,882,412	\$ 10,931,890
Short-term investments	101,032,250	100,842,438
Accounts receivable	71,420	177,239
Prepaid expenses and other current assets	2,845,226	1,842,620
Total Current Assets	<u>111,831,308</u>	<u>113,794,187</u>
Property and Equipment, net	<u>1,766,898</u>	<u>676,262</u>
Other Assets		
In-process R&D	5,866,000	5,866,000
Goodwill	1,452,338	1,452,338
Grant receivable	870,032	—
Operating lease right-of-use asset	1,885,681	2,035,882
Finance lease right-of-use asset	533,561	247,194
Other assets	8,199,850	—
Deposits	249,557	122,779
Total Other Assets	<u>19,057,019</u>	<u>9,724,193</u>
Total Assets	<u>\$ 132,655,225</u>	<u>\$ 124,194,642</u>
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 1,065,663	\$ 1,051,764
Deferred revenue, current portion	—	603,717
Operating lease liability, current portion	341,977	278,753
Finance lease liability, current portion	222,313	108,127
Accrued expenses and other liabilities	1,660,288	1,614,534
Total Current Liabilities	<u>3,290,241</u>	<u>3,656,895</u>
Long Term Liabilities		
Other long-term liabilities	50,511	36,243
Derivative warrant liability	30,971	33,779
Deferred tax liability	361,911	361,911
Deferred revenue, net of current portion	237,500	237,500
Operating lease liability, net of current portion	1,152,008	1,301,636
Financing lease liability, net of current portion	348,128	160,240
Contingent consideration	2,564,608	2,250,844
Contingent consideration, related party	753,907	661,671
Total Liabilities	<u>8,789,785</u>	<u>8,700,719</u>
Commitments and Contingencies		
Stockholders' Equity		
Common stock, \$.0002 par value; 250,000,000 and 250,000,000 shares authorized, 25,143,315 and 22,592,500 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	5,028	4,519
Additional paid-in capital	277,097,787	247,048,349
Accumulated deficit	(152,155,580)	(130,647,485)
Accumulated other comprehensive loss	(52,545)	(166,056)
Total Stockholders' Equity - Heat Biologics, Inc.	<u>124,894,690</u>	<u>116,239,327</u>
Non-Controlling Interest	<u>(1,029,250)</u>	<u>(745,404)</u>
Total Stockholders' Equity	<u>123,865,440</u>	<u>115,493,923</u>
Total Liabilities and Stockholders' Equity	<u>\$ 132,655,225</u>	<u>\$ 124,194,642</u>

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Revenue:				
Grant and contract revenue	\$ 501,567	\$ 849,732	\$ 1,499,706	\$ 2,344,777
Operating expenses:				
Research and development	4,381,542	3,172,663	12,004,084	8,745,966
General and administrative	3,390,093	6,579,193	11,011,003	11,651,415
Change in fair value of contingent consideration	295,000	229,000	406,000	1,045,000
Total operating expenses	<u>8,066,635</u>	<u>9,980,856</u>	<u>23,421,087</u>	<u>21,442,381</u>
Loss from operations	<u>(7,565,068)</u>	<u>(9,131,124)</u>	<u>(21,921,381)</u>	<u>(19,097,604)</u>
Change in fair value of warrant liability	6,831	(37,230)	2,808	(1,039,303)
Investor relations expense	—	—	—	(66,767)
Interest income	195,344	140,614	567,307	249,404
Other (expense) income, net	(185,332)	111,307	(440,675)	127,599
Total non-operating income (loss)	<u>16,843</u>	<u>214,691</u>	<u>129,440</u>	<u>(729,067)</u>
Net loss before income taxes	(7,548,225)	(8,916,433)	(21,791,941)	(19,826,671)
Income tax expense	—	—	—	—
Net loss	<u>(7,548,225)</u>	<u>(8,916,433)</u>	<u>(21,791,941)</u>	<u>(19,826,671)</u>
Net loss - non-controlling interest	<u>(115,505)</u>	<u>(64,824)</u>	<u>(283,846)</u>	<u>(228,526)</u>
Net loss attributable to Heat Biologics, Inc.	<u>\$ (7,432,720)</u>	<u>\$ (8,851,609)</u>	<u>\$ (21,508,095)</u>	<u>\$ (19,598,145)</u>
Net loss per share, basic and diluted	<u>\$ (0.30)</u>	<u>\$ (0.43)</u>	<u>\$ (0.87)</u>	<u>\$ (1.42)</u>
Weighted-average common shares outstanding, basic and diluted	25,137,628	20,532,696	24,828,438	13,783,039
Comprehensive loss:				
Net loss	\$ (7,548,225)	\$ (8,916,433)	\$ (21,791,941)	\$ (19,826,671)
Unrealized gain (loss) on foreign currency translation	<u>68,582</u>	<u>(63,954)</u>	<u>113,511</u>	<u>(24,660)</u>
Total comprehensive loss	<u>(7,479,643)</u>	<u>(8,980,387)</u>	<u>(21,678,430)</u>	<u>(19,851,331)</u>
Comprehensive loss attributable to non-controlling interest	<u>(115,505)</u>	<u>(64,824)</u>	<u>(283,846)</u>	<u>(228,526)</u>
Comprehensive loss - Heat Biologics, Inc.	<u>\$ (7,364,138)</u>	<u>\$ (8,915,563)</u>	<u>\$ (21,394,584)</u>	<u>\$ (19,622,805)</u>