

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): **May 15, 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 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 May 15, 2020, Heat Biologics, Inc., a Delaware corporation (the “Registrant”), issued the attached press release that included financial information for its quarter ended March 31, 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. Dated May 15, 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: May 15, 2020

HEAT BIOLOGICS, INC.

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



Heat Biologics Provides First Quarter 2020 Business Update

Durham, NC – May 15, 2020 – Heat Biologics, Inc. (“Heat”) (NASDAQ: HTBX), a clinical-stage biopharmaceutical company specialized in the development of novel therapeutic and prophylactic vaccines, including one for coronavirus COVID-19, today provided financial, clinical and operational updates for the first quarter ended March 31, 2020.

Jeff Wolf, Chief Executive Officer of Heat Biologics, commented, “We continue to make progress advancing our unique COVID-19 vaccine utilizing our robust gp-96 vaccine platform in collaboration with researchers at University of Miami. We plan to commence preclinical testing for the COVID-19 vaccine this quarter and are finalizing our manufacturing plans, which we believe will help shorten the clinical timeline. Additionally, we are applying for grants to support clinical development of this program and are advancing collaboration discussions. Earlier this year we also announced a collaboration with the University of Miami to develop a proprietary COVID-19 point-of-care diagnostic test. We suspended this program due to the progress made by other diagnostic manufacturers utilizing a similar approach, and our desire to focus resources on our highly-differentiated COVID-19 vaccine. Nevertheless, in the process, we developed our own unique diagnostic intellectual property, and plan to opportunistically explore partnership opportunities around this technology.”

“We also continue to achieve key milestones related to HS-110 in combination with Opdivo® (nivolumab) in advanced non-small cell lung cancer (NSCLC). We recently announced that an abstract has been posted on The American Society of Clinical Oncology’s (ASCO) website. We look forward to presenting additional data at the upcoming ASCO Conference on May 29. Importantly, given the strength of the data, we plan to initiate an end of Phase 2 Type B meeting with the FDA to discuss our registrational strategy.

“We ended the quarter with over \$26 million of cash and short-term investments as of March 31, 2020, which we believe provides us significant resources to advance each of our programs,” concluded Mr. Wolf.

Q1 2020 Financial Results

- Research and development expenses decreased approximately 12.5% to \$2.8 million for the quarter ended March 31, 2020 compared to \$3.2 million for the quarter ended March 31, 2019.
 - General and administrative expense was \$3.3 million for the quarters ending March 31, 2020 and 2019.
 - Net loss attributable to Heat Biologics was approximately \$6.3 million, or (\$0.11) per basic and diluted share for the quarter ended March 31, 2020 compared to a net loss of \$5.7 million, or (\$0.17) per basic and diluted share for the quarter ended March 31, 2019.
 - As of March 31, 2020, the Company had approximately \$26.4 million in cash, cash equivalents and short-term investments.
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About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer and other diseases using its proprietary gp96 platform to activate CD8+ "Killer" T-cells. Heat has completed enrollment in its Phase 2 clinical trial for advanced non-small cell lung cancer with its gp96-based HS-110 therapeutic vaccine. 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. Heat Biologics has also launched a program in collaboration with the University of Miami to develop a vaccine designed to protect against the COVID-19 coronavirus. Heat has numerous other pre-clinical programs at various stages of development. For more information, please visit www.heatbio.com.

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 continuing to make progress advancing our unique COVID-19 vaccine utilizing our robust gp-96 vaccine platform in collaboration with researchers at University of Miami, plans to commence preclinical testing for the COVID-19 vaccine this quarter, finalizing our manufacturing plans, which we believe will help shorten the clinical timeline, plans to opportunistically explore partnership opportunities around the diagnostic intellectual property, presenting additional data at the upcoming ASCO Conference on May 29, plans to initiate an end of Phase 2 Type B meeting with the FDA to discuss our registrational strategy and cash and short-term investments as of March 31, 2020, providing us significant resources to advance each of our 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.

Media and Investor Relations Contact

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HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	March 31, 2020 (unaudited)	December 31, 2019
Current Assets		
Cash and cash equivalents	\$ 20,738,776	\$ 9,039,887
Short-term investments	5,706,082	5,713,922
Accounts receivable	144,119	34,986
Prepaid expenses and other current assets	537,653	420,328
Total Current Assets	27,126,630	15,209,123
Property and Equipment, net	705,553	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	2,211,506	2,287,500
Finance lease right-of-use asset	336,368	187,573
Deposits	122,905	394,637
Total Other Assets	9,989,117	10,188,048
Total Assets	\$ 37,821,300	\$ 25,956,581
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 1,350,476	\$ 1,503,342
Deferred revenue, current portion	2,508,809	3,410,319
Contingent consideration, current portion	1,659,000	1,579,334
Operating lease liability, current portion	222,752	216,832
Finance lease liability, current portion	103,269	49,104
Accrued expenses and other liabilities	1,092,235	1,676,467
Total Current Liabilities	6,936,541	8,435,398
Long Term Liabilities		
Other long-term liabilities	14,216	—
Derivative warrant liability	41,360	—
Deferred tax liability	361,911	361,911
Deferred revenue, net of current portion	200,000	200,000
Operating lease liability, net of current portion	1,462,005	1,519,574
Financing lease liability, net of current portion	241,938	142,667
Contingent consideration, net of current portion	2,032,515	2,139,181
Total Liabilities	11,290,486	12,798,731
Commitments and Contingencies (Note 9 and 13)		
Stockholders' Equity		
Common stock, \$.0002 par value; 100,000,000 shares authorized, 77,924,516 and 33,785,999 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	15,627	6,757
Additional paid-in capital	137,692,553	118,173,843
Accumulated deficit	(110,889,854)	(104,597,748)
Accumulated other comprehensive income (loss)	207,554	(11,250)
Total Stockholders' Equity - Heat Biologics, Inc.	27,025,880	13,571,602
Non-Controlling Interest	(495,066)	(413,752)
Total Stockholders' Equity	26,530,814	13,157,850
Total Liabilities and Stockholders' Equity	\$ 37,821,300	\$ 25,956,581

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

	Three Months Ended March 31,	
	2020	2019
Revenue:		
Grant and licensing revenue	\$ 901,880	\$ 701,062
Operating expenses:		
Research and development	2,782,506	3,172,247
General and administrative	3,270,548	3,347,601
Change in fair value of contingent consideration	(27,000)	114,290
Total operating expenses	6,026,054	6,634,138
Loss from operations	(5,124,174)	(5,933,076)
Change in fair value of warrant liability	(977,710)	—
Investor relations expense	(66,767)	—
Interest income	52,710	150,852
Other (expense) income, net	(257,479)	8,321
Total non-operating income (loss)	(1,249,246)	159,173
Net loss before income taxes	(6,373,420)	(5,773,903)
Income tax (expense) benefit	—	(45,178)
Net loss	(6,373,420)	(5,819,081)
Net loss - non-controlling interest	(81,314)	(103,605)
Net loss attributable to Heat Biologics, Inc.	\$ (6,292,106)	\$ (5,715,476)
Net loss per share attributable to Heat Biologics, Inc.-		
Net loss per share attributable to Heat Biologics, Inc.-basic and diluted	\$ (0.11)	\$ (0.17)
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	57,282,075	33,225,164
Comprehensive loss:		
Net loss	\$ (6,373,420)	\$ (5,819,081)
Unrealized gain (loss) on foreign currency translation	218,804	(8,189)
Total comprehensive loss	(6,154,616)	(5,827,270)
Comprehensive loss attributable to non-controlling interest	(81,314)	(103,605)
Comprehensive loss – Heat Biologics, Inc.	\$ (6,073,302)	\$ (5,723,665)