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Heat Biologics Commences Manufacturing Process for ZVX-60

DURHAM, NC / ACCESSWIRE / January 19, 2021 /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 announces it has transferred its gp96-based COVID-19 vaccine cell line ("ZVX-60") to Waisman Biomanufacturing to initiate the manufacturing process for ZVX-60, which is being developed for use as either a standalone vaccine, or in combination with other vaccines, to enhance prophylactic protection against COVID-19.

Jeff Wolf, Heat's CEO, commented, "Initiation of our manufacturing process is an important milestone as we progress ZVX-60 into human clinical trials. As previously announced, recent data generated with our collaborators at the University of Miami Miller School of Medicine confirmed ZVX-60 expression of gp96, OX40L and the COVID-19 Spike protein. We believe ZVX-60 holds promise to enhance protection as a stand-alone vaccine or in combination with other vaccine approaches, and look forward to working with Waisman to manufacture ZVX-60 for our first-in-human clinical trial."

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 ZVX-60 holding promise to enhance protection as a stand-alone vaccine or in combination withother vaccine approaches and the gp96 platform activating immune responses against cancer or

pathogenic antigens. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of ZVX-60 to enhance protection as a stand-alone vaccine or in combination with other vaccine approaches, 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

David Waldman
+1 919 289 4017
investorrelations@heatbio.com

HEAT BIOLOGICS, INC.
Consolidated Balance Sheets

	September 30, 2020 (unaudited)	December 31, 2019
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	**Nine Months Ended**

	September 30,		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	9,980,856	6,361,492	21,442,381	18,392,230
Loss from operations	(9,131,124)	(6,355,053)	(19,097,604)	(17,342,242)
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)	214,691	24,140	(729,067)	292,521
Net loss before income taxes	(8,916,433)	(6,330,913)	(19,826,671)	(17,049,721)
Income tax expense	-	-	-	(45,178)
Net loss	(8,916,433)	(6,330,913)	(19,826,671)	(17,094,899)
Net loss - non-controlling interest	(64,824)	(136,315)	(228,526)	(413,955)
Net loss attributable to Heat Biologics, Inc.	$ (8,851,609)	$ (6,194,598)	$ (19,598,145)	$ (16,680,944)
Net loss per share attributable to Heat Biologics, Inc.-				
Net loss per share attributable to Heat Biologics, Inc.-basic and diluted	$ (0.06)	$ (0.18)	$ (0.20)	$ (0.50)
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	(8,980,387)	(6,267,202)	(19,851,331)	(17,022,765)
Comprehensive loss attributable to non-controlling interest	(64,824)	(136,315)	(228,526)	(413,955)
Comprehensive loss - Heat Biologics, Inc.	$ (8,915,563)	$ (6,130,887)	$ (19,622,805)	$ (16,608,810)

SOURCE: Heat Biologics, Inc.

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https://www.accesswire.com/624776/Heat-Biologics-Commences-Manufacturing-Process-for-ZVX-60