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Heat Biologics Provides Year-End Business Update

DURHAM, NC / ACCESSWIRE / March 25, 2021 /Heat Biologics, Inc. (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 year ended December 31, 2020.

Jeff Wolf, Chief Executive Officer of Heat, commented, "We made tremendous progress on our clinical programs in 2020. Earlier this year, we reported positive interim data from our Phase 2 trial of HS-110, which demonstrated evidence of substantial survival benefit. We are currently evaluating possible Phase 3 registration pathways for HS-110 in combination with a checkpoint inhibitor and intend to review these plans with the FDA as well as potential partners. In 2020, we initiated a Phase 1 clinical trial of our first-in-class antibody therapeutic PTX-35 in patients with solid tumors. Leveraging our proprietary gp96 platform and in response to the COVID-19 pandemic, we initiated a COVID-19 vaccine program in collaboration with the University of Miami and have advanced this program forward into scale-up manufacturing. We have a strong balance sheet with approximately $132 million of cash, which should allow us to accelerate our current clinical programs and enhance our development and manufacturing capability to expand our therapeutic portfolio. We look forward executing key milestones in our growing pipeline in 2021."

Pipeline Highlights and Updates

HS-110

- In previously treated, checkpoint inhibitor naïve patients with advanced non-small cell lung cancer (NSCLC) (Cohort A, N = 47), the median overall survival (OS) observed was 24.6 months was with a median follow-up time of 19.4 months and the one-year survival rate was 61.7%.
    - The median OS data was 12.2 months and the 1-year survival rate was 50.7% in previously treated, advanced NSCLC patients who received nivolumab as a single agent, according to published data of the BMS CheckMate 057 study[1].
    - The addition of HS-110 to a checkpoint inhibitor has the potential to improve survival benefit for checkpoint inhibitor naïve NSCLC patients.
- For NSCLC patients who had previously been treated with a checkpoint inhibitor and whose disease had subsequently progressed (Cohort B, N = 68), a median OS of 11.9 months was observed.
    - Published data from other studies reported median OS of 6.8 to 9.0 months for NSCLC patients treated with chemotherapies after PD-(L)1 progression[2,3].
    - NSCLC patients whose disease progresses following checkpoint inhibitor therapy have limited treatment options[4].

    - The addition of HS-110 to a checkpoint inhibitor has the potential to improve survival benefit for NSCLC patients whose disease progressed following treatment with PD-(L)1 therapy.
- As of this data cut, there were no treatment-emergent serious adverse reactions related to HS-110.

PTX-35

- In June 2020, the Company initiated a first-in-human Phase 1 clinical trial evaluating PTX-35.
- PTX-35 is a novel, potential first-in-class antibody T-cell co-stimulator targeting TNFRSF25 (death receptor 3), a receptor that is preferentially expressed by antigen-experienced T cells. TNFRSF25 agonism leads to activation of antigen-experienced memory CD8+ T cells, which are instrumental for tumor destruction.

COVID-19

- In March 2020, the Company initiated a COVID-19 vaccine program leveraging its proprietary gp96 technology platform in collaboration with University of Miami.
- Positive preclinical data demonstrated a robust T-cell mediated immune response directed against the spike protein of SARS-CoV-2, including induction of systemic and tissue-specific memory CD8+ T-cells and tissue-resident memory CD8+ T-cells in the lung.
- The Company has initiated manufacturing of ZVX-60 and is conducting IND-enabling activities.

2020 Financial Results

- As of December 31, 2020, the Company had approximately $111.8 million in cash and cash equivalents and short-term investments.
- Research and development expenses stayed consistent at $12.9 million and $13.0 million for the years ended December 31, 2020 and December 31, 2019.
- General and administrative expense increased approximately 59% to $14.9 million for the year ended December 31, 2020 compared to $9.4 million for the year ended December 31, 2019. The increase of $5.5 million is primarily due to the increase in personnel and stock compensation expense.
- Net loss attributable to Heat Biologics, Inc. was $26.0 million, or ($1.63) per basic and diluted share for the year ended December 31, 2020 compared to a net loss attributable to Heat Biologics, Inc. of $20.0 million, or ($4.21) per basic and diluted share for the year ended December 31, 2019.

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 infectious diseases. The Company has multiple product candidates in development leveraging the gp96 platform, including HS-110, which has completed enrollment in its Phase 2 trial, and a COVID-19 vaccine program in preclinical development. In addition, Heat Biologics is also developing a pipeline of proprietary immunomodulatory antibodies and cell-based therapies, including PTX-35 and

HS-130 in Phase 1 clinical trials.

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 Heat's strong balance sheet allowing it to accelerate its current clinical programs and enhance our development and manufacturing capability to expand its therapeutic portfolio, he addition of HS-110 to a checkpoint inhibitor to improve survival benefit for NSCLC patients whose disease progressed following treatment with PD-(L)1 therapy, and possible Phase 3 registration pathways of HS-110 in combination with a checkpoint inhibitor and intended discussion of these plans with the FDA as well as potential partners. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of HS-110 when added to a checkpoint inhibitor to improve survival benefit for NSCLC patients whose disease progressed following treatment with PD-(L)1 therapy, the ability of Heat to successfully design a registrational pathway for HS-110, the ability of Heat's platform to have utility for NSCLC and potentially other types of cancer , the ability of Heat to accelerate its current clinical programs and enhance its development and manufacturing capability to expand its therapeutic portfolio, 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.

Reference

[1] Borghaei et al. Five-Year Outcomes from the Randomized, Phase III Trials CheckMate 017 and 057: Nivolumab Versus Docetaxel in Previously Treated Non-Small-Cell Lung Cancer. J Clin Oncol. 2021 Jan 15.

[2] Costantini et al. Efficacy of next treatment received after nivolumab progression in patients with advanced nonsmall cell lung cancer. ERJ Open Res. 2018 Apr 20;4(2):00120-2017.

[3] Schvartsman et al. Response rates to single-agent chemotherapy after exposure to immune checkpoint inhibitors in advanced non-small cell lung cancer. Lung Cancer. 2017 Oct;112:90-95.

[4] NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer Version 2.2021-Dec 15, 2020.

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(tables follow)

HEAT BIOLOGICS, INC.

Consolidated Balance Sheets

	December 31, 2020	December 31, 2019
Current Assets		
Cash and cash equivalents	$ 10,931,890	$ 9,039,887
Short-term investments	100,842,438	5,713,922
Accounts receivable	177,239	34,986
Prepaid expenses and other current assets	1,842,620	420,328
Total Current Assets	113,794,187	15,209,123
Property and Equipment, net	676,262	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	2,035,882	2,287,500
Finance lease right-of-use asset	247,194	187,573
Deposits	122,779	394,637
Total Other Assets	9,724,193	10,188,048
Total Assets	$ 124,194,642	$ 25,956,581
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 1,051,764	$ 1,503,342
Deferred revenue, current portion	603,717	3,410,319
Contingent consideration, current portion	-	1,124,970
Contingent consideration, related party - current portion	-	454,364
Operating lease liability, current portion	278,753	216,832
Finance lease liability, current portion	108,127	49,104
Accrued expenses and other liabilities	1,614,534	1,676,467
Total Current Liabilities	3,656,895	8,435,398

Long Term Liabilities		
Other long-term liabilities	36,243	-
Derivative warrant liability	33,779	-
Deferred tax liability	361,911	361,911
Deferred revenue, net of current portion	237,500	200,000
Operating lease liability, net of current portion	1,301,636	1,519,574
Financing lease liability, net of current portion	160,240	142,667
Contingent consideration, net of current portion	2,250,844	1,653,197
Contingent consideration, related party - net of current portion	661,671	485,984
Total Liabilities	8,700,719	12,798,731
Commitments and Contingencies		
Stockholders' Equity		
Common stock, $.0002 par value; 250,000,000 and 100,000,000 shares authorized, 22,592,500 and 4,826,565 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	4,519	965
Additional paid-in capital	247,048,349	118,179,635
Accumulated deficit	(130,647,485)	(104,597,748)
Accumulated other comprehensive loss	(166,056)	(11,250)
Total Stockholders' Equity - Heat Biologics, Inc.	116,239,327	13,571,602
Non-Controlling Interest	(745,404)	(413,752)
Total Stockholders' Equity	115,493,923	13,157,850
Total Liabilities and Stockholders' Equity	$ 124,194,642	$ 25,956,581

HEAT BIOLOGICS INC.

Consolidated Statements of Operations and Comprehensive Loss

	Year ended December 31,	
	2020	**2019**
Revenue:		
Grant and contract revenue	$ 2,947,969	$ 3,049,104
Operating expenses:		
Research and development	12,938,895	13,013,604
General and administrative	14,934,436	9,431,015
Goodwill impairment loss	-	737,000
Change in fair value of contingent consideration	1,199,000	613,290
Total operating expenses	29,072,331	23,794,909
Loss from operations	(26,124,362)	(20,745,805)
Change in fair value of warrant liability	(1,012,167)	-
Investor relations expense	(66,767)	-

Interest income	566,718	431,824
Other income (expense), net	255,189	(25,557)
Total non-operating (loss) income	(257,027)	406,267
Net loss before income taxes	(26,381,389)	(20,339,538)
Income tax expense	-	(45,178)
Net loss	(26,381,389)	(20,384,716)
Net loss - non-controlling interest	(331,652)	(367,148)
Net loss attributable to Heat Biologics, Inc.	$(26,049,737)	$(20,017,568)
Net loss per share attributable to Heat Biologics, Inc.-		
Net loss per share attributable to Heat Biologics, Inc.-basic and diluted	$ (1.63)	$ (4.21)
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	15,982,568	4,754,542
Comprehensive loss:		
Net loss	(26,381,389)	(20,384,716)
Unrealized (loss) gain on foreign currency translation	(154,806)	8,654
Total comprehensive loss	(26,536,195)	(20,376,062)
Comprehensive loss attributable to non-controlling interest	(331,652)	(367,148)
Comprehensive loss - Heat Biologics, Inc.	$(26,204,543)	$(20,008,914)

SOURCE: Heat Biologics, Inc.

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