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 29, 2020**

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction of incorporation)

001-35994	**26-2844103**
(Commission File Number)	*(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(b) 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 7.01. Regulation FD Disclosure.

On May 29, 2020, Heat Biologics, Inc. (the "Company') announced the presentation at the 2020 Annual Meeting of the American Society of Clinical Oncology (ASCO) of a poster (the "Poster") with topline data for cohort A from its ongoing Phase 2 study of HS-110 in combination with nivolumab for the treatment of advanced non-small lung cancer in multiple treatment settings. A copy of the Poster is attached hereto as Exhibit 99.1 and is incorporated herein by reference. In addition, a transcript of the virtual presentation of the Poster provided at ASCO is attached hereto as Exhibit 99.2.

The furnishing of the attached Poster is not an admission as to the materiality of any information therein. The information contained in the Poster is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the SEC and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

The information in the transcript shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 8.01 Other Information

On May 29, 2020, the Company issued a press release announcing the presentation of a poster (the "Poster") at the 2020 Annual Meeting of the American Society of Clinical Oncology (ASCO). The data presented in the Poster was obtained from cohort A from the Company's ongoing Phase 2 trial in combination with Bristol-Myers Squibb's (BMS) Opdivo® (nivolumab) for multiple treatment settings in advanced NSCLC. A copy of the press release is furnished as Exhibit 99.3 to this Current Report on Form 8-K and is incorporated herein by reference.

The data demonstrated that significant survival benefit was observed in a cohort of previously treated, checkpoint inhibitor (CPI) naïve patients with advanced NSCLC; with a median overall survival (mOS) of 28.7 months for the intent-to-treat (ITT) patients (N = 47). This data compares favorably with published data of Checkmate-057, which reported a mOS of 12.2 months in patients who received nivolumab as single agent in a similar treatment setting. Notably, a statistically significant survival benefit with mOS of 42.1 months was observed in patients with injection site reaction (p = 0.0001). Exploratory biomarker analyses showed that overlapping CTA expression in patients' tumors at baseline with HS-110, as well as the expression of a specific CTA were both associated with statistically significant improved overall survival (p = 0.028 and 0.008, respectively).

The Company also updated its corporate presentation, to among other things, include the updated data from the Company's ongoing Phase 2 trial in combination with Bristol-Myers Squibb's (BMS) Opdivo® (nivolumab) for in advanced NSCLC that was presented at ASCO. A copy of the corporate presentation is attached hereto as Exhibit 99.4 and is incorporated herein by reference.

The information in the press release shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed with this Current Report on Form 8-K.

Exhibit Number	Description
99.1	Heat Biologics, Inc. Poster presentation
99.2	Transcript of Oral Poster Discussion
99.3	Press Release of Heat Biologics, Inc. dated May 29, 2020
99.4	Heat Biologics Corporate Presentation

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 29, 2020

HEAT BIOLOGICS, INC.

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

TUMOR ANTIGEN EXPRESSION AND SURVIVAL OF PATIENTS WITH PREVIOUSLY-TREATED ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC) RECEIVING VIAGENPUMATUCEL-L (HS-110) PLUS NIVOLUMAB

Daniel Morgensztern[1], Saiama N Waqar[1], Lyudmila Bazhenova[2], Lori McDermott[3], Jeff Hutchins[3], David H. Taylor[3], Fred L. Robinson[4], Alexa K. Dowdell[4], Brian D. Piening[4], Wael Harb[5], Nathan Pennell[6], Roger B. Cohen[7]

[1]Washington University School of Medicine, St. Louis, MO; [2]UC San Diego, Moores Cancer Center, San Diego, CA; [3]Heat Biologics, Inc, Durham, NC; [4]Earle A. Chiles Research Institute, Providence Cancer Institute, Portland, OR [5]Horizon Oncology Center, Lafayette, IN, [6]Taussig Cancer Institute, Cleveland Clinic, Cleveland, OH, [7]University of Pennsylvania Perelman School of Medicine, Philadelphia, PA

Background

Viagenpumatucel-L (HS-110) is an allogeneic cellular immunotherapy that incorporates a broad range of tumor antigens (cancer testis antigens, CTAs) that are known to be shared amongst a high proportion of patients with non-small cell lung cancer (NSCLC). This cell system expresses secretory gp96-Ig, which acts as an antigen delivery chaperone of tumor antigens expressed by Viagenpumatucel-L (HS-110) and an immune activator of tumor specific T cells. Functionally, gp96 is a unique chaperone that up-regulates multiple factors including MHC, cytokine release, and T-cell co-stimulators. This action drives the differentiation of APCs to dendritic cells and cross-presentation of chaperoned antigens for display via MHC I to initiate a highly specific CD8+ T-cell mediated immune response[1,2] to the patient's own tumor.

The HS110-102 "DURGA" trial is a Phase 2, multi-cohort master protocol evaluating HS-110 in combination with anti-PD1 antibodies in the treatment of advanced non-small lung cancer. Here we present top line data from Cohort A. This cohort is comprised of previously-treated patients who have not received a checkpoint inhibitor (CPI) prior to study entry.

Study endpoints include safety, objective response rate (ORR) and overall survival (OS). Patients received 1 x 10^7 HS-110 cells intradermally every week for 18 weeks and nivolumab every two weeks until disease progression or unacceptable toxicity.

To evaluate the association between clinical outcomes and CTA overexpression in patient tumor samples, RNA sequencing was performed on baseline tumor specimens as well as the HS-110 drug product under in vitro culture conditions. RNA-seq libraries were prepared via hybrid-capture from macro-dissected formalin fixed paraffin embedded tumor tissue or HS-110 cultured cells and sequenced on an Illumina NovaSeq 6000. Gene-level transcripts were quantified using the Salmon software package.

In this analysis, 39 CTAs were highly expressed and only present in tumor-associated tissue. Of the 28 patients with evaluable tissue for RNA-seq, 14 patient tumors contained 8 or more of these 39 highly expressed CTAs.

NCT Trial ID: NCT02439450

Mechanism of Action

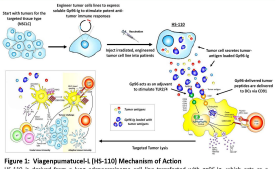

Figure 1: Viagenpumatucel-L (HS-110) Mechanism of Action
HS-110 is derived from a lung adenocarcinoma cell line transfected with gp96-Ig, which acts as a chaperone protein for tumor associated antigens and is recognized by CD91 on APCs, resulting in cross-presentation of antigen to MHC I for the selection of antigen-specific CD8 cells. Gp96-Ig also binds to TLR-2/4 leading to upregulation of co-stimulatory molecules including MHC II and secretion of cytokines and chemokines.

Study Schema

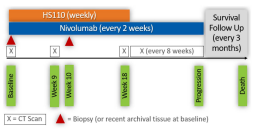

Figure 2: HS110-102 Study Schema
Patients receive weekly HS-110 (1 x 10^7 cells via 5 intradermal injections of 0.1ml each) for 18 weeks and nivolumab (240 mg IV) biweekly until disease progression or unacceptable toxicity.

Patient Characteristics (ITT Population)

		ITT (N = 47)
Age (median, range)		65 (37-87)
Gender	Female	26 (55%)
Race	Caucasian	42 (89%)
ECOG PS (0 or 1)	1	32 (68%)
EGFR mutation	Positive	5 (11%)
Histology	Adenocarcinoma Squamous	44 (94%) 3 (6%)
Smoking status	Current/past Never	39 (83%) 8 (17%)
Prior lines of treatment	1 2 3 or more	32 (68%) 7 (15%) 8 (17%)
PD-L1 status	< 1% ≥ 1% Unevaluable	22 (47%) 9 (19%) 16 (34%)

Frequently Reported Adverse Events

Adverse Events	N=47
Any adverse event	47 (100%)
Any event ≥ Grade 3	16 (34%)
Injection site reaction	28 (60%)
Fatigue	13 (28%)
Arthralgia	9 (19%)
Cough	8 (17%)
Constipation	7 (15%)
Diarrhea	7 (15%)
Decreased appetite	7 (15%)
Nausea	7 (15%)
Anemia	7 (15%)

Most commonly reported treatment-emergent adverse events (regardless of attribution) occurring in the safety population. There were one grade 4 event (hyponatremia) and two grade 5 events (acute myocardial infarction and pulmonary embolism due to disease progression), none of which were deemed related to study treatment.

Overall Survival: ITT & Landmark Analysis

Landmarks	% (# Alive)
6 months	75% (35)
12 months	57% (27)
18 months	40% (19)
24 months	36% (17)

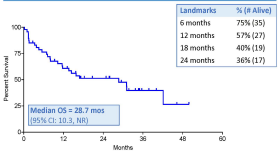

Figure 3: Overall Survival – ITT Population (Kaplan Meier Analysis)
Overall survival of ITT population (N=47). Twenty-one (21) patients censored.

Overall Survival: Subset Analyses

Injection Site Reaction	N (%)	# Censored	Median OS, 95% CI (mos)	
Positive	28 (60%)	17	42.1	(28.7, NR)
Negative	19 (40%)	4	4.6	(1.4, 11.6)
p = 0.0001	HR: 0.20 (95% CI: 0.09 - 0.46)			

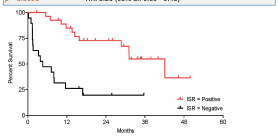

Figure 4: Overall Survival – by Injection Site Reaction (ISR)
ISR positive refers to patients who experienced at least one injection site reaction at any time during treatment.

PD-L1	N (%)	# Censored	Median OS, 95% CI (mos)	
Positive	9 (19%)	5	42.1	(1.6, 42.1)
Negative	22 (47%)	10	28.7	(5.5, NR)
p = 0.40	HR: 0.61 (95% CI: 0.19 - 1.91)			

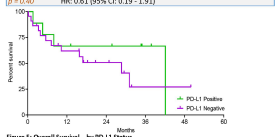

Figure 5: Overall Survival – by PD-L1 Status
PD-L1 positive is defined as PD-L1 expression ≥ 1% using SP142.

Response Rate & Disease Control

Response Rate*	% (N)
ORR	21% (10)
PR	21% (10)
SD	21% (10)
Not Evaluable	13% (6)
DCR	43% (20)

*Per RECIST 1.1

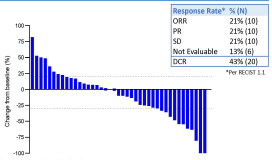

Figure 6: Best Target Lesion Response
Waterfall plot of evaluable ITT patients (N=41) using RECIST 1.1 Target Lesion Response. Post-baseline scans not available for 6 patients. Tumor shrinkage was observed in 42% of ITT patients.

Cancer Testis Antigen (CTA) Expression Analyses

# Shared CTAs	N (%)	# Censored	Median OS, 95% CI (mos)	
≥ 8	14 (50%)	9	NR	(10.3, NR)
< 8	14 (50%)	4	6.7	(1.4, NR)
p = 0.028	HR: 0.32 (95% CI: 0.11 - 0.94)			

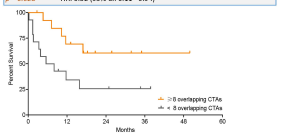

Figure 7: Overall Survival – by Shared Antigen Expression
Subset analysis was conducted in patients whose tumors have 8 or more overlapping CTAs with the 39 CTAs overexpressed by HS-110 at baseline.

ZNF492	N (%)	# Censored	Median OS, 95% CI (mos)	
Yes	11 (39%)	8	NR	(11.6, NR)
No	17 (61%)	6	7.2	(1.6, NR)
p = 0.009	HR: 0.20 (95% CI: 0.05 - 0.74)			

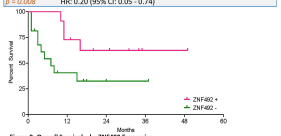

Figure 8: Overall Survival – by ZNF492 Expression
Zinc finger protein 492 (ZNF492) is a transcription factor that is expressed in multiple cancers. Subset analysis was conducted in patients whose tumors overexpressed ZNF492 at baseline.

Duration of Clinical Benefit

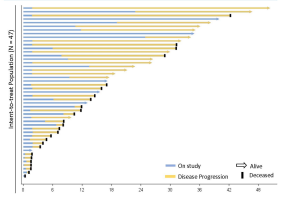

Figure 9: Duration of Clinical Benefit
Swimmer plot of time until disease progression and current survival status. Status with median follow-up of 15.7 months, median duration of response = 17.2 months, median PFS = 1.9 months. As of this data cut, 6 patients (15%) have not progressed, and 21 patients (46%) are still alive.

Conclusions

- **HS-110 in combination with nivolumab is well tolerated with a median overall survival (OS) of 28.7 months**
  - **Favorable survival benefit observed in both PD-L1 positive and PD-L1 negative patients**
  - **Significantly greater OS observed in ISR+ patients**
  - **In an exploratory biomarker analysis, improved OS was observed in patients whose tumors express ≥ 8 shared antigens with HS-110 at baseline, and in patients who expressed ZNF492 at baseline**

References

1.Strbo N, Garcia-Soto A, Schreiber TH, Podack ER. Secreted heat shock protein gp96-Ig: next-generation vaccines for cancer and infectious diseases. Immunol Res 2013;57:311-25.

2.Dizumi S, Strbo N, Pahwa S, Deyev V, and Podack ER. Molecular and cellular requirements for enhanced antigen cross-presentation to CD8 cytotoxic T lymphocytes. J immunol 2007; 179, 2310-2317.

Acknowledgements

The authors are grateful for the investigators, study staff, patients and their families for their commitment to this trial to help advance the treatment of non-small cell lung cancer.

For any additional information, please contact lmcdermott@heatbio.com

Exhibit 99.2

Heat Biologics Transcript- ASCO May 29, 2020 Poster Presentation

Thank you for your interest in our poster presentation. This is Jeff Hutchins, CS and OO of Heat Biologics. We are pleased to provide an update to our ongoing Phase 2 study of HS-110 in combination with nivolumab for the treatment of advanced non-small lung cancer in multiple treatment settings. Today, we are presenting top line data for our Cohort A, comprised of previously treated patients who have not received a checkpoint inhibitor prior to study entry.

HS-110 is an off-the-shelf, allogeneic, cell-based therapy utilizing the company's gp96 platform to secrete multiple cancer testis antigens or CTAs to stimulate an immune response against the patient's tumor. The illustration in Figure 1 highlights HS-110's ability to drive the innate stimulation of APCs to mature dendritic cells while delivering CTA peptides that are cross-presented to directly stimulate and expand CD8 positive T cells.

Figure 2 outlines the study schema, whereby HS-110 is administered intradermally every week for 18 weeks with nivolumab per standard of care until disease progression or unacceptable toxicity.

A total of 47 patients were enrolled, and patient characteristics are presented.

As shown in the adverse events table, HS-110 in combination with nivolumab was well tolerated. No toxicities were observed except for injection site reactions or ISR; which from the subset analysis of overall survival data I describe later, may be a possible clinical outcome measurement tool.

The median overall survival of the ITT population is 28.7 months shown in Figure 3. In figure 6, we provide a waterfall plot of best target lesion response where tumor shrinkage was observed in 42% of the ITT patients. The ORR was 21% with a disease control rate of 43%. The median duration of clinical benefit was 17.2 months in Figure 9; where 46% of the patients were still alive.

Several subset analyses on overall survival was performed. We would like to highlight the subset analysis of patients who experienced ISR. Figure 4 represents a highly statistically significant improvement of overall survival observed in ISR positive patients. With median overall survival of 42.1 months, the ISR positive patients accounted for 60% of the patients treated.

We also performed a subset analysis by PD-L1 status shown in Figure 5. We observed favorable survival benefit of both PD-L1 positive and negative patients.

In addition, we conducted exploratory biomarker analyses based on the mechanism of action of HS-110. Using RNA sequencing, we performed an analysis to compare the CTA expression in patient tumor tissue and HS-110. In Figure 7, statistically significant overall survival improvements were observed in patients whose tumor overexpressed 8 or more CTAs shared with HS-110. Overexpression of a single CTA in common with HS-110, ZNF492, is also positively correlated with significant improved overall survival as shown in Figure 8.

In conclusion, we present topline data and subset analysis of HS-110 in combination with nivolumab in 2nd line or greater, checkpoint-naïve, non-small cell lung cancer patients. In the ITT population of 47 patients, the median overall survival was 28.7 months. Statistically significant overall survival of 42.1 months was observed in ISR positive patients. We believe that the clinical outcomes observed with ISR and CTA overlap supports the HS-110 mechanism of action of innate and adaptive immune activation via gp96. These observations support the conduct of a registrational study of defined patient subgroups receiving HS-110 in combination with an anti-PD-1 antibody.

If you need further information, please contact me or one of our distinguished authors.

Thank you.

EXHIBIT 99.3

Heat Biologics Presents Positive Survival Benefit for HS-110 in Combination with Nivolumab in Phase 2 Lung Cancer Trial at 2020 American Society of Clinical Oncology (ASCO) Annual Meeting

- *Median overall survival of 28.7 months in previously treated checkpoint inhibitor naïve non-small cell lung cancer patients*
- *Significantly greater median overall survival of 42.1 months observed in patients with injection site reaction*
- *Planning to engage FDA for end-of-phase 2 meeting*

Durham, NC – May 29, 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 presented its latest data at the ASCO Annual Meeting. The poster presentation can be viewed on the ASCO meeting website at: https://meetinglibrary.asco.org/record/184864/poster and on Heat Biologics' website at: https://www.heatbio.com/product-pipeline/scientific-publications

HS-110 is an "off-the-shelf" allogeneic cell-based therapy designed to activate patients' immune system against multiple cancer testis antigens (CTAs) to elicit a diverse and robust T-cell attack against tumor cells. A Phase 2 trial of HS-110 in combination with Bristol-Myers Squibb's (BMS) Opdivo® (nivolumab) for multiple treatment settings in advanced non-small cell lung cancer (NSCLC) is ongoing, with enrollment of this trial completed in July 2019.

This data demonstrated that significant survival benefit was observed in a cohort of previously treated, checkpoint inhibitor (CPI) naïve patients with advanced NSCLC; with a median overall survival (mOS) of 28.7 months for the intent-to-treat (ITT) patients (N = 47). This data compares favorably with published data of Checkmate 057, which reported a mOS of 12.2 months in patients who received nivolumab as single agent in a similar treatment setting. Notably, a statistically significant survival benefit with mOS of 42.1 months was observed in patients with injection site reaction ($p = 0.0001$). Exploratory biomarker analyses showed that overlapping CTA expression in patients' tumors at baseline with HS-110, as well as the expression of a specific CTA were both associated with statistically significant improved overall survival ($p = 0.028$ and 0.008, respectively).

“Our exploratory biomarker analysis solidly establishes additional clinical evidence for the HS-110 mechanism of action,” said Jeff Hutchins, Chief Scientific and Operating Officer of Heat. “This extended mOS also suggests that HS-110 treatment in combination with a CPI should be considered for any solid tumor type with sufficient CTA overlap with HS-110.”

This study has completed enrollment, and 21 of the 47 patients enrolled (45%) are still alive as of this data cut. HS-110 now has a positive safety profile in over 200 patients, and combination of HS-110 and nivolumab appears to be safe and well-tolerated.

“This updated data demonstrates the potential utility of HS-110 in combination with a checkpoint inhibitor as a frontline treatment for NSCLC”, said Jeff Wolf, Chief Executive Officer of Heat. “Heat is planning an end-of-phase 2 meeting with the FDA to discuss registration trial design.”

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. Multiple product candidates in development leveraging the gp96 platform, including HS-110 in phase 2, HS-130 in phase 1, and COVID-19 vaccine program in preclinical development. In addition, Heat Biologics is also developing a pipeline of proprietary immunomodulatory antibodies, including PTX-35. 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 the extended mOS suggesting that HS-110 treatment in combination with a CPI should be considered for any solid tumor type with sufficient CTA overlap with HS-110, the potential utility of HS-110 in combination with a checkpoint inhibitor as a frontline treatment for NSCLC, the planned end-of-phase 2 meeting with the FDA to discuss registration trial design and Heat’s 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 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, Heat's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, the ability of Heat together with researchers at the University of Miami to develop a proprietary COVID-19 vaccine, 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 for the year ended December 31, 2019 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

NASDAQ: HTBX

CORPORATE PRESENTATION

MAY 2020

Forward Looking Statements

This presentation includes statements that are, or may be deemed, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drugs targeting cancer, autoimmune diseases and infectious diseases, our planned discovery and development of a COVID-19 vaccine, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to complete clinical trials and make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our ability to partner our product development, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation as a result of, among other factors, the factors referenced in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2019, our quarterly reports on Form 10-Q for the subsequent quarters and our other subsequent filings with the Securities and Exchange Commission (collectively, our "SEC Filings"). In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this presentation, they may not be predictive of results or developments in future periods. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation, except as required by law.

Snapshot of Heat Biologics (Nasdaq: HTBX)

- **US-based biopharmaceutical company developing potential first-in-class immunotherapy products**
- **HS-110, an "off-the-shelf" cell-based immunotherapy product that has the potential to improve PD(L)-1 therapy**
  - Ongoing Phase 2 program demonstrates signals of efficacy in PD(L)-1 progressor and PD(L)-1 naïve patients
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- **Experienced management team with proven track record advancing oncology drugs to the market**

Heat Biologics

Product Pipeline

Product	MOA (Modality)	Indication	Preclinical	Phase 1	Phase 2	Phase 3
HS-110	gp96 + CTAs (Cell Therapy)	NSCLC				
HS-130	OX40L (Cell Therapy)	Solid Tumor				
COVID-19 Vaccine	gp96 + Viral Antigens (Cell Therapy)	COVID-19				
PTX-35	TNFRSF25 (mAb)	Solid Tumor				

CTA = cancer testis antigen; NSCLC = Non-small cell lung cancer

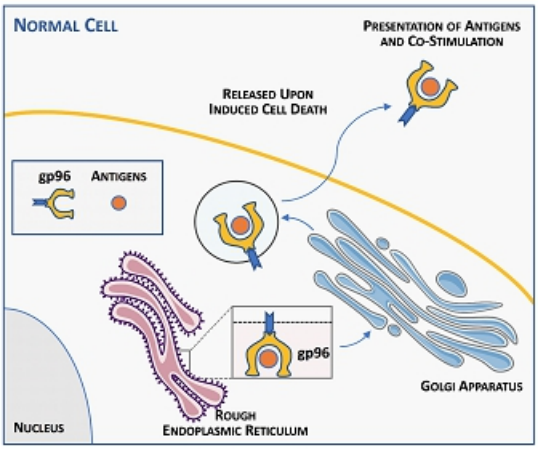
HS-110 Overview

- **HS-110 is a Phase 2 cell-based immunotherapy administered in combination with PD-(L)1 therapies to improve clinical outcomes for NSCLC patients**
  - Allogeneic cells with engineered gp96 to present multiple cancer testis antigens
  - Selectively activate CD8+ "killer" T cells
  - gp96 can up-regulate T-cell co-stimulation and maturation of antigen presenting cells (APCs)
- **PD-(L)1 is approved for multiple cancers and combination approaches may enhance survival benefits**
- **Combination of HS-110 and PD-(L)1 therapy may benefit patients in multiple treatment settings**

References: Strbo et al 2013. Immunologic research; Strbo et al 2013. Journal of immunology; Yifei Wang et al. 2018. J Immunol; Heat Biologics Internal data; † Shukuya & Carbone 2016. Journal of Thoracic Oncology, Vol.11 No.7: 976 - 988

Heat Biologics' gp96 Platform

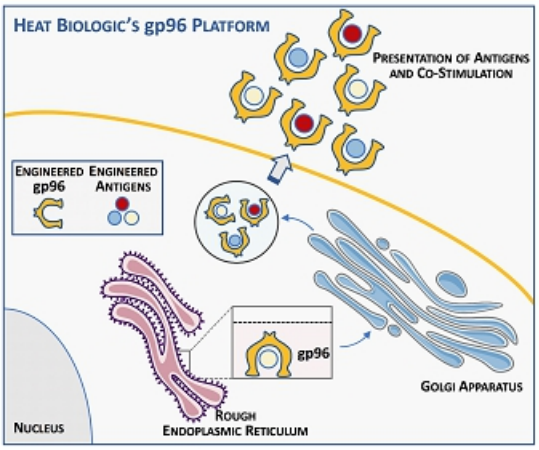
Activating the Immune System



- Function of heat shock protein gp96:
  - Potent mucosal adaptive memory inducer
  - Chaperones antigens (pathogens or tumor) to the immune system
  - Activates B cell response and drives antigen-specific CD4 and CD8 T cell activation

Heat Biologics' gp96 Platform

Activating the Immune System



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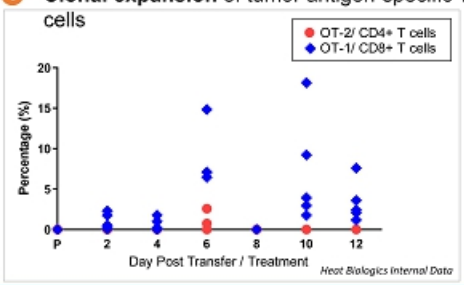
  - Potent mucosal adaptive memory inducer
  - Chaperones antigens (pathogens or tumor) to the immune system
  - Activates B cell response and drives antigen-specific CD4 and CD8 T cell activation
- Key features of Heat's gp96 platform
  - Leverages gp96's role as a natural molecular warning system
    - Engineered to secrete viral antigens bound to gp96
  - Off-the-shelf allogeneic cell vaccine
    - Feasible for large scale manufacturing
    - Amenable to stockpiling
  - Broad applications in infectious diseases and cancer
- Lead product in Phase 2 trial for NSCLC

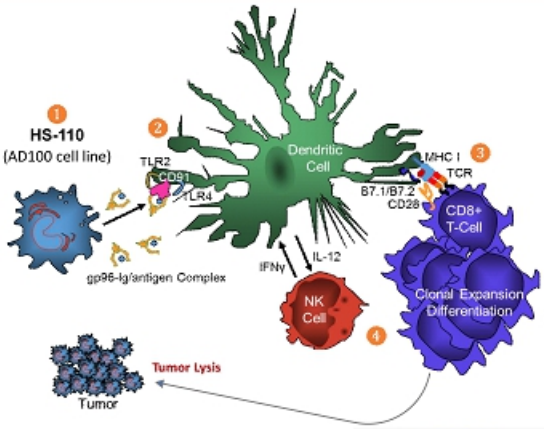
Heat Biologics

Heat Biologics' gp96 Platform

Applications in Oncology: HS-110

1. **Secretion of gp96-Ig** carrying tumor specific proteins represented on the patients' tumor
2. **Activation of APCs** (TLR2/4) and cross-presentation of antigens (CD91)
3. **Specific T-cell receptor** engagement
4. **Clonal expansion** of tumor antigen-specific T cells





Heat Biologics

Clinical Proof-of-Concept Achieved

HS-110 in Combination with Nivolumab

Cohort A: 2+ line Checkpoint Inhibitor (CPI) naïve patients

	HS-110 + Nivolumab Δ		
	93% Non-squamous and 7% Squamous		
mos	All (N=47)	ISR+ (N=28)	PD-L1+ (N=9)
PFS	1.9	6.1	8.0
OS	28.7 (45% still alive)	42.1	42.1

	Nivolumab	
	Non-Squamous	Squamous
mos	Checkmate 57* (N=292)	Checkmate 17‡ (N=135)
PFS	2.3	3.5
OS	12.2	9.2

Δ Heat Biologics Cohort A interim results as of January 2020 data cut. Median progression free survival (PFS) and median overall survival (OS) are reported here. Median follow-up time = 15.7 months. Subgroup analyses were retrospective. * Borghaei et al. 2015 New England Journal of Medicine. 373:1627-39 ‡ Brahmer et al. 2015 New England Journal of Medicine. 373:123-135. ISR = injection site reaction. PD-L1 (Positive ≥ 1%, Negative < 1%).

Cohort B: 2+ line patients that progressed after CPI

	HS-110 + Nivolumab at a 2nd line after CPI failure Δ		
mos	All (N=56)	ISR+ (N=39)	PD-L1- (N=22)
PFS	3.2	3.7	3.6
OS	11.8 (70% still alive)	12.0	12.0

	Treatment Options at a 2nd line after CPI failure		
mos	Gemcitabine† (N=27)	Docetaxel† (N=25)	Chemotherapy‡ (N=28)
PFS	2.8	2.7	4.7
OS	7.5	6.8	9.0

Δ Heat Biologics Cohort B as of July 2019 data cut estimate. Median progression free survival (PFS) and median overall survival (OS) are reported here.. † Single agent chemotherapy, Constantini et al 2018 ERJ Open Research ‡ Schvartsman et al 2017 Lung Cancer. ISR = injection site reaction.

- HS-110 in combination with nivolumab compares favorably with published data
- Two 2+ line NSCLC settings are under evaluation:
  - 2+ line Checkpoint Inhibitor (CPI) naïve patients
  - 2+ line patients that progressed after CPI
- Potential strategy to accelerate clinical development
  - Improved OS in subsets of patients with injection site reaction (ISR)

Heat Biologics

OS by Injection Site Reaction (ISR)

In Both Cohort A and Cohort B, Significantly Improved OS in Patients who Experienced Dermal Injection Site Reaction

Cohort A:

CPI naïve pts treated by HS-110 + Nivolumab at ≥2L

ISR	N (%)	# Censored	Median OS, 95% CI (mos)	
Yes	28 (60%)	17	42.1	(28.7, NR)
No	19 (40%)	4	4.6	(1.4, 11.6)

HR: 0.20 (95% CI: 0.09 - 0.46)

$p = 0.0001$

As of January 2020 data cut

Cohort B:

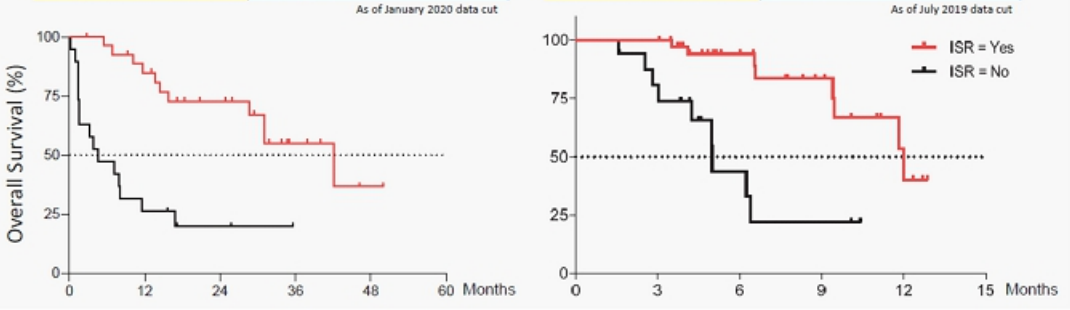
CPI progressors treated by HS-110 + Nivolumab at ≥2L

ISR	N (%)	# Censored	Median OS, 95% CI (mos)	
Yes	39 (70%)	31	12.0	(9.4, NR)
No	17 (30%)	8	5.0	(3.0, NR)

HR: 0.16 (95% CI: 0.05 - 0.45)

$p = 0.0005$

As of July 2019 data cut



ISR = Yes refers to patients who experienced at least one injection site reaction at any time during treatment

Heat Biologics

Product Pipeline

Product	MOA (Modality)	Indication	Preclinical	Phase 1	Phase 2	Phase 3
HS-110	gp96 + CTAs (Cell Therapy)	NSCLC				
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COVID-19 Vaccine	gp96 + Viral Antigens (Cell Therapy)	COVID-19				
PTX-35	TNFRSF25 (mAb)	Solid Tumor				

CTA = cancer testis antigen; NSCLC = Non-small cell lung cancer

Heat Biologics

HS-130 Overview

- **HS-130 is the first allogeneic, off-the-shelf, cell therapy approach** utilizing OX40-mediated co-stimulation to enhance activation of dormant immune signal
  - Leverage HS-110 clinical experience and manufacturing know-how
  - Addition of OX40L fusion protein to extend and expand T cell memory
- **Mechanism of action offers broad market potential**
- **Phase 1 currently enrolling**
- **Heat Biologics has worldwide rights**

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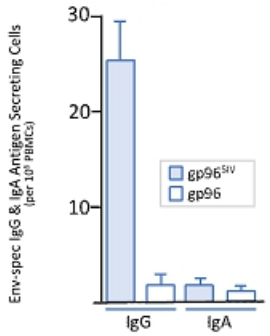
gp96 Platform for Infectious Disease

- gp96 platform demonstrated efficacy in multiple infectious diseases
  - Significant mucosal protection against simian immunodeficiency virus (SIV) in monkey
  - Induction of Zika-specific CD8 T cells in mouse
    - No pathological changes in placenta or fetus
  - Elevation of malaria-specific CD8 T cells in mouse
- Multiple grants received to utilize gp96 platform for various infectious diseases
  - National Institute of Health (NIH)
  - Department of Defense (DoD)
  - Florida Department of Health
- Heat Biologics leverages the body of work done to date to develop our COVID-19 vaccine program

Induction of Humoral Immune Response by gp96^{SIV}Ig Vaccines



Reference:
Strbo et al 2013 J Immunol. 2013 March 15; 190(6): 2495–2499
Strbo et al 2016 J Immunol May 1, 2016, 196 (1 Supplement) 146.10
Strbo et al 2018 J Immunol May 1, 2018, 200 (1 Supplement) 180.19

Heat Biologics

Key Differentiation of gp96 Platform

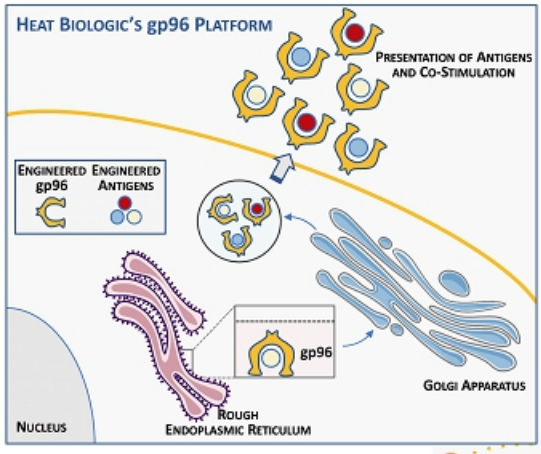
	gp96 Platform*
No Anti-Vector Immunity	✓
No Viral Activation	✓
No Integration of Foreign DNA into Host Genome	✓
Activation of T Cells	✓
Activation of B Cells	✓
High Immunogenicity	✓
Induction of Mucosal Immunity	✓
Long-Term Memory Response	✓

*Target product profile for infectious disease

- Heat's gp96 platform-based products evaluated in 300+ patients to date
  - HS-110 (Phase 2) demonstrated favorable safety profile and clinical efficacy in combination with PD-1 inhibitors for treatment of NSCLC
- Potential first-in-class for infectious disease
  - Based on human cells engineered to secrete gp96-bound viral antigens
    - Platform designed to be antigen-specific and pathogen-specific
  - Aim to trigger mucosal immunity by activating both B and T cell responses at the point of pathogen entry
  - Preclinical work using gp96 platform includes SIV/ HIV, malaria and zika
- Heat's COVID-19 vaccine program focuses on multiple SARS-CoV-2 antigens
  - Target to utilize natural immune process to induce long-lasting memory responses

Heat Biologics' COVID-19 Vaccine Program

- Leverages our proprietary gp96 platform to effectively deliver multiple SARS-CoV-2 antigens to activate the immune system
- Designed to elicit long-lasting immune response against SARS-CoV-2 virus
- We plan to collaborate with companies, researchers, government agencies and funding organizations to accelerate our COVID-19 vaccine program



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PTX-35 Overview

- **Potential first-in-class T cell co-stimulator targeting TNFRSF25, with preferential specificity to generate "memory" CD8+ T cells**
  - IND clearance and first patient dosing expected by end of Q2 2020
- **Broad market potential**
  - Efficacy demonstrated in multiple preclinical *in vivo* colon, lung and breast cancer models
- **Synergistic combination with immunotherapies including HS-110 and checkpoint inhibitors**
- **Awarded a $15.2M grant to fund 70 patients clinical trial**
- **Worldwide rights licensed by Heat Biologics**

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NASDAQ: HTBX