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): **August 27, 2021**

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 Stock Market (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.

Heat Biologics, inc. (the "Company") will be making several presentations to investors over the next several weeks. In connection with the presentations, the Company intends to discuss the investor presentation, which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and in the investor presentation attached as Exhibit 99.1 to this Current Report on Form 8-K 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. The information contained in this Item 7.01 and in the investor presentation attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The investor presentation attached as Exhibit 99.1 to this Current Report on Form 8-K includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosures.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit 99.1 is furnished with this Current Report on Form 8-K:

Exhibit Number	Description
99.1	Investor Presentation of Heat Biologics, Inc. dated August 2021
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

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: August 27, 2021

HEAT BIOLOGICS, INC.

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

Heat Biologics

Heat Biologics

Nasdaq: HTBX

CORPORATE PRESENTATION

AUGUST 2021

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, non-oncology and infectious diseases, our planned discovery and development of a COVID-19 vaccine, our planned biosecurity/biodefense initiative, our planned bioanalytics, process development and manufacturing activities, our biologics drug discovery, 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, 2020, 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.

Heat Biologics

Snapshot of Heat Biologics (Nasdaq: HTBX)

Headquarters: Morrisville, NC

- **US-based biopharmaceutical company developing potential first-in-class immunotherapy products**
  - Solid balance sheet with $122.5M* in cash and cash equivalents
  - Experienced management team with proven track record developing drugs and advancing them to market
- **Key strategic immuno-oncology programs include**
  - **HS-110, "off-the-shelf" cell-based immunotherapy product that has the potential to improve checkpoint inhibitor therapy**
    - Phase 2 results demonstrate signals of efficacy in NSCLC patients
  - **PTX-35 first-in-class immunomodulatory antibody**
    - Phase 1 trial in solid tumors currently enrolling
- **Biothreat Advisory Board to support new biodefense initiatives**
- **Heat 's emerging subsidiary ecosystem provides end-to-end development from bench to clinic**

SKUNKWORX bio

Unique proprietary biologics drug discovery platform to accelerate novel target identification

SCORPION BIOLOGICAL SERVICES

Biologics manufacturing, immunoassays, cell-based assays, and biomarker support

*June 30, 2021

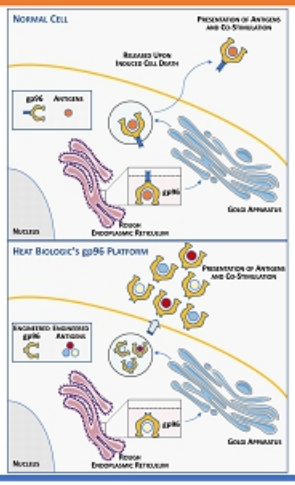
Product Pipeline

PRODUCT	MOA (MODALITY)	INDICATION	IND-ENABLING	PHASE 1	PHASE 2	PHASE 3	UPCOMING ACTIVITIES
HS-110	gp96 + CTAs (Cell Therapy)	NSCLC					End-of-Phase 2 Meeting
HS-130	OX40L (Cell Therapy)	Solid Tumors					Phase 1 Enrollment Ongoing
PTX-35	TNFRSF25 (mAb)	Solid Tumors					Phase 1 Enrollment Complete H1 2022
COVID-19/ Biodefense Initiative	gp96 + Pathogen-derived Antigens (Cell Therapy)	Infectious Disease					Preclinical Development

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

Heat Biologics' gp96 Platform

Activating the Immune System



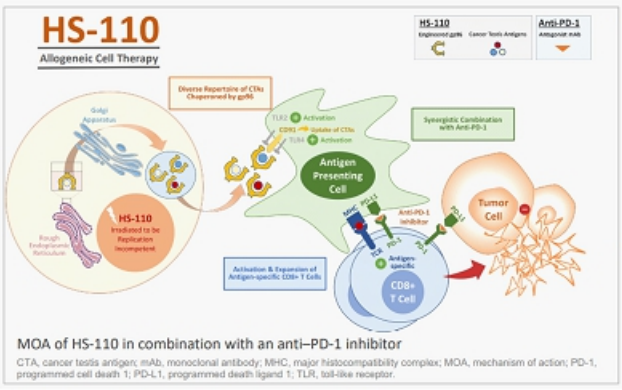
- **Function of heat shock protein gp96**
  - Potent mucosal adaptive memory inducer
  - Chaperones antigens (pathogens or tumor) to the immune system
  - Antigen-specific $CD4^+$ and $CD8^+$ T cell activation
- **Key features of Heat's gp96 platform**
  - Leverages gp96's role as a natural molecular warning system
  - Engineered to secrete 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 completed Phase 2 trial for NSCLC**

HS-110 Overview

- **HS-110 is a first-in-class, "off-the-shelf", allogeneic cell-based immunotherapy**
  - Designed to secrete multiple cancer testis antigens chaperoned by heat shock protein gp96, to co-stimulate antigen presenting cells and to expand tumor antigen-specific T cells
  - Broad potential for providing multiple treatment options to NSCLC patients in combination with a PD-1 inhibitor
  - Worldwide rights available
- **Clinical proof-of-concept in combination with PD-1 therapy for multiple treatment settings of NSCLC**
  - Enrollment for Phase 2 NSCLC trial (n=122) completed
  - Positive interim survival data demonstrated in in previously treated PD-(L)1 naïve and PD-(L)1 progressor NSCLC patients
  - Plan to discuss Phase 3 registrational pathways with FDA as well as potential partners
- **Combination of HS-110 and PD-(L)1 therapies may confer additional survival benefit in multiple cancers**
  - Line extension strategy to include additional indications that have been approved for PD-(L)1 therapies

Mechanism of Action of HS-110

Combination with an Anti-PD-1 Inhibitor



MOA of HS-110 in combination with an anti–PD-1 inhibitor

CTA, cancer testis antigen; mAb, monoclonal antibody; MHC, major histocompatibility complex; MOA, mechanism of action; PD-1, programmed cell death 1; PD-L1, programmed death ligand 1; TLR, toll-like receptor.

- **HS-110 is designed to utilize gp96 to**
  - Chaperon multiple CTAs for effective update by antigen presenting cells via CD91
  - Activate antigen presenting cells via stimulation of toll-like receptor (TLR)-2 and TLR-4
  - Activate & expand antigen-specific cytotoxic $CD8^+$ T cells
- **Synergistic combination of HS-110 and anti-PD-1 inhibitor demonstrated**
  - Preclinical anti-tumor activity in multiple cancer models
  - Clinical proof-of-concept in multiple settings of NSCLC

Clinical Proof-of-Concept Achieved

HS-110 in Combination with Nivolumab

Cohort A: Previously treated Checkpoint Inhibitor (CPI) naïve NSCLC patients

	HS-110 + Nivolumab Δ (94% non-squamous and 6% squamous)			Nivolumab (Non-squamous)
	All (N=47)	ISR+ (N=28)	PD-L1+ (N=9)	BMS Checkmate 057 Study* (N=292)
OS (mos)	24.6 (11.7, 36.0) 29.7% still alive	36.0 (28.7, NE)	40.5 (8.0, NE)	12.2 (9.7, 15.1)

Δ Heat Biologics Cohort A interim results as of November 2020 data cut. Median follow-up time = 19.4 months. Subgroup analyses were retrospective.
* Borghaei et al 2021. J Clin Oncol § Please note Heat Biologics' trial did not have a comparative nivolumab only arm. Published data in green is historical data and not HS-110 data. Injection site reaction (ISR), yes (+) or no (–); and baseline PD-L1 expression, – (<1%) or + (≥1%).

Cohort B: NSCLC patients whose disease had progressed on or after prior CPI treatment

	HS-110 + Nivolumab (at ≥ 2nd line after CPI failure§)				Treatment Options (at ≥ 3rd line after CPI failure)		
	All (N=68)	ISR+ (N=52)	bTMB-L (N=32)	PD-L1+ (N=23)	Gemcitabine† (N=27)	Docetaxel† (N=25)	Chemotherapy‡ (N=28)
OS (mos)	11.9 (9.7, 16.3) 26.5% still alive	12.1 (11.1, 20.8)	18.2 (12.9, NE)	12.0 (9.4, NE)	7.5 (3.0, 13.4)	6.8 (5.2, 11.5)	9.0 (7.7, 24.2)

Δ Heat Biologics Cohort B interim results as of November 2020 data cut. Median follow-up time = 11.9 months. Subgroup analyses were retrospective.
† Constatini et al 2018 ERJ Open Research ‡ Schvartsman et al 2017 Lung Cancer. § Please note Heat Biologics' trial did not have a chemotherapy only arm. Published data in green is historical data and not HS-110 data. Injection site reaction (ISR), yes (+) or no (–); baseline blood tumor mutational burden (bTMB), bTMB-L (<10 mutations/ megabase [mut/Mb]) or bTMB-H (≥10 mut/Mb) by FoundationACT test; and baseline PD-L1 expression, – (<1%) or + (≥1%).

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

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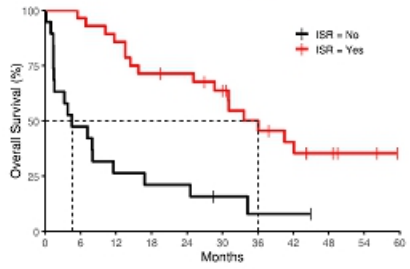
OS by Injection Site Reaction (ISR)

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 (%)	Events	Median OS, 95% CI (mos)	
Yes	28 (60%)	16	36.0	(28.7, NE)
No	19 (40%)	17	4.5	(1.6, 24.6)

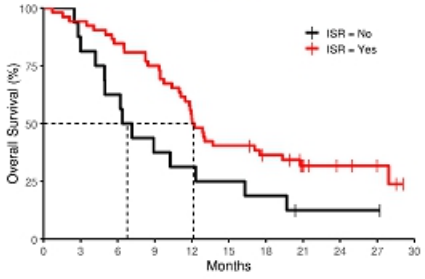
Adjusted HR: 0.23 (95% CI: 0.11, 0.49)
$p < 0.001$



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

ISR	N (%)	Events	Median OS, 95% CI (mos)	
Yes	52 (76%)	36	12.1	(11.1, 20.8)
No	16 (24%)	14	6.8	(4.9, 19.7)

Adjusted HR: 0.48 (95% CI: 0.25, 0.92)
$p = 0.03$



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

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 As of November 2020 datacut

HS-130 Overview

- **HS-130 is the first "off-the-shelf", cell therapy approach utilizing OX40-mediated co-stimulation to enhance immune signals**
  - Leverage HS-110 clinical experience and manufacturing insights
  - Addition of OX40L fusion protein to promote the extension and expansion of T cell memory
  - Worldwide rights available
- **Mechanism of action offers broad market potential**
- **Phase I oncology trial ongoing**

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PTX-35 Overview

- **PTX-35 offers a unique opportunity to modulate T effector or regulatory T-cells**
  - Context driven depending on specific disease settings
  - Broad applications in oncology and non-oncology

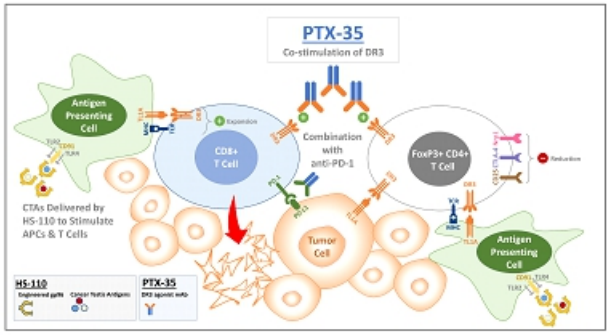
- **Potential first-in-class antibody targeting TNFRSF25 for oncology**
  - Phase 1 trial in solid tumors currently enrolling
  - Anti-tumor activity demonstrated in multiple preclinical *in vivo* colon, lung and breast cancer models
  - Preclinical data demonstrate anti-tumor activity, expansion of antigen-specific $CD8^+$ T cells and decreased Treg suppression in the presence of tumor antigen
  - Awarded a $15.2M CPRIT grant to fund Phase 1 clinical development

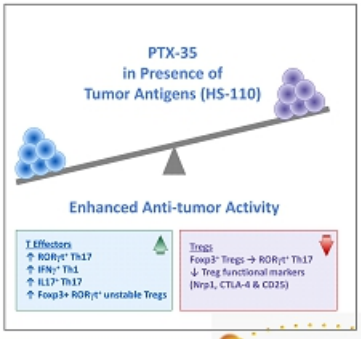
- **Worldwide rights licensed by Heat Biologics**

Mechanism of Action PTX-35

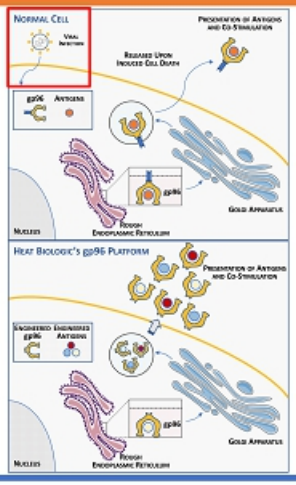
In Combination with Antigen-driven Immunotherapy

- Presented latest preclinical data on mechanism of action on PTX-35 at AACR 2021
  - PTX-35 has anti-tumor activities in presence of tumor antigens: Reduction of Treg suppression and enhancement of T effector response was observed





COVID-19 / Biothreat Vaccine Program Overview



- **Modular vaccine design engineered for rapid response to emergent biothreats**
  - Utilizes gp96 platform to induce long-lasting memory responses
  - Heat gp96 platform-based products evaluated in 250+ patients
  - Platform feasibility supports large scale manufacturing and stockpiling
  - Vaccine candidates demonstrated activity in preclinical infectious disease models include SARS-CoV-2, SIV/HIV, CMV, Zika, and Malaria

Heat Biologics

Biological Threat Advisory Board of Heat Biologics

Bipartisan Advisory Board providing counsel and guidance on Heat's biodefense initiatives

David Lasseter

Former Deputy Asst. Sec. of Defense for Countering Weapons of Mass Destruction

Andrew Weber

Former Asst. Sec. of Defense for Nuclear, Chemical & Biological Defense Programs

Jack Kingston

Former US Representative, Secretariat of the Alliance for Biosecurity (current)

Dr. Gregory Koblentz

Professor of Biodefense at George Mason University, Expert on Chemical and Biological Weapons

Mark Pryor

Former US Senator, AR

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