

## Heat Biologics, Inc.

(HTBX - NASDAQ)

### September Business Update

Based on our DCF model and a 15% discount rate, Heat Biologics is valued at approximately \$19.00 per share. Our model applies a 15% probability of ultimate approval and commercialization for HS-110 in a broad NSCLC setting. The model includes contributions from the US, EU and rest of world.

Current Price (9/3/2021) **\$6.53**  
 Valuation **\$19.00**

### OUTLOOK

Heat Biologics has three novel immunotherapies in clinical development: HS-110, HS-130 & PTX-35. The candidates use genetically-modified cells to secrete a broad array of cancer antigens accompanied by a gp96 adjuvant to stimulate a CD8+ T cell mediated anti-cancer immune response. In response to COVID-19, Heat has launched a vaccine program using the gp96 platform.

The company's lead indication in NSCLC is addressed with portfolio candidates HS-110 and HS-130, both administered in conjunction with checkpoint inhibitors. Heat is currently conducting Phase II trials for HS-110 and began dosing HS-130 patients in a Phase I study. Other pipeline constituents emerged from the company's acquisition of Pelican Therapeutics in 2017. Pelican is developing a T cell co-stimulating antibody targeting the cell surface receptor TNFRSF25 designated PTX-35 which began Phase I trial in June 2020.

The valuation assumes a 2023 FDA approval of HS-110 and a 2024 launch of the compound in the US, followed by a 2025 launch in the EU and rest of world that will be achieved through the efforts of partners. HS-130 and PTX-35 are anticipated to be launched in 2028 in the US and 2029 in other regions.

### SUMMARY DATA

52-Week High **17.00**  
 52-Week Low **5.22**  
 One-Year Return (%) **-18.0**  
 Beta **0.43**  
 Average Daily Volume (sh) **931,467**

Shares Outstanding (mil) **25.4**  
 Market Capitalization (\$mil) **162**  
 Short Interest Ratio (days) **13.7**  
 Institutional Ownership (%) **12.1**  
 Insider Ownership (%) **4.36**

Annual Cash Dividend **\$0.00**  
 Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates  
 Sales (%) **N/A**  
 Earnings Per Share (%) **N/A**  
 Dividend (%) **N/A**

P/E using TTM EPS **N/A**  
 P/E using 2020 Estimate **N/A**  
 P/E using 2021 Estimate **N/A**

Zacks Rank **N/A**

Risk Level **Above Average**  
 Type of Stock **Small-Growth**  
 Industry **Med-Biomed/Gene**

### ZACKS ESTIMATES

#### Revenue

(In millions of USD)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2020	\$0.9 A	\$0.6 A	\$0.8 A	\$0.6 A	\$2.9 A
2021	\$0.5 A	\$0.5 A	\$0.4 E	\$0.4 E	\$1.8 E
2022					\$0.0 E
2023					\$0.0 E

#### Earnings per Share

	Q1	Q2	Q3	Q4	Year
2020	-\$0.77 A	-\$0.35 A	-\$0.43 A	-\$0.28 A	-\$1.63 A
2021	-\$0.31 A	-\$0.26 A	-\$0.27 E	-\$0.30 E	-\$1.15 E
2022					-\$1.33 E
2023					-\$1.36 E

## WHAT'S NEW

### Business Update Conference Call

Heat Biologics, Inc. (NASDAQ: HTBX) hosted a business update conference call on September 2, 2021 to discuss the status of active programs, objectives of new subsidiaries, and longer term opportunities for the company. The replay for the call is available through September 16<sup>th</sup>.

### **New Subsidiaries: SkunkWorx and Scorpion**

Heat CEO, Jeff Wolf, opened the meeting by providing an update on the company's progress. He began by reviewing developments related to Heat's recently [announced](#), wholly-owned drug discovery and development subsidiary Skunkworx Bio, Inc. Skunkworx features diverse and proprietary libraries of small biologics ("Pocket Biologics"), namely antibody fragments and proteins that have the potential to bind to critical domains of druggable targets and become potential product candidates.

Skunkworx is structured to rapidly and precisely discover and develop new innovative therapeutics. Its biologics library targeting is guided by computational methods and bioinformatics, enhancing efficiency. The subsidiary has already identified modulators for a number of targets and is evaluating them in preclinical *in vivo* studies to begin by 1Q:22. Skunkworx will develop therapies in both oncology and non-oncology indications as well as in biodefense. Programs started at Skunkworx can be developed at Heat and manufactured by Heat's other newly announced wholly-owned subsidiary [Scorpion Biological Services](#).

#### Exhibit I – SkunkWorx Bio and Scorpion Biological Services<sup>1</sup>



Unique proprietary biologics drug discovery platform  
to accelerate novel target identification



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

Next, Wolf reviewed the [groundbreaking](#) of its new San Antonio Facility announced August 9th. In an effort to augment the company's internal R&D abilities, Heat is investing in a large molecule bioanalytical research and manufacturing facility under the control of Heat's wholly owned subsidiary, Scorpion Biological Services. Scorpion will utilize the biomanufacturing/bioanalytic facility for in-house development of immunoassays and biomarkers, while maintaining Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and current Good Manufacturing Practices (cGMP) manufacturing capabilities.

Heat received approval for an estimated \$1.0 million in tax abatements from the City of San Antonio and Bexar County. In addition to supporting Heat's development activities, excess capacity at the facility will be available to support other biopharma companies. Management expects the facility to be self-sustaining through cash flows generated through services rendered to outside companies, all the while supporting Heat's internal initiatives, including producing product for Heat's clinical trials. Scorpion is expected to become operational next year and employee headcount is forecasted to reach 50. With cGMP manufacturing in house, Heat will circumvent queues, save costs, improve quality control, and boost flexibility in pursuing programs.

<sup>1</sup> Source: Heat Biologics September 2021 Corporate Presentation

## The Pipeline

The discussion proceeded to review active clinical candidates HS-110, HS-130, PTX-35 and the COVID-19 program.

**Exhibit II – Heat Biologics Pipeline<sup>2</sup>**

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 Antigen (Cell Therapy)	Infectious Disease					Preclinical Development

### HS-110

Additional data for HS-110 was presented at the 2021 ASCO Annual Meeting held in June, publicized in a June 4<sup>th</sup> [press release](#). Highlights from the data were a 24.6 month median overall survival (mOS) in previously treated, checkpoint naïve patients with advanced non-small cell lung cancer (NSCLC). The data compared favorably with historical published data of BMS' nivolumab trial Checkmate 057 which reported mOS of only 12.2 months, single agent, in a similar treatment setting as Phase II HS-110. With these promising data, management now sets its sights on Phase III for the candidate and is actively evaluating registrational pathways with key opinion leaders and others in thorough preparation for strategy talks at the End-of-Phase-II meeting with the FDA, to ensure a smooth meeting and to garner FDA support. Following the meeting, management will be then equipped with details regarding logistics and costs associated with progressing the candidate. Multiple settings are being considered, including patients that are checkpoint naïve as 1L setting, or patients who progress on 1L checkpoints, a 2L setting. Injection Site Reaction, PDL-1 status, tumor mutation burden status are all being considered as biomarkers and management is in conversation with key opinion leaders and oncologists to continue to refine trial design.

### HS-130

Heat concluded enrollment in the Phase I trial for HS-130, and is now in the process of evaluating the next steps forward, including enhancements to the platform based on updated information.

Regarding PTX-35, earlier in 2021, Heat announced promising preclinical data at both the AACR Oncology Meeting and 3<sup>rd</sup> Annual T-reg Directed Therapy Summit. Given the promising data, Heat is expanding (increasing) patient dosing of PTX-35 in patients with solid tumors and expects to update stakeholders with interim data later in 2021. Management is also exploring applications of PTX-35 outside of oncology and is actively pursuing collaborations in various indications.

### COVID-19

The COVID-19 program continues. Despite the approval of multiple vaccines, management believes there is opportunity in the emergence of variants, namely the delta variant, that will require combination approaches, and Heat is leveraging expertise into new research to elicit more robust immune response. Clinical trials are very expensive and Heat expected to pursue COVID-19 with government support and will not pursue trials without government support. Heat remains in talks with public support resources. COVID-19 made apparent the general lack of resources and preparedness to respond to new and emerging biosecurity threats, and in response Heat formed its Blackhawk subsidiary focused on emerging biothreats. Blackhawk was originally conceived as a result of research following the pandemic. Management believes that the platform is highly adaptable and can provide versatile and timely responses to protect the US from known and unknown future biological threats.

<sup>2</sup> Source: Heat Biologics September 2021 Corporate Presentation

## BioThreat Advisory Board

Heat has filed patents for a novel gp96 approach with biosecurity applications, while strategically keeping much of the research art under wraps. Heat has also established collaborations with leading institutions to further research and plans to provide updates as soon as practical. Heat established a BioThreat Advisory Board, [announced](#) August 18<sup>th</sup>, that is well versed on Blackhawk's platform, including David Lasseter, Former Deputy Assistant Secretary of Defense for Countering Weapons of Mass Destruction, Former US Representative Jack Kingston, Andrew C. Weber, Former Assistant Secretary of Defense for Nuclear, Chemical & Biological Defense Programs; Dr. Gregory Koblentz, Associate Professor at George Mason University and leading expert on chemical and biological weapons, and Mark Pryor, former US Senator from the State of Arkansas. Together with key appointees on the Biothreat Advisory Board and Heat's technology and expertise, management sees potential in becoming a leader in the US for biothreat defense.

## Financial Matters

CFO Bill Ostrander provided a brief overview of Heat's financial position. Ostrander reported \$122.5 million in cash, equivalents and short term investments as of June 30<sup>th</sup>, 2021. For the past six months, Heat has been well capitalized and has not utilized its ATM facility. Equity capitalization includes 25.4 million common shares outstanding and just over 747,000 warrants outstanding with an average strike price of approximately \$11 per share, generating \$8 million if fully exercised.

## Summary

In summary, Heat has made progress launching new subsidiaries, breaking ground on its Scorpion San Antonio manufacturing facility, and establishing its Skunkworx subsidiary for the rapid discovery and development of drugs, creating a vertically integrated biologics company with Heat's technology at the center. Clinical trial results for the year so far have been positive, creating a strong foundation to target next steps, namely Phase III in lead candidate HS-110, with an expected end-of-Phase II meeting with the FDA in the near term.

## PROJECTED FINANCIALS

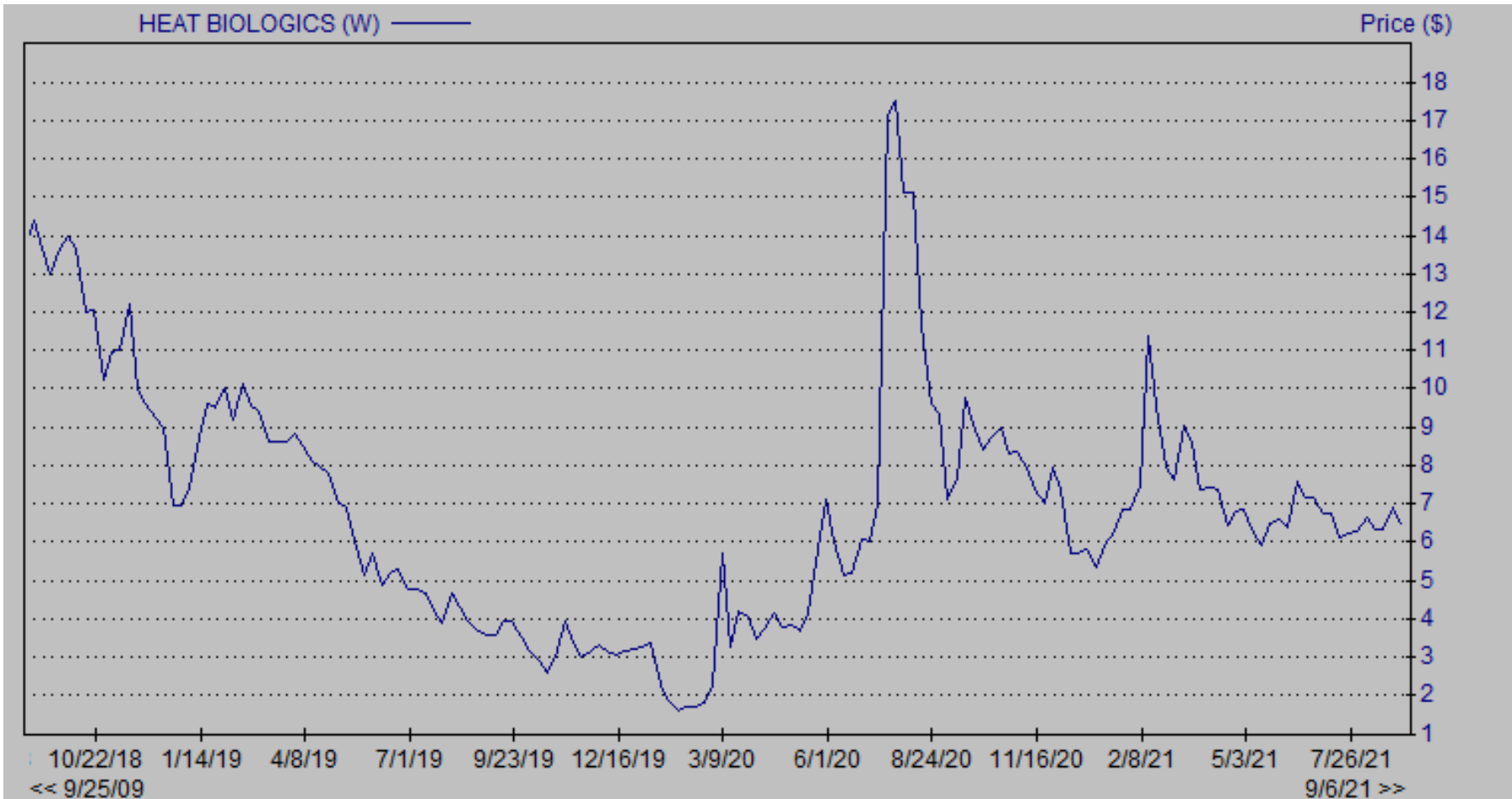
### Heat Biologics, Inc. - Income Statement

Heat Biologics Inc.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
<b>Total Revenues (\$MM)</b>	<b>\$2.9</b>	<b>\$0.5</b>	<b>\$0.5</b>	<b>\$0.4</b>	<b>\$0.4</b>	<b>\$1.8</b>	<b>\$0.0</b>	<b>\$0.0</b>
Research & Development	\$12.9	\$3.4	\$4.2	\$4.5	\$4.9	\$17.0	\$22.1	\$23.2
General & Administrative	\$14.9	\$4.8	\$2.9	\$3.2	\$3.6	\$14.4	\$13.2	\$13.6
Other	\$1.2	\$0.0	\$0.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<b>Income from operations</b>	<b>(\$26.1)</b>	<b>(\$7.6)</b>	<b>(\$6.7)</b>	<b>(\$7.3)</b>	<b>(\$8.1)</b>	<b>(\$29.6)</b>	<b>(\$36.3)</b>	<b>(\$38.8)</b>
Interest Income	\$0.6	\$0.2	\$0.2	\$0.2	\$0.2	\$0.7	\$0.0	\$0.0
Other Income	(\$0.8)	(\$0.2)	(\$0.1)	\$0.0	\$0.0	(\$0.3)	\$0.0	\$0.0
<b>Pre-Tax Income</b>	<b>(\$26.4)</b>	<b>(\$7.6)</b>	<b>(\$6.6)</b>	<b>(\$7.1)</b>	<b>(\$7.9)</b>	<b>(\$29.2)</b>	<b>(\$36.3)</b>	<b>(\$38.8)</b>
Provision for Income Tax	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$1.0	\$2.0
<i>Tax Rate</i>	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	100.0%	200.0%
<b>Net Income</b>	<b>(\$26.4)</b>	<b>(\$7.6)</b>	<b>(\$6.6)</b>	<b>(\$7.1)</b>	<b>(\$7.9)</b>	<b>(\$29.2)</b>	<b>(\$35.3)</b>	<b>(\$36.8)</b>
Non-controlling Interest	(\$0.3)	(\$0.1)	(\$0.1)	(\$0.1)	(\$0.1)	(\$0.4)	(\$0.4)	
<b>Net Income After NCI</b>	<b>(\$26.0)</b>	<b>(\$7.5)</b>	<b>(\$6.5)</b>	<b>(\$7.0)</b>	<b>(\$7.8)</b>	<b>(\$28.8)</b>	<b>(\$34.9)</b>	<b>(\$36.8)</b>
<i>Net Margin</i>	-89.5%	-14.15%	-14.1%	-17.3%	-19.5%	-	#DIV/0!	#DIV/0!
<b>Reported EPS</b>	<b>(\$1.63)</b>	<b>(\$0.31)</b>	<b>(\$0.26)</b>	<b>(\$0.27)</b>	<b>(\$0.30)</b>	<b>(\$1.15)</b>	<b>(\$1.33)</b>	<b>(\$1.36)</b>
<i>YOY Growth</i>	-6.1%	-59.5%	-26.6%	-36.4%	7.0%	-3.0%	16%	
Basic Shares Outstanding	15.98	24.20	25.14	25.62	25.71	25.17	26.31	27.15

Source: Company Filing // Zacks Investment R

# HISTORICAL STOCK PRICE

Heat Biologics, Inc. – Share Price Chart



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