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Heat Biologics, Inc. (HTBX - NASDAQ)

Y'all Can Find me Down in San Antone

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 (8/11/2021)	$6.63
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 (%)	**-48.8**
Beta	**0.41**
Average Daily Volume (sh)	**936,375**
Shares Outstanding (mil)	**25.4**
Market Capitalization ($mil)	**168**
Short Interest Ratio (days)	**11.8**
Institutional Ownership (%)	**12.2**
Insider Ownership (%)	**4.4**
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 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (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

Second Quarter 2021 Results

Heat Biologics, Inc. (NASDAQ: HTBX) reported second quarter 2021 results on August 11, 2021, concurrent with the submission of Form 10-Q to the SEC.

Highlights for the second quarter ending June 30, 2021 and to date include:

- Preclinical data report on PTX-35 demonstrating delayed tumor progression - April 2021
- Appointment of Anthony Manning, Ph.D. as Chief Scientific Advisor - May 2021
- Additional results from Phase II HS-110 presented at ASCO - June 2021
- Expansion of R&D and pre-clinical capabilities at headquarters - June 2021
- Inclusion as constituent in Russell Microcap Index - June 2021
- Groundbreaking for San Antonio facility - August 2021

In the financial sphere, Heat generated $0.5 million in grant revenue versus $0.6 million in the same quarter last year, and posted a loss attributable to common shareholders of ($6.5) million or ($0.26) per share compared to a loss of ($4.5) million or ($0.35) per share for the prior year period. As of June 30th, Heat has grant receivable balance of $0.4 million for CPRIT proceeds not yet received.

For the second quarter ending June 30, 2021 versus the quarter ending June 30, 2020:

- Research & development expenses totaled $4.2 million, up 51% from $2.8 million, driven by increases in the HS-110, PTX-35 and the COVID programs partially offset by declines in uncategorized programs;
- General & administrative expenses rose 58% to $2.9 million from $1.8 million, due to increased personnel cost of $0.2 million, increased stock-based compensation expense of $0.3 million, higher franchise tax expense of $0.2 million, a rise in directors and officers insurance of $0.1 million and an uptick of $0.3 million for consulting and other professional services;
- Net loss was ($6.5) million, or ($0.26) per basic and diluted share, compared to ($4.5) million or ($0.35) per basic and diluted share.

At the end of the quarter, Heat held cash, equivalents and short-term investments totaling $122.5 million, compared to $47.0 million twelve months earlier. The increase was driven primarily by a $102.5 million contribution from financing over the last four quarters offset by cash burn of ($26.7) million. Cash burn for the six months year-to-date is approximately ($14.6) million versus approximately ($10.3) million in the 2020 comparable period.

Groundbreaking at New San Antonio Facility

In an effort to augment the company's internal R&D abilities, Heat announced on August 9th that it had broken ground on its new San Antonio facility. Heat's wholly owned subsidiary, Scorpion Biological Services, will utilize the biomanufacturing/bioanalytic facility for in-house development of immune-assays and biomarkers, while maintaining Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and cGMP manufacturing capabilities. Heat also received approval for an estimated $1.0 million in tax abatements from the City of San Antonio and Bexar County. Excess capacity at the facility will be made available to support other biopharma companies. We have increased our capital expenditure estimates over the next several quarters to reflect the construction costs.

Expansion of R&D Capabilities at Headquarters

On June 23, 2021, Heat announced its intent to expand its Morrisville, North Carolina headquarters' research and development capabilities. These investments are intended to accelerate development timelines and reduce development expenses. The added capabilities include in-house synthesis of antibodies and other drugs/reagents as well as an expanded vivarium to support *in vivo,* preclinical studies.

Addition to Russell Microcap Index

Following the annual Russell reconstitution, HTBX was added as a constituent to the Russell Microcap Index, effective on market open June 28, 2021, as announced in a press release. Membership in the index will be for at least one year, until the next reconstitution.

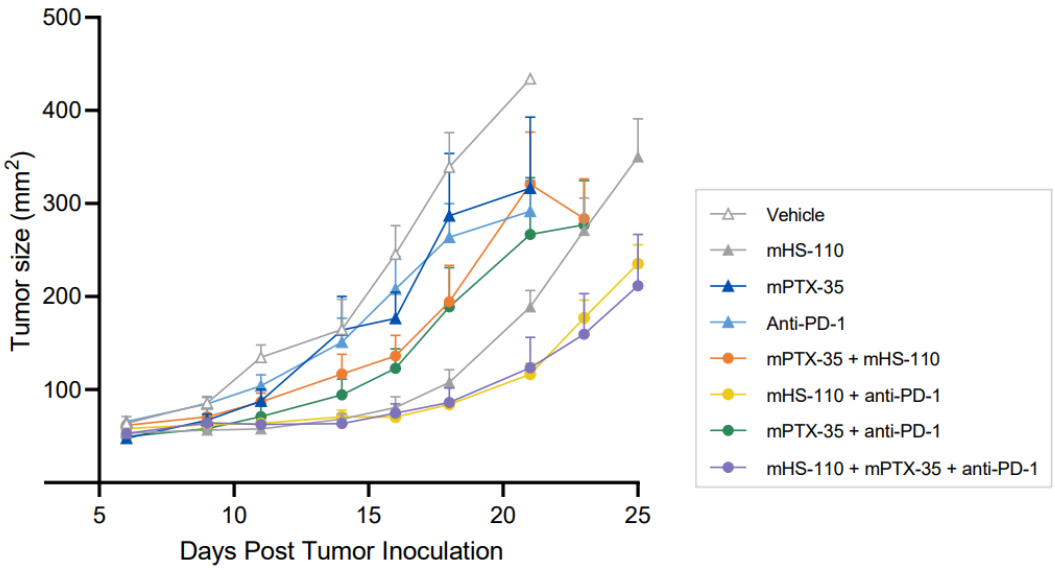
PTX-35

In early June 2020, Heat announced that the FDA had cleared its investigational new drug application (IND) for PTX-35 followed shortly after by the initiation of the first clinical site for the trial and the appointment of Anthony Tolcher, MD as lead investigator. By the end of June, the first patient had been treated in the Phase I trial. Up to 30 patients are expected to be enrolled with advanced solid tumors refractory to standard of care.

Preclinical Data on PTX-35 Demonstrating Delayed Tumor Progression

Heat presented a poster[1] at the American Association for Cancer Research (AACR) Annual Meeting 2021 featuring data from PTX-35 in a murine melanoma model. The study aimed to characterize mouse PTX-35 (mPTX-35) on tumor growth, Treg functionality and stability. Tregs, or regulatory T cells, are a type of T cell that modulate the immune system. Because of their immunosuppressive abilities, Tregs are of interest in cancer biology, where tumors escape immunity. Tregs that express CTLA-4 and CD25 are responsible for suppressive activity, and neuropilin-1 (NRP1), a coreceptor protein, is highly expressed on Treg cells implicit in cancer immune evasion. Furthermore, Tregs can vary as can their effector responses. C57BL/6 mice[2] were inoculated with melanoma cells expressing ovalbumin and then were administered fluorescently-labeled, ovalbumin-specific CD8+ T cells. The mice were then administered mPTX-35, mHS-110 and anti-PD-1 inhibitor, in varying combinations. 14 days later, the mice were administered a second dose of mPTX-35 and mHS-110. Samples were then taken from the peripheral blood, spleen and tumor microenvironment, analyzed for CD4+ regulatory T cells and effector Th1 and Th17 cells.

Exhibit I - Tumor Growth Inhibition by mPTX-35[3]



Results showed that a combination of mPTX-35, mHS-110 and anti-PD-1 inhibitor was able to suppress tumor growth. Analysis of Tregs in the tumor and spleen revealed that there was an increase in percentage of Foxp3+ Tregs, an indicator of reduction in Treg suppression, in the arms administered mPTX-35 that were absent in other arms. Furthermore, functional Treg markers were reduced with mPTX-35 and mHS-110, with or without anti-PD-1 as measured by NRP1, CTLA-4 in the tumor and CD25 in the spleen. Regarding effector cells, mPTX-35 in the presence of mHS-110, with or without anti-PD-1 inhibitor resulted in increased propensity to convert unstable Tregs into Th17 cells. Finally, measures for IFNγ-producing Th1 cells and IL17-producing Th17 cells, which play an important antitumor role, were increased in mPTX-35 treated arms with or without mHS-110.

[1] Kalim KW *et al.* PTX-35, a Potential First-in-class Agonist, Reduced the Suppressive Activity of Regulatory T cells and Enhanced CD4+ T cell Effector Responses in the Presence of Tumor Antigens in a Murine Melanoma Model. April 15, 2021. AACR 2021
[2] C57BL/6 is a common laboratory mouse model used to evaluate medicines against human disease, especially cancer.
[3] Kalim KW *et al.* PTX-35, a Potential First-in-class Agonist, Reduced the Suppressive Activity of Regulatory T cells and Enhanced CD4+ T cell Effector Responses in the Presence of Tumor Antigens in a Murine Melanoma Model. April 15, 2021. AACR 2021

COVID-19 Program

Heat's wholly-owned subsidiary, Zolovax, has been focused on developing medicines and vaccines for infectious diseases using the glycoprotein platform, gp96. Previous research has been conducted for simian immunodeficiency virus, malaria and Zika. In March 2020, Heat entered into a research agreement with the University of Miami (UM) to sponsor new research and development of a SARS-CoV-2 (COVID-19) vaccine. The agreement granted Zolovax exclusive worldwide rights to research, develop and make use of UM technology until last-patent expiry, or 15 years from first sale, in exchange for upfront fees, annual payments and royalties tied to percentage of net sales of licensed product.

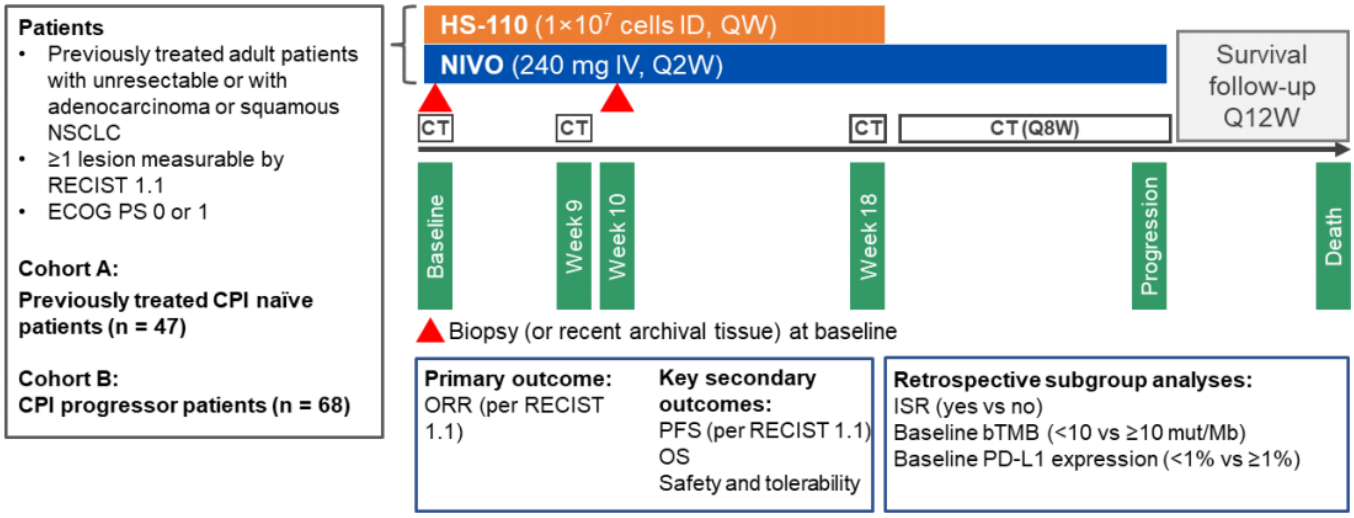
Additional preclinical COVID-19 vaccine results were published in the journal *Frontiers in Immunology* in late January 2021. The publication highlighted additional data sets around memory T cells and built on previously reported data. The new information demonstrated polyfunctional, antiviral cytokine releasing CD8+ and CD4+ T cell memory responses specific to the SARS-CoV-2 spike protein, specifically in the lungs and spleen of immunized animals at 30 days post vaccination. In the lungs of mice, memory CD8+ T cell response was observed 60 days post vaccination, indicating a durable immune response attributed to lung tissue-resident memory T cells that are required for clearing viral infections of the lungs.

Heat has made the case for using its approach, if ultimately approved, along with other vaccines to improve resistance to COVID-19. Many other vaccines that are being developed for the virus stimulate an antibody response and, if used in conjunction with Heat's gp96 approach, would add T cell immunity to improve protection. A pre-investigational new drug (IND) meeting with the FDA is planned.

Positive Interim Data for Phase II HS-110 in NSCLC

Heat announced positive interim survival data for its Phase II trial of HS-110 (viagenpumatucel-L) in combination with leading checkpoint blockade inhibitors (CBIs). The trial was not a comparator trial; however, similarities in design with past trials enable comparison of competitors' performance with HS-110. Heat is investigating HS-110 in a Phase II non-small cell lung cancer (NSCLC) trial designated DURGA. It features two treatment settings, as first line maintenance and second line or later therapy. Additional information is expected to be provided later this year clarifying the setting that will be pursued in Phase III trials. NSCLC considerations include first line, second line and salvage therapy among others.

Exhibit II - HS-110 Phase II Structure[4]



The treatment setting in first line maintenance is divided into two arms, HS-110 and pembrolizumab (KEYTRUDA) with and without pemetrexed (ALIMTA), a chemotherapy agent. The second arm features HS-110 and nivolumab (Opdivo). Pembrolizumab and nivolumab are monoclonal antibodies targeting programmed death receptor-1 (PD-1) and are known as checkpoint inhibitors. Checkpoint inhibitors interfere with the ability of tumor cells to defy immune response, allowing the body to attack the tumors. Finally, the cohorts within the nivolumab arm, cohorts A and B, evaluate the combination of HS-110 and nivolumab in both checkpoint inhibitor naïve and checkpoint inhibitor progressor subjects. The study is intended as proof of concept in a defined patient population. Enrollment has completed with 122 patients.

[4] Source: Heat Biologics May 2021 Corporate Presentation

Interim data was positive and compared favorably to historical data. The CheckMate 057 study was conducted in 2015 by Bristol Myers Squibb to evaluate Opdivo in non-squamous NSCLC. CheckMate 057 was a Phase III trial evaluating nivolumab versus docetaxel in patients with previously-treated non-squamous NSCLC. Patients were randomized 1:1 to nivolumab and docetaxel, with primary endpoint of overall survival (OS). Secondary endpoints included progression-free survival (PFS) and safety. Results showed that median OS was 12.2 months in the nivolumab only group versus docetaxel at 9.4 months.[5] Median PFS was 2.3 months and 4.2 months for nivolumab and docetaxel, respectively. This compares to cohort A of Heat's HS-110 trial in an almost completely non-squamous population (94%) that had median OS of 24.6 months and median PFS of 1.84 months. The interim data supports the trial's objective of clinical proof-of-concept and interim data compared favorably to historic data.

Exhibit III – Overall Survival Curve, Cohort A[6]

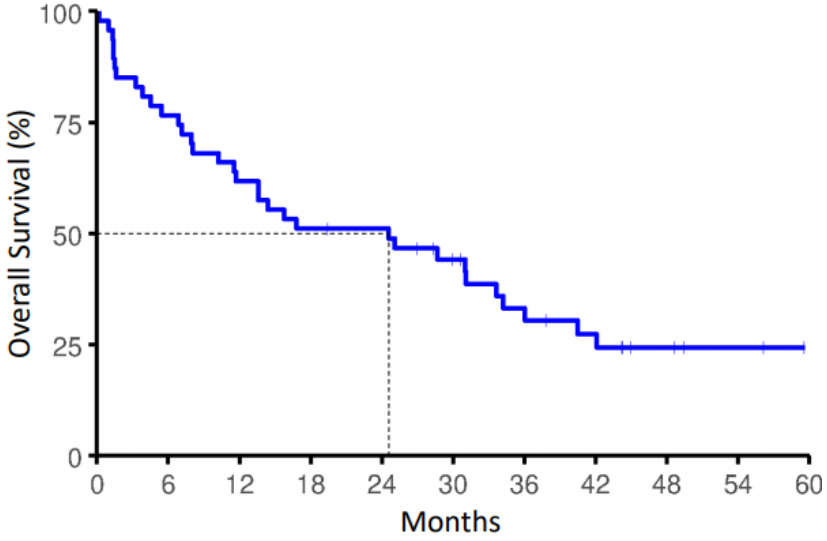


Exhibit IV - Cohort A versus Historical Data[7]

Months	HS-110 + Nivolumab Δ 94% non-squamous and 6% squamous All (N=47)
Median PFS	1.84
Median OS	24.60 29.7% still alive

Months	Nivolumab Non-squamous BMS Checkmate 057 Study* (N=292)
Median PFS	2.3
Median OS	12.2

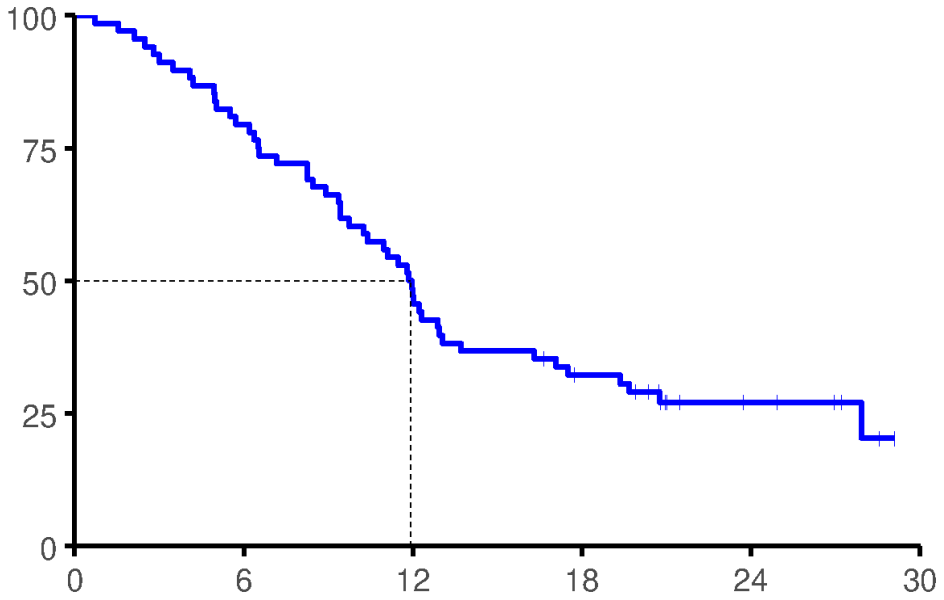
Results from Cohort B, checkpoint inhibitor progressors, were also compared to historical data. Constantini *et al.* 2018[8] and Schvartsman *et al.* 2017 investigated third-line or greater chemotherapy in CBI-failed subjects. Median OS ranged between 6.8 months and 9 months and median PFS ranged from 2.7 to 4.7 months in the studies. This compared to cohort B data with median OS of 11.9 and median PFS of 2.76, exceeding the upper end of median OS in the chemotherapies studied by almost three months. HS-110 has a favorable safety profile with approximately 200 patients receiving the drug and no treatment-related serious adverse reactions. For additional detail on results for HS-110, refer to our previous article. DURGA lacks a control arm and there are limitations to comparing it with other trials; however, Heat's interim results cast a favorable light on the candidate.

[5] Borghaei, H., Paz-Ares, L., Horn, L., Spigel, D. R., Steins, M., Ready, N. E. & Brahmer, J. R. (2015). Nivolumab versus docetaxel in advanced non-squamous non–small-cell lung cancer. *New England Journal of Medicine*, *373*(17), 1627-1639.
[6] Source: Heat Biologics March 2021 Corporate Presentation
[7] Heat Biologics Corporate Presentation February 2021
[8] Costantini, A., Corny, J., Fallet, V., Renet, S., Friard, S., Chouaid, C. & Cadranel, J. (2018). Hyper-progressive disease in patients with advanced non-small cell lung cancer (NSCLC) treated with nivolumab (nivo).

Exhibit V - Cohort B versus Historical Data[9]

Months	HS-110 + Nivolumab at ≥ 2nd line after CPI failure[Δ]	Treatment Options at ≥ 3rd line after CPI failure		
	All (N=68)	Gemcitabine† (N=27)	Docetaxel† (N=25)	Chemotherapy‡ (N=28)
Median PFS	2.76	2.8	2.7	4.7
Median OS	11.90 26.5% still alive	7.5	6.8	9.0

Exhibit VI – Overall Survival Curve, Cohort B[10]



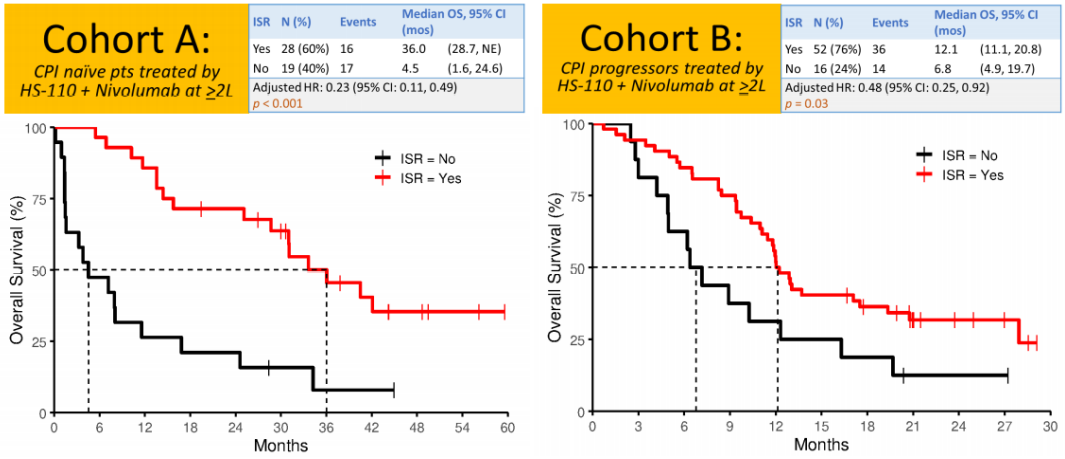
Additional data was presented at the 2021 ASCO Annual Meeting held in June, publicized in a June 4th press release. Injection Site Reaction (ISR) data was provided; ISR stratification was statistically significant ($p < 0.001$) in Cohort A, with subjects that were CBI naïve. Cohort A ISR-positive subjects (n=28, 60%) reached an mOS[11] of 36 months as of the November 2020 data cut while ISR-negative subjects (n=19, 40%) had mOS of 4.5 months. In Cohort B, with CBI progressor patients, the effect was less pronounced but was significant at the 3% level. ISR positive patients had mOS of 12.1 months vs 6.8 months for ISR negative patients. ISR may be used as a biomarker to identify patients most likely to benefit from the therapy.

Similarly, tumor PD-L1 expression stratification in Cohort A was significant at the 2% level, with patients greater than or equal to 1% PD-L1 (n=9) expression having a mOS of 40.5 months versus patients with less than 1% having mOS of 20.7 months. PD-L1 expression stratification in Cohort B was not statistically different.

The presentation and results are available on Heat's website and in Heat's May 2021 Corporate Presentation.

[9] Heat Biologics Corporate Presentation February 2021
[10] Source: Heat Biologics March 2021 Corporate Presentation
[11] Median Overall Survival

Exhibit VII - ISR Stratified Overall Survival[12]



Appointment of William L. Ostrander to Chief Financial Officer

Heat promoted William Ostrander to the position of Chief Financial Officer, effective January 4, 2021. Mr. Ostrander joined Heat in September 2019 as Vice President of Finance bringing two decades of experience to the role. Ostrander held leadership positions at Liquidia Technologies, serving as Director of Finance & Controller then Executive Director of Finance between 2014 and 2019, at KBI Biopharma for seven years as Senior Director, Finance & Accounting, and at LexisNexis, Seisint, and Boca Research in Finance and Accounting roles.

Pipeline

Exhibit VIII – Heat Biologics Product Pipeline[13]

Product	MOA (Modality)	Indication	IND-Enabling	Phase 1	Phase 2	Phase 3	Upcoming Activities
HS-110	gp96 + CTAs (Cell Therapy)	NSCLC					ASCO 2021 Poster End-of-Phase 2 Meeting
HS-130	OX40L (Cell Therapy)	Solid Tumors					Initial Data Readout in H2 2021
COVID-19 Vaccine	gp96 + Viral Antigens (Cell Therapy)	COVID-19					Pre-IND Meeting with FDA
PTX-35	TNFRSF25 (mAb)	Solid Tumors					Initial Data Readout in H2 2021

[12]Source: Heat Biologics May 2021 Corporate Presentation
[13] Source: Heat Biologics May 2021 Corporate Presentation.

Corporate Milestones

- William Ostrander appointed CFO - January 2021
- Various coronavirus vaccine milestones – 2021
    - Began manufacturing process for ZVX-60 - January 2021
    - Investigational New Drug (IND) Application
    - Phase I launch
- Positive interim survival data from HS-110 Ph2 NSCLC - February 2021
- Discussion with potential partners – ongoing
- Complete HS-130 Phase I trial – 1H:21
- Complete PTX-35 Phase I trial – 1H:21
- Data readout at ASCO for HS-110 – June 2021
- End of Phase II meeting for HS-110 – 2021
- Data readout on Phase I HS-130 – 2H:21
- Data readout on Phase I PTX-35 – 2H:21
- Additional detail regarding Phase III target NSCLC settings for HS-110 – 2022

Summary

Heat Biologics expects to provide readouts in 2021 for HS-110, HS-130 and PTX-35. Additional detail on how HS-110 will progress into the clinic is also expected and we expect to see which setting will be pursued in lung cancer later this year. Year to date, Heat has continued to raise capital with proceeds from a common stock offering adding $26 million to the balance sheet that along with existing cash should sustain operations for the next several years.

Heat Biologics' interim data from the DURGA trial reflect results from a combination approach of HS-110 with checkpoint inhibitors. The results compare favorably to historical data reflecting CBIs alone. This is an early confirmation of the opportunity for Heat's gp96/CTA technology. The interim data show HS-110's potential as a second line or later therapy, in conjunction with an anti-PD-1, in either CBI naïve or progressor patients. Based on this interim data, it appears that HS-110 and nivolumab could be superior to CBIs or chemotherapy alone. As Heat completes the Phase II trial, we look forward to topline and final analysis from the study, which was recently presented at ASCO. Heat management is in the process of arranging an End-of-Phase II meeting with the FDA where trial design and appropriate setting for the anticipated Phase III will be a primary point of discussion. Management is also in talks with key opinion leaders (KOLs) regarding the optimal regulatory path to pursue for the candidate. HS-110 may be pursued as a frontline treatment for NSCLC or as second line in checkpoint inhibitor-progressed patients. We maintain our valuation of $19.00 per share.

PROJECTED FINANCIALS

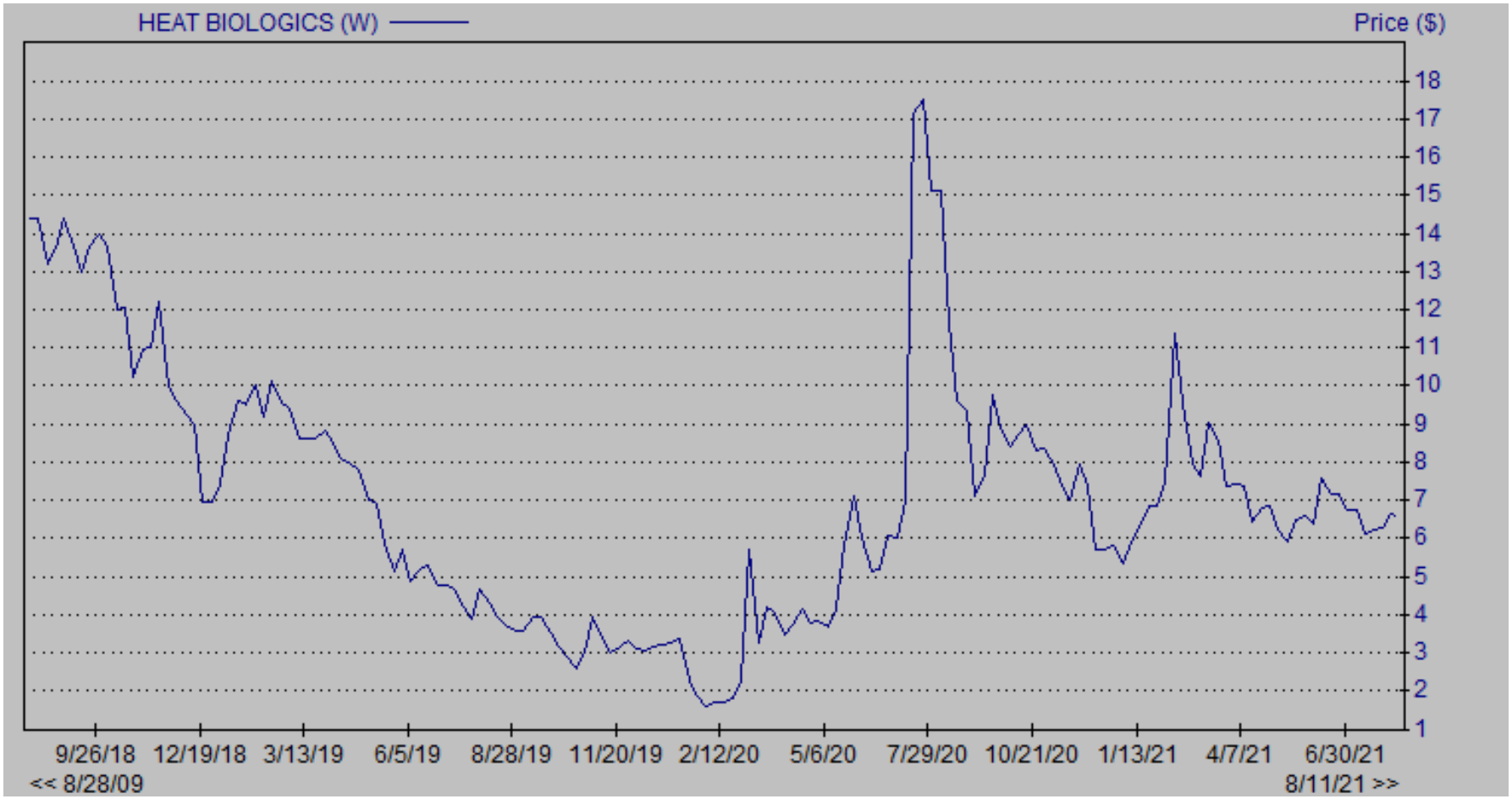
Heat Biologics, Inc. - Income Statement

Heat Biologics Inc.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($MM)	**$2.9**	**$0.5**	**$0.5**	**$0.4**	**$0.4**	**$1.8**	**$0.0**	**$0.0**
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
Income from operations	($26.1)	($7.6)	($6.7)	($7.3)	($8.1)	($29.6)	($36.3)	($38.8)
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
Pre-Tax Income	($26.4)	($7.6)	($6.6)	($7.1)	($7.9)	($29.2)	($36.3)	($38.8)
Provision for Income Tax	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0	$2.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*100.0%*	*200.0%*
Net Income	**($26.4)**	**($7.6)**	**($6.6)**	**($7.1)**	**($7.9)**	**($29.2)**	**($35.3)**	**($36.8)**
Non-controlling Interest	($0.3)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.4)	
Net Income After NCI	**($26.0)**	**($7.5)**	**($6.5)**	**($7.0)**	**($7.8)**	**($28.8)**	**($34.9)**	**($36.8)**
Net Margin	*-895%*	*-1415%*	*-1441%*	*-1783%*	*-1985%*	-	*# DIV/0!*	*# DIV/0!*
Reported EPS	**($1.63)**	**($0.31)**	**($0.26)**	**($0.27)**	**($0.30)**	**($1.15)**	**($1.33)**	**($1.36)**
YOY Growth	*-61%*	*-59.5%*	*-26.6%*	*-36.4%*	*7.0%*	*-30%*	*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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