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Heat Biologics Inc (HTBX - NASDAQ)

The Antigen Chaperone: gp96

Based on our DCF model and a 15% discount rate, Heat Biologics is valued at approximately $2.50 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 (5/18/2020)	$0.77
Valuation	**$2.50**

OUTLOOK

Heat Biologics has two novel immunotherapies in clinical development designated ImPACT & ComPACT. 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 begun 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 called PTX-35 which is awaiting IND clearance.

The valuation assumes a 2023 FDA approval of HS-110 and a 2023 launch of the compound in the US, followed by a 2024 launch in the EU and global availability by 2025 that will be achieved through the efforts of partners.

SUMMARY DATA

52-Week High	**1.25**
52-Week Low	**0.20**
One-Year Return (%)	**-3.8**
Beta	**-0.09**
Average Daily Volume (sh)	**15,382.430**
Shares Outstanding (mil)	**84.7**
Market Capitalization ($mil)	**65.2**
Short Interest Ratio (days)	**0.1**
Institutional Ownership (%)	**13.6**
Insider Ownership (%)	**6.0**
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 2019 Estimate	**N/A**
P/E using 2020 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)
2019	$0.7 A	$0.3 A	$0.0 A	$2.0 A	$3.0 A
2020	$0.9 A	$0.6 E	$0.6 E	$0.6 E	$2.8 E
2021					$0.0 E
2022					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	-$0.17 A	-$0.14 A	-$0.18 A	-$0.10 A	-$0.60 A
2020	-$0.11 A	-$0.07 E	-$0.07 E	-$0.09 E	-$0.33 E
2021					-$0.23 E
2022					-$0.23 E

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WHAT'S NEW

Full Year 2019 Results

Heat Biologics, Inc. (NASDAQ: HTBX) reported first quarter 2020 results in a May 15th release along with the submission of the 10-Q to the SEC. For the first five months of the year, Heat has been busy advancing preclinical work for a coronavirus vaccine, assembling data related to the Phase II HS-110 DURGA trial and raising significant capital to support the pipeline of projects. Heat management has also attended scientific and investor events sharing the company's progress. The company is in the process of preparing a data package to share with the FDA in an End-of-Phase II meeting that we expect will be scheduled in the next few months. The IND for PTX-35 has been submitted and clearance is expected in 2Q:20.

Revenues were $0.9 million for 1Q:20, from CPRIT grant money supporting the PTX-35 T cell activation platform. Research and development expenditures totaled $2.8 million, down 12% compared with the prior year first quarter amounts on lower clinical trial expense for HS-110 as trial completed enrollment. PTX-35 spend was also down compared to the prior year. HS-130 experienced a slight spending increase as did unallocated R&D related to increases in costs for the Zika program. General and administrative expenses were essentially flat at $3.3 million. Other expenses of ($1.2) million were primarily related to a ($1.0) million change in fair value of warrant liability and ($0.3) million in other expense. Net loss for 1Q:20 was ($6.3) million or ($0.11) per share compared with ($5.7) million or ($0.17) per share in 1Q:19.

Cash and equivalents as of March 31, 2020 were $26.4 million, compared to $14.8 million at the end of 2019. Heat continues with no debt on the books. Cash burn was ($5.8) million in the first quarter compared with ($4.2) million in 1Q:19. Add-back of stock based compensation and change in fair value of warrants partially offset by recognition of deferred revenue explained the majority of the difference between the ($6.3) million net loss and the ($5.8) million cash used in operations. Net cash provided by financing activities totaled $17.6 million, reflecting cash from the issuance of common stock and warrant exercise. Following the end of the reporting period, Heat raised an additional $2.9 million in capital from an at-the-market (ATM) facility.

Coronavirus

The global threat of coronavirus has changed the landscape for many biotechnology research and development companies. The spread of the virus may delay trial progression and the availability of drug product. But, it also has accelerated programs that many companies, including Heat Biologics, have developed in infectious disease. Heat's wholly-owned subsidiary, Zolovax, has been focused on developing medicines and vaccines for infectious diseases using the gp96 platform for many years. 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 and diagnostic test. As others in the space were able to advance diagnostic tests at a much faster rate, Heat subsequently abandoned its efforts to pursue the point of care test and centered its efforts on the gp96 based vaccine.

The vaccine incorporates multiple SARS-CoV-2 antigens using the gp96 platform. The approach is expected to induce long-term immunity and provide protection against future infections. As no viral vector is used, Heat's coronavirus vaccine avoids anti-vector immunity and viral activation while activating T and B cells with high immunogenicity. The activation of T and B cells drives induction of mucosal immunity and long-term memory response. In early March, the company filed multiple provisional patent applications for its technology that treat and prevent infection from the SARS-CoV-2 virus. Heat's approach may also be appropriate in combination with other vaccines that activate the humoral immune system on account of its complementary stimulation of the adaptive immune system.

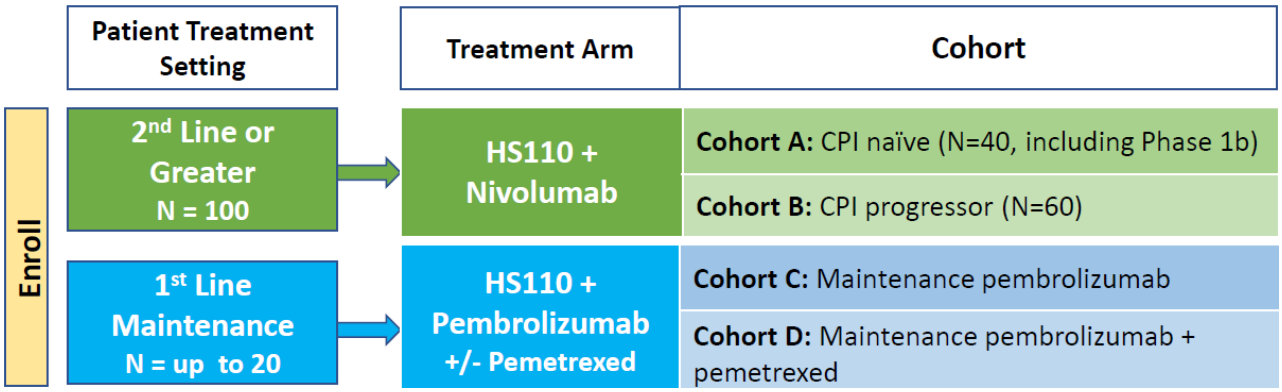
Heat has identified several milestones for the COVID-19 vaccine program in second quarter 2020. These include the completion of a cell-based vaccine containing gp96-Ig; OX40L-Ig; and SARS-CoV-2 protein S, development of proof-of-concept; animal-model data demonstrating vaccine immunogenicity and continued sourcing of funding to support the development efforts.

HS-110

The HS-110 Phase II Durga trial provided the latest update to its interim data in mid-November 2019. Cohort A enrolled checkpoint-inhibitor naïve patients and Cohort B enrolled patients previously on checkpoint inhibitor

therapy that have progressed. Both groups are treated with a combination of HS-110 and nivolumab. Initial results have been promising. There are two additional cohorts, designated C and D, which will examine HS-110 in combination with pembrolizumab, and pembrolizumab and chemotherapy which are intended to evaluate safety with an alternative checkpoint inhibitor. About 20 patients are expected to be enrolled in the C and D cohorts with 122 patients enrolled overall.

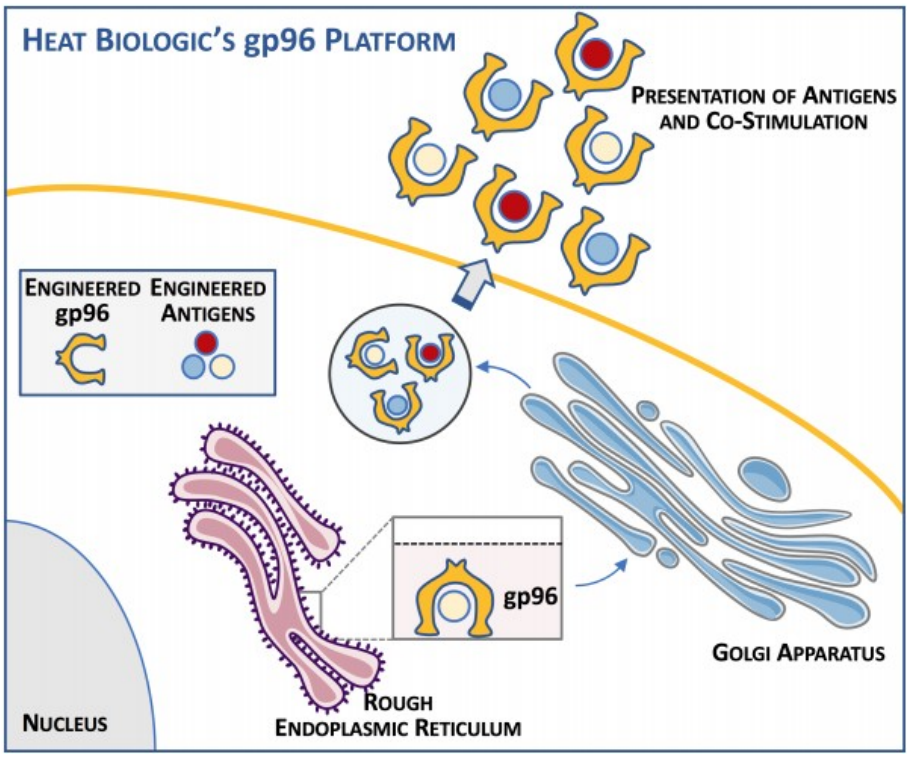
Exhibit I – HS-110 Trial Design[1]



ASCO 2020 Abstract

Heat is scheduled to present at the 2020 American Society of Clinical Oncology (ASCO) annual meeting to be held virtually. The conference will run from May 29th to June 2nd and will feature the company's poster entitled: "Tumor antigen expression and survival of patients with previously treated advanced non-small cell lung cancer (NSCLC) receiving viagenpumatucel-L (HS-110) plus nivolumab." The abstract highlights Cohort A in the Durga trial, which combines HS-110 with nivolumab in the 47-patient study. Subjects enrolled in this group exhibited an overall survival duration of 28.7 months. The cohort was divided into patients based on whether their tumor-antigens were similar to those in HS-110. (≥8 vs <8 antigens in common). Where HS-110 had a higher similarity to the patients' CTA, patients experienced a longer median overall survial.

Exhibit II – gp96 Platform[2]



[1] Source: Heat Biologics Corporate Presentation. November 5, 2019.
[2] Source: Heat Biologics Corporate Presentation. May 2020.

HS-130 and PTX-35

In an August 12, 2019 release, Heat announced that its IND for HS-130 had been submitted and received clearance from the FDA to begin a Phase I safety trial. On December 16, the first patient was dosed in the dose escalation trial. The combination study, which will pair HS-130 with HS-110, will enroll patients with advanced solid tumors refractory to standard of care. The candidate is in development to treat solid tumors and will employ the ComPACT technology which delivers the gp96 heat shock protein along with a T-cell co-stimulatory fusion protein (OX40L). The associated trial expects to enroll up to 30 patients and have primary endpoints of safety and optimal dose determination for its Phase II trial.

In November 2019 the period of the CPRIT grant was extended to May 30, 2020. Clearance for the PTX-35 IND is expected in 2Q:20, after which we expect the launch of the Phase I trial. CPRIT grant funds are expected to allow Pelican to develop PTX-35 through a 70-patient Phase I clinical program.

Corporate Milestones

Below we list key milestones for Heat Biologics.

- Complete HS-110 Phase II NSCLC enrollment – 2Q:19
- HS-130 (ComPACT) IND filing and FDA Clearance – August 2019
- HS-110 interim data readout – November 2019
- HS-110 Phase II interim readout – 4Q:19
- PTX-35 IND clearance and first patient dosing – 2Q:20
- Various coronavirus vaccine milestones – 2Q:20
- ASCO Poster Presentation – May 29, 2020
- Discussion with potential partners – Ongoing
- Schedule End of Phase II Meeting with FDA – 2H:20
- Complete HS-130 Phase I trial – 4Q:20
- Develop Phase III / commercial manufacturing capacity for HS-110 – 2020

Pipeline

Exhibit III – Heat Biologics Product Pipeline[3]

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				

[3] Source: Heat Biologics May 2020 Corporate Presentation.

Sources of Capital

Heat Biologics started 2020 with a solid $15 million in cash on the balance sheet. With multiple programs in the pipeline, management saw the opportunity to accelerate development by raising additional capital. Financing activities provided $17.6 million during the first quarter from a public share offering.

Following the end of the quarter, Heat filed a shelf registration enabling the company to conduct up to $150 million in equity fundraising. Along with this effort, an agreement was signed with B. Riley FBR to serve as Heat's sales agent and offer shares of common stock under an ATM facility. During the second quarter of 2020, $2.9 million was raised through the issuance of 5,352,234 shares under this program.

Summary

Heat Biologics made substantial progress in 2019 with advancements for all four cohorts in its Phase II NSCLC trial. A poster will be presented for HS-110 at ASCO at the end of the month featuring updated data for the Durga trial, after which Heat will schedule an End of Phase II meeting with the FDA to help chart the course forward for the treatment. Year to date, Heat has been opportunistic in raising capital and has established an ATM facility. They have also re-energized their work on infectious disease and have launched programs to develop a coronavirus vaccine using the gp96 platform.

Checkpoint inhibitors have been an exciting new area of immunotherapy; however, they are only successful in a minority of patients. Heat's portfolio seeks to awaken the immune system and increase the effectiveness of checkpoint inhibitors even in patients previously treated with checkpoint inhibitors. Interim data suggest that there may be a synergy between the two approaches.

Progress in being made across the portfolio. In addition to HS-110 progress, HS-130 received clearance to commence a Phase I dose-finding trial and has dosed its first patient. We also anticipate the start of a trial for PTX-35 in the near term. The company has a favorable cash position and should have sufficient funds to support operations into 2021. We maintain our valuation of $2.50 per share.

PROJECTED FINANCIALS

Heat Biologics, Inc. - Income Statement

Heat Biologics Inc.	2019 A	Q1 A	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues	**$3.0**	**$0.9**	**$0.6**	**$0.6**	**$0.6**	**$2.8**	**$0.0**	**$0.0**
YOY Growth								
Research & Development	$13.0	$2.8	$4.2	$4.8	$6.2	$18.0	$18.5	$18.5
General & Administrative	$9.4	$3.3	$2.5	$2.2	$2.4	$10.4	$10.0	$11.2
Other	$1.4	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Income from operations	($20.7)	($5.1)	($6.1)	($6.4)	($8.0)	($25.6)	($28.5)	($30.7)
Interest Income	$0.4	$0.1	$0.1	$0.1	$0.1	$0.4	$0.0	$0.0
Other Income	($0.0)	($1.3)	$0.0	$0.0	$0.0	($1.3)	$0.0	$0.0
Pre-Tax Income	($20.3)	($6.4)	($6.0)	($6.3)	($7.9)	($26.5)	($28.5)	($30.7)
Provision for Income Tax	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*100.0%*
Net Income	**($20.4)**	**($6.4)**	**($6.0)**	**($6.3)**	**($7.9)**	**($26.5)**	**($28.5)**	**($29.7)**
Non-controlling Interest	($0.4)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.8)	
Net Income After NCI	**($20.0)**	**($6.3)**	**($5.9)**	**($6.2)**	**($7.8)**	**($26.1)**	**($27.7)**	**($29.7)**
Net Margin	*-669%*	*-707%*	*-1000%*	*-1050%*	*-1317%*	*-947%*	-	*# DIV/0!*
Reported EPS	**($0.60)**	**($0.11)**	**($0.07)**	**($0.07)**	**($0.09)**	**($0.33)**	**($0.23)**	**($0.23)**
YOY Growth	*-33%*	*-35.6%*	*-49.8%*	*-61.7%*	*-13.6%*	*-45%*	*-30%*	*-1%*
Basic Shares Outstanding	33.28	57.28	82.00	88.00	90.00	79.32	120.00	130.00

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Heat Biologics, Inc. – Share Price Chart



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