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Heat Biologics Inc (HTBX - NASDAQ)

$25 M in Cash to Advance Portfolio

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 (4/3/2020)	$0.50
Valuation	**$2.50**

OUTLOOK

Heat Biologics has two novel immunotherapies in clinical development designated ImPACT & ComPACT and one other awaiting IND clearance. 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.

The company's key 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. 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	**1.27**
52-Week Low	**0.20**
One-Year Return (%)	**-59.3**
Beta	**1.16**
Average Daily Volume (sh)	**12,996,273**
Shares Outstanding (mil)	**79.4**
Market Capitalization ($mil)	**39.7**
Short Interest Ratio (days)	**0.1**
Institutional Ownership (%)	**13.5**
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)
2018	$0.8 A	$1.1 A	$1.8 A	$2.1 A	$5.8 A
2019	$0.7 A	$0.3 A	$0.0 A	$2.0 A	$3.0 A
2020					$2.8 E
2021					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2018	-$0.75 A	-$0.27 A	-$0.16 A	-$0.17 A	-$0.90 A
2019	-$0.17 A	-$0.14 A	-$0.18 A	-$0.10 A	-$0.60 A
2020					-$0.30 E
2021					-$0.30 E

*2018 quarterly EPS does not sum due to distortion from share issuance.

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WHAT'S NEW

Full Year 2019 Results

Heat Biologics, Inc. (NASDAQ: HTBX) reported full year 2019 results in a March 30 release along with the submission of the 10-K to the SEC. During 2019 and year to date, Heat has attended numerous scientific and investment conferences and advanced its Phase II trial for HS-110. An investigational new drug application (IND) was submitted for HS-130, resulting in clearance to start in-human trials and dosing of the first patient. The IND for PTX-35 has been submitted and clearance is expected in 2Q:20. There have also been several posters presented that provide an interim look at the multiple cohorts in the Durga trial. The focus has been on the interim data from Cohorts A and B in the Durga trial, which is examining HS-110 in combination with checkpoint inhibitors for both checkpoint naïve and experienced patients. Both groups demonstrated impressive overall survival (OS) and other clinical efficacy in interim findings.

Revenues were $3.0 million for 2019, representing CPRIT grant money which is directed towards the PTX-35 T cell activation platform. Heat caught up with expectations in the fourth quarter after the IND filing for PTX-35 and received $2.0 million in CPRIT funds. Research and development costs totaled $13.0 million, down 20% compared to 2018 on lower clinical trial expense for HS-110 as the trial completed enrollment. Other programs, including HS-130 and PTX-35 were also down in spend compared to the prior year. These declines were offset by increases in costs for the Zika program, T-cell costimulatory programs and higher stock compensation expense. General and administrative expenses rose 34% to $9.4 million due to an increase in personnel and greater stock-based compensation. Other expenses of $1.3 million were related to goodwill impairment and change in fair value of contingent consideration.

As of the end of 2019, Heat has received $13.7 million in funds from the CPRIT grant, out of a total award of $15.2 million. The remaining balance will be awarded after all requirements have been met. The company must contribute an additional $2.4 million to the PTX-35 program as a condition of receiving the balance of funds.

Cash and equivalents as of December 31, 2019 were $14.8 million, compared to $27.7 million at the end of 2018. Heat continues with no debt on the books. Cash burn was ($13.0) million for the year compared to the ($22.3) million in 2018. Add-back of deferred revenue, the goodwill impairment loss related to the 2017 Pelican acquisition and change in fair value of contingent consideration explained the majority of the difference between net loss of ($20.0) million and the ($12.8) million cash used in operations. Following the end of the reporting period, Heat raised additional capital from a variety of sources and reports over $25 million in cash as of March 23, 2020.

Coronavirus

The expansion of the coronavirus into a pandemic 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. However, it also has highlighted and advanced programs to the forefront 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 (coronavirus) vaccine and diagnostic test.

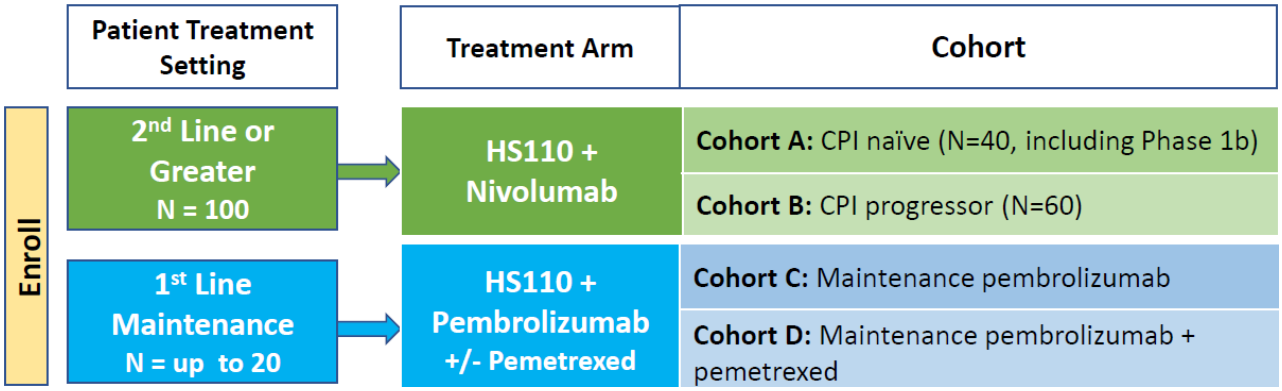
The vaccine incorporates multiple SARS-CoV-2 antigens using the gp96 platform. The approach is expected to induce long-term immunity and provide protection against future infections. Heat's coronavirus vaccine avoids anti-vector immunity and viral activation, as no virus is used, while activating T and 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 apply to treating and preventing infection from the SARS-CoV-2 virus.

The coronavirus diagnostic will be a rapid, inexpensive, point-of-care, paper-based test specific for SARS-CoV-2. It is a non-polymerase chain reaction (PCR) based rapid diagnostic that uses a combination of reverse transcription recombinase polymerase amplification (RT-RPA) and a paper-based microfluidic analytical detection platform. This simple structure of the diagnostic eliminates the need for the instruments and reagents used in PCR testing.

HS-110

The HS-110 Phase II Durga trial provided the latest update to its interim data with a presentation and poster 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 look at HS-110 used in combination with pembrolizumab and pembrolizumab and chemotherapy. About 20 patients are expected to be enrolled in the C and D cohorts and 122 patients overall.

Exhibit I – HS-110 Trial Design[1]



In the first part of November, updated interim analysis of the trial was provided in two posters that were presented at the American Association for Cancer Research (AACR) special conference on Tumor Immunology and the Immunotherapy Society for Immunotherapy of Cancer (SITC).

The AACR poster updated stakeholders on Cohort A progress reflecting data current as of the end of July. This group was checkpoint naïve and included 46 patients. Based on iRECIST[2] criteria, PR was observed in 10 patients (22%), SD in 12 patients (26%) and DCR in 22 patients (48%). Median OS was 16.9 months; however, when stratified by PD-L1 positive or injection site reaction (ISR) positive, mOS increased to 42.1 months. Adverse events at grade 3 or above affected 37% of patients and the most common adverse event was injection site reaction at 57%. Conclusions from the interim analysis found that:

- The effect of HS-110 in combination with nivolumab is not dependent on baseline PD-L1 expression,
- ISR is associated with improved PFS/OS, and
- Best overall response is associated with T cell subset biomarker that indicated terminal differentiation (CD57)

Exhibit II – Typical Injection Site Reaction[3]



[1] Source: Heat Biologics Corporate Presentation. November 5, 2019.
[2] iRECIST is immune Response Evaluation Criteria in Solid Tumors and measures progression on a number of factors. iRECIST was created to recognize that in immunotherapy tumor size can increase as T cells infiltrate the lesion. As compared to RECIST 1.1, iRECIST allows patients to continue to receive treatment if there are no other signs of clinical progression other that tumor size.
[3] Source: Heat Biologics Corporate Presentation. November 5, 2019.

The SITC poster, entitled "Treating Advanced Non-Small Lung Cancer (NSCLC) Patients After Checkpoint Inhibitor Treatment Failure With A Novel Combination Of Viagenpumatucel-L (HS-110) Plus Nivolumab" updated viewers to Cohort B's progress up to July. This group, which has received previous treatment with a checkpoint inhibitor includes 56 patients. Partial response (PR) was observed in 7 patients (13%), stable disease (SD) in 26 patients (46%) and the disease control rate (DCR) was 59%. Median overall survival (mOS) is 11.8 months with 39 patients (70%) still alive. When examining patients based on injection site reaction (ISR), mOS improved to 12 months. The study concluded that:

- HS-110 in combination with nivolumab is not dependent on PD-L1 expression,
- The occurrence of ISR is associated with progression free survival (PFS), and
- OS and data suggest that re-challenging the immune system with nivolumab and HS-110 after checkpoint inhibitor treatment restores responsiveness and clinical benefit for some patients.

HS-130 and PTX-35

In an August 12 release, Heat announced that its IND for HS-130 had been submitted and clearance received from the FDA to begin a Phase I safety trial. On December 16, the first patient was dosed. The combination study, which will pair HS-130 with HS-110, will be administered in 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). As of mid-December, the first patient had been dosed in the dose escalation trial. The associated trial expects to enroll up to 30 patients with primary endpoints of safety and the determination of the optimal dose for a 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.

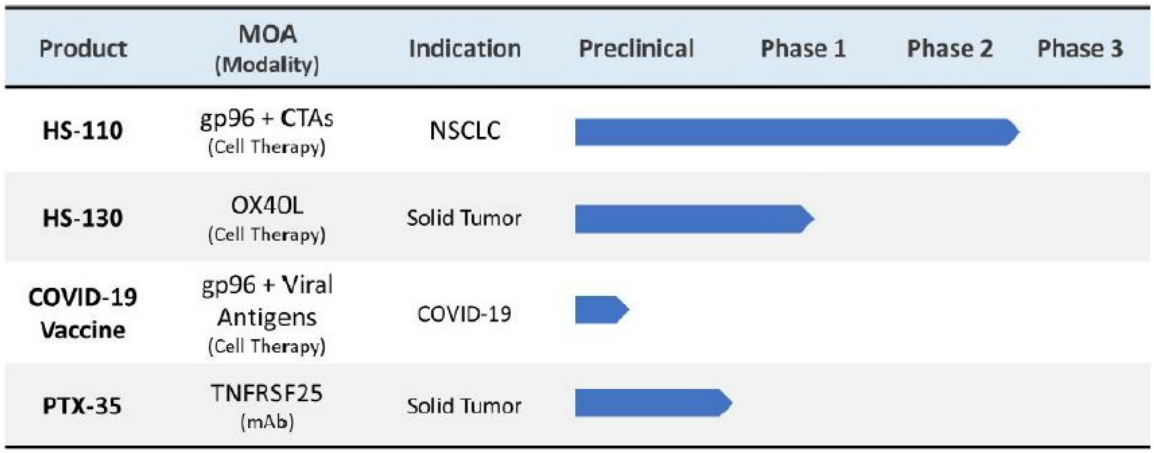
Corporate Milestones

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 – 2Q:20
- Discussion with potential partners – Ongoing
- Develop Phase III / commercial manufacturing capacity for HS-110 – 2019

Pipeline

Exhibit III – Heat Biologics Product Pipeline[4]



[4] Source: Heat Biologics 2019 10-K.

Summary

Heat Biologics made substantial progress in 2019 with advancements for all four cohorts in its Phase II trial for NSCLC. In November, the team presented data at the Society for Immunotherapy of Cancer (SITC), with several posters summarizing data from the company's pipeline. During the first quarter of 2020, Heat was opportunistic in raising capital raising and reported over $25 million in cash at the end of the period. They have also re-energized their work on infectious disease and have launched programs to develop a coronavirus vaccine using the gp96 platform and construct a diagnostic test for the virus.

Checkpoint inhibitors have been an exciting new are 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 and we are eagerly awaiting additional data to determine whether may be the case.

Progress in being made across the portfolio and in addition to updates for HS-110, 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 following IND clearance.

The company has a favorable cash position and should have sufficient funds to support operations into 2021. We adjust our valuation to reflect the increase in shares and warrants outstanding reducing it to $2.50 per share.

PROJECTED FINANCIALS

Heat Biologics, Inc. - Income Statement

Heat Biologics Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 A	2019 A	2020 E	2021 E
Total Revenues	**$5.8**	**$0.7**	**$0.3**	**$0.0**	**$2.0**	**$3.0**	**$2.8**	**$0.0**
YOY Growth								
Research & Development	$16.2	$3.2	$3.4	$3.1	$3.3	$13.0	$18.0	$18.5
General & Administrative	$7.0	$3.3	$1.9	$2.0	$2.2	$9.4	$8.2	$8.6
Other	$0.5	$0.1	$0.1	$1.2	($0.1)	$1.4	$0.0	$0.0
Income from operations	($18.0)	($5.9)	($5.1)	($6.4)	($3.4)	($20.7)	($23.4)	($27.1)
Operating Margin	*-310%*	*-846%*	*-1476%*	*-98696%*	*-170%*	*-680%*	*-836%*	*-*
Interest Income	$0.3	$0.2	$0.1	$0.1	$0.1	$0.4	$0.0	$0.0
Other Income	$0.1	$0.0	($0.0)	($0.1)	$0.1	($0.0)	$0.0	$0.0
Pre-Tax Income	($17.6)	($5.8)	($4.9)	($6.3)	($3.3)	($20.3)	($23.4)	($27.1)
Provision for Income Tax	$1.0	$0.0	$0.0	$0.0	($0.0)	($0.0)	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($16.6)**	**($5.8)**	**($4.9)**	**($6.3)**	**($3.3)**	**($20.4)**	**($23.4)**	**($27.1)**
Non-controlling Interest	($0.9)	($0.1)	($0.2)	($0.1)	$0.0	($0.4)	($0.8)	($0.8)
Net Income After NCI	**($15.7)**	**($5.7)**	**($4.8)**	**($6.2)**	**($3.4)**	**($20.0)**	**($22.6)**	**($26.3)**
Net Margin	*-286%*	*-824%*	*-1444%*	*-98321%*	*-167%*	*-669%*	*-836%*	*-*
Reported EPS	**($0.90)**	**($0.17)**	**($0.14)**	**($0.18)**	**($0.10)**	**($0.60)**	**($0.30)**	**($0.30)**
YOY Growth	*-71%*	*-77.2%*	*-47.8%*	*16.4%*	*-40.8%*	*-33%*	*-50%*	*-1%*
Basic Shares Outstanding	17.49	33.23	33.26	33.65	33.72	33.28	74.90	88.00

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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