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Heat Biologics Inc (HTBX - NASDAQ)

HS-110 Interim Data Read: Cohorts A & B

Based on our DCF model and a 15% discount rate, Heat Biologics is valued at approximately $5.00 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 (11/21/2019)	$0.47
Valuation	**$5.00**

OUTLOOK

Heat Biologics has two novel immunotherapies in clinical development designated ImPACT & ComPACT. They utilize 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 received FDA clearance to start the HS-130 trial in 3Q:19. 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 expected to be the subject of an IND filed in 4Q:19.

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	**1.80**
52-Week Low	**0.35**
One-Year Return (%)	**-66.9**
Beta	**1.75**
Average Daily Volume (sh)	**285,678**
Shares Outstanding (mil)	**34.1**
Market Capitalization ($mil)	**16.0**
Short Interest Ratio (days)	**4.8**
Institutional Ownership (%)	**16.1**
Insider Ownership (%)	**3.6**
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	$1.1 E	$3.2 E
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	-$0.15 E	-$0.61 E
2020					-$0.61 E
2021					-$0.66 E

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

WHAT'S NEW

Third Quarter 2019 Results

Heat Biologics, Inc. (NASDAQ: HTBX) reported third quarter 2019 results in a November 15 release following the submission of the companion 10-Q to the SEC the prior day. Since the beginning of the year, 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. There have also been several posters presented that provide an interim look at the multiple cohorts in the Durga trial.

Recent 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. Other efforts by Heat continue to progress the IND for PTX-35 which we expect in the near term.

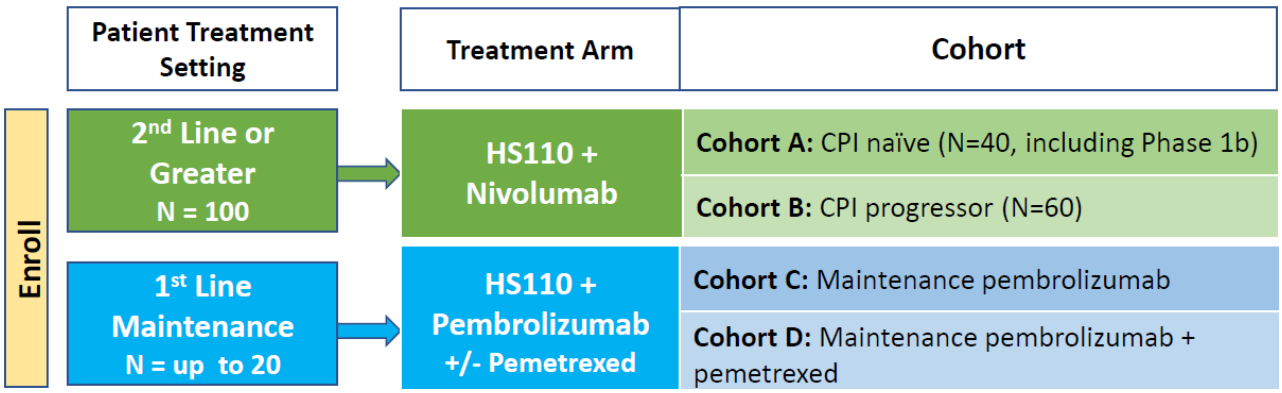
Revenues were minimal in the third quarter, representing CPRIT grant money which is directed towards the PTX-35 T cell activation platform. This compares to our estimates of $1.1 million with the difference attributable to timing of CPRIT funds received and the delay in IND filing for PTX-35 relative to our expectations. Research and development costs totaled $3.1 million, down 29% compared to 3Q:18 on slightly lower spending for the PTX-35 offset by increases in HS-110 and unallocated spending. General and administrative expenses rose 26% to $2.0 million on increased personnel costs, stock-based compensation expense and consulting expenses. Other expenses of $$1.2 million were related to goodwill impairment and change in fair value of contingent consideration.

Cash and equivalents as of September 30, 2019 were $15.0 million, compared to $27.7 million at the end of 2018. Heat continues with no debt on the books. Cash burn was ($4.3) million for 3Q:19 slightly ahead of the ($4.0) million in the comparable 2018 period. Add-back of the goodwill impairment loss related to the 2017 Pelican acquisition, change in fair value of contingent consideration and stock based compensation explained the majority of the difference between net loss of ($6.3) million and the ($4.0) million cash used in operations.

HS-110

The HS-110 Phase II Durga trial continues to provide updated interim data. 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, which will be 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 120 patients overall.

Exhibit I – HS-110 Trial Design[1]



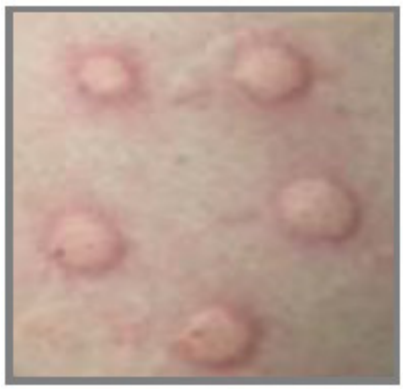
In the first part of November, updated interim analysis of the trial was provided in two posters that were presented at the American Association for Cancer Research (AACR) special conference on Tumor Immunology and the Immunotherapy Society for Immunotherapy of Cancer (SITC).

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

The AACR poster updated viewers on Cohort A 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 event 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]



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.

PTX-35 and HS-130

In an August 12 release, Heat announced that their IND for HS-130 had been submitted and clearance received from the FDA to begin a Phase I safety trial. The combination study, which will join 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 November, the first patient has been dosed in the dose escalation trial.

There has been a delay in submitting the PTX-35 IND application and anticipate that it will be presented to the FDA in the near term, which should be followed shortly after by the receipt of the next tranche of CPRIT funds. The CPRIT Grant is expected to allow Pelican to develop PTX-35 through a 70-patient Phase I clinical program.

[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.

Presentations & Interim Results

Heat presented four posters at The Society for Immunotherapy of Cancer (SITC) in National Harbor in Maryland. The most important of these, we discussed above. The other three posters summarized preclinical analysis for PTX-35 in combination with other agents as we summarize below.

1. Preclinical Development Of A Novel, Allogeneic, OX40L-Secreting, Therapeutic Cancer Vaccine For Use In Combination With A gp96-Secreting Vaccine For Solid Tumors
    a. Combining an allogeneic tumor line expressing gp96-Ig and OX40L-Ig is a potent stimulator of anti-tumor CD8+ T-cell immune responses in animals
    b. Optimal ratio of gp96-Ig to OX40L-Ig falls within the range of 1-to-1.3 and 1-to-2.5; with 1-to-1.3 providing the best expansion and anti-tumor immunity
    c. Addition of OX40L-Ig secreting cells to gp96-Ig provides a synergistic impact on both transferred and endogenous tumor specific T-cells
    d. The minimal anticipated biological effect level for this dose combination is 113 ng of gp96-Ig to 147 ng of OX40L, with the no observed effect level being 38 ng of gp96-Ig to 50 ng of OX40L-Ig
2. Preclinical Development Of A Novel TNFRSF25 Agonist Antibody, PTX-35, For Cancer Immunotherapy Combinations
    a. PTX-35 is a potent TNFRSF25 agonist mAb with a favorable safety profile targeted for combinations with antigen-driven cancer immunotherapy
    b. PTX-35 can expand conventional and regulatory T-cells in mouse, monkey and human without deleterious cytokine release or impact on mounting successful immune responses
    c. Five dose levels of PTX-35 will be explored in humans using traditional 3+3 design based on dose limiting toxicities until optimal immunological dose is reached
3. A Novel TNFRSF25 Agonist, PTX35, Synergizes with Gp96-Ig/OX40L-Ig to Enhance Effector and Memory Anti-Tumor CD8+ T Cell Responses and Delay Tumor Growth
    a. PTX35 synergizes with Gp96-Ig/OX40L-Ig to enhance activated tumor-specific CD8+ T cells and effector memory CD8+ T cells
    b. Tumor-Infiltrating Lymphocytes (TILs) are significantly increased after PTX35 addition and results in a substantial reduction in tumor growth
    c. Checkpoint inhibition (αPD1) with GP96-Ig and PTX35 results in a significant increase in antigen-specific CD8+ T cell responses, reduction in tumor burden, and an increase in OS

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
- Receipt of $6.9 MM in CPRIT grant funds (PTX-35) – Upon filing of IND
- PTX-35 IND filing – 4Q:19/1Q:20
- HS-110 Phase II interim readout – 4Q:19
- Interim PTX-35 data readout – 4Q:19
- Interim ComPACT data readout – 4Q:19
- Discussion with potential partners – Ongoing
- Develop Phase III / commercial manufacturing capacity for HS-110 – 2019

Pipeline

Exhibit III – Heat Biologics Product Pipeline[4]

Combination Therapies	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	Comments
HS-110	NSCLC					*ImPACT™* activation technology in combination with nivolumab and pembrolizumab
HS-130	Multiple Solid Tumors					*ComPACT™* activation technology in combination with checkpoint inhibitors
Co-stimulators						
PTX-35	Multiple Solid Tumors					Humanized monoclonal antibody, functional agonist of human TNFRSF25 ($15.2M CPRIT grant)

Summary

Heat Biologics has participated in numerous investment and scientific conferences year to date presenting impressive data on HS-110 in combination with nivolumab. The most recent interim analysis as of July demonstrates mOS of 16.9 months for Cohort A and 11.8 months for Cohort B. For certain populations with ISR, this extends to 42 and 12 months respectively. We anticipate that the mOS will improve from here as the cohorts mature. 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 this 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 which will be accompanied by a cash inflow from CPRIT.

The company has a favorable cash position, holding $15 million in funds which will be augmented by additional CPRIT dollars for advancement of PTX-35. Cash is sufficient to advance pipeline activities until 2020. We maintain our target price of $5.00 per share.

[4] Source: Heat Biologics Corporate Presentation November 5, 2019.

PROJECTED FINANCIALS

Heat Biologics, Inc. - Income Statement

Heat Biologics Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 E
Total Revenues	**$5.8**	**$0.7**	**$0.3**	**$0.0**	**$1.1**	**$2.1**	**$2.8**	**$0.0**
YOY Growth								
Research & Development	$16.2	$3.2	$3.4	$3.1	$4.7	$14.4	$18.0	$18.5
General & Administrative	$7.0	$3.3	$1.9	$2.0	$2.0	$9.2	$8.2	$8.6
Other	$0.5	$0.1	$0.1	$1.2	$0.0	$0.0	$0.0	$0.0
Income from operations	($18.0)	($5.9)	($5.1)	($6.4)	($5.6)	($21.5)	($23.4)	($27.1)
Operating Margin	*-310%*	*-846%*	*-1476%*	*-98696%*	*-509%*	*-999%*	*-836%*	*-*
Interest Income	$0.3	$0.2	$0.1	$0.1	$0.0	$0.4	$0.0	$0.0
Other Income	$0.1	$0.0	($0.0)	($0.1)	$0.0	($0.1)	$0.0	$0.0
Pre-Tax Income	($17.6)	($5.8)	($4.9)	($6.3)	($5.6)	($21.2)	($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)**	**($5.6)**	**($21.2)**	**($23.4)**	**($27.1)**
Non-controlling Interest	($0.9)	($0.1)	($0.2)	($0.1)	($0.2)	($0.6)	($0.8)	($0.8)
Net Income After NCI	**($15.7)**	**($5.7)**	**($4.8)**	**($6.2)**	**($5.4)**	**($20.6)**	**($22.6)**	**($26.3)**
Net Margin	*-286%*	*-824%*	*-1444%*	*-98321%*	*-509%*	*-985%*	*-836%*	*-*
Reported EPS	**($0.90)**	**($0.17)**	**($0.14)**	**($0.18)**	**($0.15)**	**($0.61)**	**($0.61)**	**($0.66)**
YOY Growth	*-71%*	*-77.2%*	*-47.8%*	*16.4%*	*-10.9%*	*-33%*	*1%*	*8%*
Basic Shares Outstanding	17.49	33.23	33.26	33.65	35.90	34.01	37.00	40.00

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

HISTORICAL STOCK PRICE

Heat Biologics, Inc. – Share Price Chart

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