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Heat Biologics Inc (HTBX - NASDAQ)

HS-130 Ready To Go

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 (8/16/2019)	$0.57
Valuation	**$5.00**

OUTLOOK

Heat Biologics has developed two novel immunotherapies 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 has 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 3Q: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	**2.24**
52-Week Low	**0.51**
One-Year Return (%)	**-69.0**
Beta	**2.61**
Average Daily Volume (sh)	**369,615**
Shares Outstanding (mil)	**34.1**
Market Capitalization ($mil)	**19.4**
Short Interest Ratio (days)	**1.1**
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 2018 Estimate	**N/A**
P/E using 2019 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	$1.1 E	$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	-$0.14 E	-$0.15 E	-$0.60 E
2020					-$0.61 E
2021					-$0.66 E

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

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WHAT'S NEW

Second Quarter 2019 Results

Heat Biologics, Inc. (NASDAQ: HTBX) reported second quarter 2019 results in a August 14 release and concurrently submitted the companion 10-Q to the SEC. Since the beginning of the year, Heat has attended numerous scientific and investment conferences and advanced its Phase II trial for HS-110. An IND was submitted for HS-130, resulting in clearance to start in-human trials. Expenditures for the second quarter dipped as INDs were compiled and Heat prepares for two new compounds to enter the clinic. By the end of the year, we expect the company to have trials in process for HS-110, PTX-35 and HS-130.

The focus this summer was on the two investigational new drug (IND) applications for HS-130 and PTX-35. The IND for HS-110 was filed and clearance was granted by the FDA to start clinical trial work. The IND for PTX-35 is in process and is expected to be filed in the third quarter.

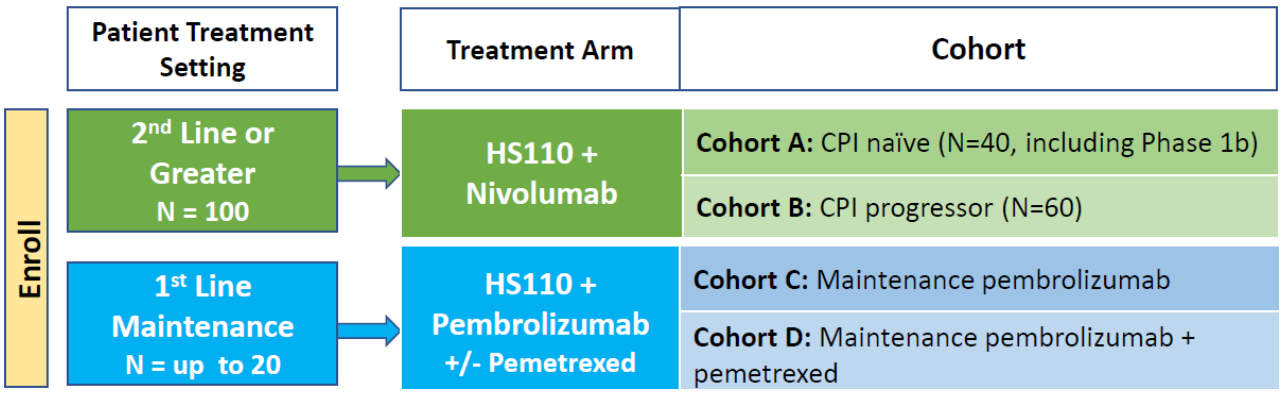
Revenues for the second quarter were $0.3 million, representing CPRIT grant money which is directed towards the PTX-35 T-cell activation platform. This compares to our estimates of $1.1 million with the difference attributable to timing of CPRIT funds received and the delay in IND filing for PTX-35. Research and development costs totaled $3.4 million, down 2% compared to 2Q:18 on slightly higher spending on the HS-110 program. General and administrative expenses rose 37% to $1.9 on increased personnel costs, including an allocation to stock-based compensation expense.

Cash and equivalents as of June 30, 2019 were $19.5 million, compared to $27.7 million at the end of 2018. Heat continues with no debt on the books. Cash burn was ($4.1) million for 2Q:19 substantially lower than the amount in the comparable 2018 period which recognized over $2 million in prepaid expenses and the payment of other liabilities co-incident with a capital raise. Add-back of stock based compensation explained the majority of the difference between net loss of ($4.8) million and the ($4.1) million cash used in operations.

HS-110

The HS-110 trial reported interim Phase II data in early March. Cohort A includes naïve patients treated with HS-110 and nivolumab and Cohort B includes checkpoint inhibitor patients that have progressed, but then treated with HS-110 and nivolumab. Initial results have been promising which we discuss in a previous article. We expect these two cohorts to complete enrollment in the second quarter. 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



The primary takeaways from the Cohort B results include the association of injection site reaction with improved progression free survival (PFS) and overall survival (OS). Over the 18-week injection cycle (1x injection per week), reactions were generally observed early in the treatment, around the third or fourth injection. As of the latest data analysis for the cohort in April 2019, median PFS was 2.7 months. Heat is currently seeking a biomarker that will predict injection site reaction (ISR), which would be expected to dramatically increase the PFS by targeting those patients who benefit the most.

Exhibit II – Typical Injection Site Reaction



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). Current good manufacturing process (cGMP) and IND-enabling activities are underway.

There has been a delay in submitting the IND due to reformulation efforts; however, these are largely resolved. We anticipate the investigational new drug (IND) application will be presented to the FDA in the third quarter, 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.

Pelican is working with Selexis for cell line expression for the CMC development of PTX-35. Selexis will also help develop PTX-15 and the TNFRSF25 agonist program.

Presentations & Interim Results

Heat's AACR Annual Meeting poster entitled "Generation of a novel, allogeneic cell-based, Gp96-Ig/OX40L cancer vaccine, improves anti-tumor immunity and long-term memory T-cell generation" was presented on April 1. It concluded that a combination of an allogeneic tumor line expressing gp96-Ig and OX40L-Ig is a potent stimulator of anti-tumor CD8+ T-cell immune responses in animals. The sub-study, which examined the effectiveness of varying ratios of gp96 and OX40L-Ig, observed the most favorable ratio between 1:0.5 and 1:1 respectively as well as synergistic impacts from the use of both compounds and minimum active biological doses. Following the issuance of the poster, work has advanced and the ratios are expected to evolve as further study is conducted.

Corporate Milestones

Heat is conducting Phase II trials for HS-110, has received clearance from the FDA for a Phase I study for HS-130 (ComPACT) and is in the process of submitting an IND for PTX-35. Below we list key milestones for Heat Biologics.

- HS-110 (NSCLC) interim data readout - 1Q:19
- Receipt of $6.9 MM in CPRIT grant funds (PTX-35) – 3Q:19
- Complete HS-110 Phase II NSCLC enrollment – 2Q:19
- HS-130 (ComPACT) IND filing and FDA Clearance – August 2019
- PTX-35 IND filing – 3Q:19
- 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

Combination Therapies	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	Comments
ImPACT® HS-110	NSCLC					*ImPACT™* activation technology in combination with nivolumab and pembrolizumab
ComPACT® 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 while concurrently developing INDs applications for HS-130 and PTX-35. The HS-130 IND was given clearance by the FDA and we expect a start to the trial in the near term. After a short delay due to reformulation, PTX-35 is on track for a 3Q:19 IND submission followed by enrollment efforts beginning shortly after. Interim results for HS-130 were presented, demonstrating that HS-110 and nivolumab may restore responsiveness to treatment in NSCLC patients after receiving prior lines of checkpoint inhibitor therapy and that injection site reaction may be a good predictor for efficacy.

The company has a favorable cash position, holding almost $20 million in funds which will be augmented by additional CPRIT dollars for advancement of PTX-35. We anticipate these additional ammounts will be received following IND submission. Cash is sufficient to advance pipeline activities until 2020. We maintain our target price of $5.00 per share.

PROJECTED FINANCIALS

Heat Biologics, Inc. - Income Statement

Heat Biologics Inc.	2018 A	Q1 A	Q2 A	Q3 E	Q4 E	2019 E	2020 E	2021 E
Total Revenues	**$5.8**	**$0.7**	**$0.3**	**$1.1**	**$1.1**	**$3.2**	**$2.8**	**$0.0**
YOY Growth								
Research & Development	$16.2	$3.2	$3.4	$4.3	$4.7	$15.5	$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	$0.0	$0.0	$0.0	$0.0	$0.0
Income from operations	($18.0)	($5.9)	($5.1)	($5.2)	($5.6)	($21.5)	($23.4)	($27.1)
Operating Margin	*-310%*	*-846%*	*-1476%*	*-468%*	*-509%*	*-663%*	*-836%*	-
Interest Income	$0.3	$0.2	$0.1	$0.0	$0.0	$0.3	$0.0	$0.0
Other Income	$0.1	$0.0	($0.0)	$0.0	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($17.6)	($5.8)	($4.9)	($5.2)	($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)**	**($5.2)**	**($5.6)**	**($21.2)**	**($23.4)**	**($27.1)**
Non-controlling Interest	($0.9)	($0.1)	($0.2)	($0.2)	($0.3)	($0.8)	($0.8)	($0.8)
Net Income After NCI	**($15.7)**	**($5.7)**	**($4.8)**	**($4.9)**	**($5.3)**	**($20.4)**	**($22.6)**	**($26.3)**
Net Margin	*-286%*	*-824%*	*-1444%*	*-468%*	*-509%*	*-655%*	*-836%*	-
Reported EPS	**($0.90)**	**($0.17)**	**($0.14)**	**($0.14)**	**($0.15)**	**($0.60)**	**($0.61)**	**($0.66)**
YOY Growth	*-71%*	*-77.2%*	*-47.8%*	*-11.3%*	*-12.5%*	*-34%*	*3%*	*8%*
Basic Shares Outstanding	17.49	33.23	33.26	35.00	35.90	34.35	37.00	40.00

Source: Company Filing // Zacks Investment R

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HISTORICAL STOCK PRICE

Heat Biologics, Inc. – Share Price Chart



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