Zacks Small-Cap Research
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Heat Biologics Inc (HTBX - NASDAQ)

INDs To Be Filed Soon

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 (5/31/2019)	$0.82
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 began the HS-130 trial in 4Q:18. 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.

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	**2.98**
52-Week Low	**0.67**
One-Year Return (%)	**-65.3**
Beta	**3.05**
Average Daily Volume (sh)	**242,612**
Shares Outstanding (mil)	**34.1**
Market Capitalization ($mil)	**27.9**
Short Interest Ratio (days)	**2.5**
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	$1.1 E	$1.1 E	$1.1 E	$4.0 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	-$0.11 E	-$0.14 E	-$0.15 E	-$0.57 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

First Quarter 2019 Results

Heat Biologics, Inc. (NASDAQ: HTBX) reported first quarter 2019 results in a May 15 release and concurrently submitted the companion 10-Q to the SEC. Since the beginning of the year, Heat attended several scientific and investment conferences including Biotech Showcase, ASCO-SITC Clinical Immuno-Oncology Symposium, the WuXi Healthcare Forum in Shanghai as well as others in the US and China. The company also provided an update on HS-110 early in the year that demonstrated encouraging data in patients whose disease had progressed after checkpoint inhibitor therapy.

Management anticipates filing two investigational new drug (IND) applications this summer. This includes HS-130, a dual-acting immunotherapy designed to deliver local T cell activation and co-stimulation and PTX-35, a T cell costimulatory antibody that is being developed by the Pelican subsidiary.

Revenues for the first quarter were $0.7 million, representing CPRIT grant money which is directed towards the PTX-35 T-cell activation platform. This compares to our estimates of $2.0 million and is a slower pace that we had forecast. Research and development costs totaled $3.2 million, rising 10% as the PTX-35 antibody and PTX-15 fusion protein program expand and greater amounts were used in unallocated R&D. General and administrative expenses rose 88% to $3.3 million on increased stock-based compensation expense.

Cash and equivalents as of March 31, 2019 were $23.5 million, compared to $27.7 million at the end of 2018. Heat continues with no debt on the books. Cash burn was ($4.2) million for 1Q:19 matching the amount in the comparable 2018 period. Add-back of $2.1 million of stock based compensation explained the majority of the difference between net loss of ($5.8) million and the ($4.2) million cash used in operations. Capital expenditures were $45,000 and were allocated towards lab equipment.

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.

PTX-35 and HS-130

In an October press release, the company highlighted its progress on Pelican's PTX-35 program citing several accomplishments. We anticipate the investigational new drug (IND) application will be presented to the FDA this summer, which should be followed shortly after by 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.

Heat is also expected to file an IND for HS-130 this summer to conduct a Phase I safety trial. 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. The Phase I trial will be focused on safety; however, the precise indication and setting have not yet been determined.

Presentations & Interim Results

Heat is a frequent participant in scientific conferences where it submits posters and discuss trial data. Since the start of the year, Heat has participated in ASCO-SITC Clinical Immuno-Oncology Symposium and at American Association for Cancer Research (AACR). In late February 2019, Heat provided preliminary data and an update to its HS-110 Durga trial which suggested that HS-110 + nivolumab may restore responsiveness to therapy after checkpoint inhibitor therapy. The combination also produced results that provided several encouraging conclusions. Patients with cold tumors demonstrated better survival than patients with hot tumors; there exists a correlation between injection site reaction and improved overall survival (cohort A) and adding HS-110 to nivolumab may restore responsiveness after progression on prior checkpoint inhibitor therapy.

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 and preparing HS-130 (ComPACT) and PTX-35 for IND submission. Below we list key milestones for Heat Biologics which have occurred in 2018 or are expected over the next several quarters.

- HS-110 (NSCLC) interim data readout - 1Q:19
- Receipt of $6.9 MM in CPRIT grant funds (PTX-35) – mid-year 2019
- Complete HS-110 Phase II NSCLC enrollment – 2Q:19
- HS-130 (ComPACT) IND filing – 2019
- PTX-35 IND filing – 2Q: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)
PTX-45	TBA	→				TL1A-Ig fusion protein, functional agonist of human TNFRSF25

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. We expect to see these INDs submitted to the FDA over the next few months and first enrollment commencing shortly after. Interim results for HS-130 were also presented, demonstrating that HS-110 and nivolumab may restore responsiveness to treatment in NSCLC patients after receiving prior lines of checkpoint inhibitor therapy.

The company has a favorable cash position, holding over $23 million in funds which will be augmented by additional CPRIT funds for advancement of PTX-35, which we anticipate will be received following IND submission. Funding 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 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
Total Revenues	**$5.8**	**$0.7**	**$1.1**	**$1.1**	**$1.1**	**$4.0**	**$2.8**	**$0.0**
YOY Growth								
Research & Development	$16.2	$3.2	$3.2	$4.3	$4.7	$15.3	$18.0	$18.5
General & Administrative	$7.0	$3.3	$2.0	$2.0	$2.0	$9.3	$8.2	$8.6
Other	$0.5	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Income from operations	($18.0)	($5.9)	($4.1)	($5.2)	($5.6)	($20.7)	($23.4)	($27.1)
Operating Margin	*-310%*	*-846%*	*-373%*	*-468%*	*-509%*	*-517%*	*-836%*	*-*
Interest Income	$0.3	$0.2	$0.0	$0.0	$0.0	$0.2	$0.0	$0.0
Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Interest Expense	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($17.6)	($5.8)	($4.1)	($5.2)	($5.6)	($20.5)	($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)**	**($4.1)**	**($5.2)**	**($5.6)**	**($20.5)**	**($23.4)**	**($27.1)**
Non-controlling Interest	($0.9)	($0.1)	($0.2)	($0.2)	($0.2)	($0.8)	($0.8)	($0.8)
Net Income After NCI	**($15.7)**	**($5.7)**	**($3.9)**	**($4.9)**	**($5.4)**	**($19.7)**	**($22.6)**	**($26.3)**
Net Margin	*-286%*	*-824%*	*-373%*	*-468%*	*-509%*	*-513%*	*-836%*	*-*
Reported EPS	**($0.90)**	**($0.17)**	**($0.11)**	**($0.14)**	**($0.15)**	**($0.57)**	**($0.61)**	**($0.66)**
YOY Growth	*-71%*	*-77.2%*	*-58.8%*	*-11.3%*	*-11.4%*	*-37%*	*7%*	*8%*
Basic Shares Outstanding	17.49	33.23	34.10	35.00	35.90	34.56	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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