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

2018 Financial & Operational Results

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 (4/5/2019)	$1.22
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	**4.30**
52-Week Low	**0.95**
One-Year Return (%)	**-6.9**
Beta	**3.32**
Average Daily Volume (sh)	**652,766**
Shares Outstanding (mil)	**33.1**
Market Capitalization ($mil)	**40.4**
Short Interest Ratio (days)	**0.62**
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)
2017	$0.0 A	$0.4 A	$0.5 A	$0.6 A	$1.5 A
2018	$0.8 A	$1.1 A	$1.8 A	$2.1 A	$5.8 A
2019					$5.3 E
2020					$2.8 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2017	-$1.18 A	-$0.91 A	-$0.64 A	-$0.81 A	-$3.08 A
2018	-$0.75 A	-$0.27 A	-$0.16 A	-$0.17 A	-$0.90 A
2019					-$0.57 E
2020					-$0.64 E

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

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WHAT'S NEW

Full Year 2018 Results

Heat Biologics, Inc. (NASDAQ: HTBX) reported full year 2018 results in a March 28 release and concurrently submitted the companion 10-K to the SEC. Heat attended several scientific and investment conferences including the European Congress of Immunology, International Cancer Immunotherapy Conference, Rodman & Renshaw and others during the most recent period, highlighting its scientific and operational progress. The company also provided an update on PTX-35, detailing the compound's advance toward the clinic. With cash from the CPRIT grant and the recent capital raise, Heat is in position to continue developing its lead pipeline candidates HS-110 and PTX-35 without financing distractions over the next year.

Heat reported grant and licensing revenues of $5.8 million compared to $1.5 million 2017. This amount represented CPRIT grant money which is directed towards the PTX-35 T-cell activation platform. Research and development costs totaled $16.2 million, rising 96% as the PTX-35 program continues to accelerate and additional funds are allocated towards HS-110. Contributors to spending growth were attributable to increases in patient enrollment for the HS-110 trial, ramp up in CMC development and preparation for production of clinical trial material, and a big jump in preclinical work for PTX-35 and other biologics against TNFRSF25. Some other R&D costs decreased, such as expenses related to HS-410 and those associated with T-cell costimulatory programs, the Zika program and laboratory supplies. General and administrative expenses rose 10% to $7.0 million as new personnel were added and operations expanded in the Texas operations. These increases were partially offset by lower acquisition related expenses related to Pelican which occurred in 2017.

Cash and equivalents as of December 31, 2018 were $27.7 million, compared to $9.8 million at the end of 2017. Heat continues with no debt on the books. Cash burn was ($22.3) million for 2018 compared to ($6.4) million for 2017. Recognition of deferred revenue and a deferred tax revenue partially offset by prepaid expenses were the largest factors explaining the difference between earnings and cash burn. Capital expenditures were $600,000 and were used to acquire lab equipment for Pelican at the San Antonio facilities.

HS-110

The HS-110 trial recently reported interim Phase II data from Cohort A which includes naïve patients treated with HS-110 and nivolumab and Cohort B which 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 these 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 to go in front of the FDA in the current quarter, 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. We anticipate that Pelican will maintain its timeline and submit its IND in the second quarter.

Heat is also expected to file an IND for HS-130 in the second quarter 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.

November Capital Raise

Heat announced a public offering in late November to raise $12 million and the issuance of 8 million shares at $1.50 per share with Alliance Global Partners (AGP) managing the deal. AGP was granted an overallotment option of 1.2 million shares which it exercised. Warrants are attached to the newly issued shares at a rate of 0.5 to 1, have an exercise price of $1.65 and expire after five years. Heat issued 9.2 million shares, 4.6 million warrants and raised gross proceeds of $13.8 million and net proceeds of $12.6 million after deducting transaction costs.

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 (poster) and at American Association for Cancer Research (AACR) (poster). 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.

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.

- Closing of $20.7 million public offering – 2Q:18
- Receive $6.9 million in CPRIT grant funds – 3Q:18
- Closing of $12 million public offering – 4Q:18
- HS-110 (NSCLC) interim data readout - 1Q:19
- Receipt of $6.9 MM in CPRIT grant funds (PTX-35) – 1Q:19
- Complete HS-110 Phase II NSCLC enrollment – 2Q:19
- HS-130 (ComPACT) IND filing – 2Q:19
- 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 – 2018 / 2019
- Develop Phase III / commercial manufacturing capacity for HS-110 – 2018 / 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 spent 2018 advancing its HS-110 study in various cohorts and preparing investigational new drug (IND) applications for HS-130 and PTX-35. We expect to see these INDs submitted to the FDA in the second quarter and first enrollment shortly after. The company has a favorable cash position, having raised over $40 million this year and receiving CPRIT funds for advancement of PTX-35, which we anticipate will avoid distractions from capital raising activities until 2020. We maintain our target price of $5.00 per share.

PROJECTED FINANCIALS

Heat Biologics, Inc. - Income Statement

Heat Biologics Inc.	2017 A	Q1 A	Q2 A	Q3 A	Q4 A	2018 A	2019 E	2020 E
Total Revenues	**$1.5**	**$0.8**	**$1.1**	**$1.8**	**$2.1**	**$5.8**	**$5.3**	**$2.8**
YOY Growth								
Research & Development	$8.3	$2.9	$3.5	$4.4	$5.5	$16.2	$17.0	$18.0
General & Administrative	$6.4	$1.8	$1.4	$1.6	$2.3	$7.0	$8.0	$8.2
Other	$0.2	$0.0	$0.5	$0.1	($0.2)	$0.5	$0.0	$0.0
Income from operations	($13.3)	($3.9)	($4.2)	($4.3)	($5.5)	($18.0)	($19.7)	($23.4)
Operating Margin	*-878%*	*-520%*	*-371%*	*-232%*	*-269%*	*-310%*	*-372%*	*-836%*
Interest Income	$0.0	$0.0	$0.0	$0.1	$0.1	$0.3	$0.0	$0.0
Other Income	$0.1	$0.2	($0.1)	$0.0	($0.0)	$0.1	$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	($13.2)	($3.7)	($4.2)	($4.1)	($5.4)	($17.6)	($19.7)	($23.4)
Provision for Income Tax	$0.8	$0.0	$0.0	$0.2	$0.8	$1.0	$0.0	$0.0
Tax Rate	*-6.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($12.4)**	**($3.7)**	**($4.2)**	**($3.9)**	**($4.7)**	**($16.6)**	**($19.7)**	**($23.4)**
Non-controlling Interest	($0.6)	($0.2)	($0.2)	($0.3)	($0.2)	($0.9)	($0.8)	($0.8)
Net Income After NCI	**($11.8)**	**($3.5)**	**($4.1)**	**($3.7)**	**($4.5)**	**($15.7)**	**($18.9)**	**($22.6)**
Net Margin	*-816%*	*-496%*	*-371%*	*-213%*	*-228%*	*-286%*	*-372%*	*-836%*
Reported EPS	**($3.08)**	**($0.75)**	**($0.27)**	**($0.16)**	**($0.17)**	**($0.90)**	**($0.57)**	**($0.64)**
YOY Growth	*-56.9%*	*-36.7%*	*-69.9%*	*-75.4%*	*-79.2%*	*-71%*	*-37%*	
Basic Shares Outstanding	3.85	4.71	14.73	23.14	26.50	17.49	33.20	35.50

Source: Company Filing // Zacks Investment R

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HISTORICAL STOCK PRICE

Heat Biologics, Inc. – Share Price Chart



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