

Heat Biologics Inc

(HTBX - NASDAQ)

Plenty of Catalysts in 2019

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 (11/23/2018) **\$1.43**
 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 expects to begin 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 **5.00**
 52-Week Low **1.09**
 One-Year Return (%) **-68.2**
 Beta **1.68**
 Average Daily Volume (sh) **252,641**

Shares Outstanding (mil) **23.3**
 Market Capitalization (\$mil) **33.3**
 Short Interest Ratio (days) **6.32**
 Institutional Ownership (%) **5.4**
 Insider Ownership (%) **0.9**

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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(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	\$1.2 E	\$4.9 E
2019					\$4.8 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	-\$0.11 E	-\$0.84 E
2019					-\$0.55 E
2020					-\$0.63 E

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

WHAT'S NEW

Third Quarter 2018 Results

Heat Biologics, Inc. (NASDAQ: HTBX) [reported](#) third quarter 2018 results in an August 14th release and concurrently submitted the companion [10-Q](#) 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.

In the third quarter, Heat reported total revenues of \$1.8 million compared to \$471 thousand in 3Q:17. This amount represented CPRIT grant money which is directed towards the PTX-35 T-cell activation platform. Research and development costs totaled \$4.4 million, rising 141% as the PTX-35 program continues to accelerate and expenditures are allocated towards HS-110. Contributors to spending growth were attributable to continued pre-clinical development of PTX-35, patient testing of other biologics against TNFRSF25 and increased patient enrollment for the Phase II HS-110 program. General and administrative expenses rose 33% to \$1.6 million stemming from increases in professional services/consulting fees associated with the 2018 Annual Shareholder Meeting as well as an increase in investor relations and new business development fees.

Cash and equivalents as of September 30, 2018 were \$21.0 million, compared to \$9.8 million at the end of 2017. Heat continues with no debt on the books. Cash burn was (\$4.0) million in 3Q:18 and (\$16.3) million for the first nine months of the year compared to (\$4.0) million in 3Q:17 and (\$9.5) million for the first nine months of 2017. Recognition of deferred revenue and purchase of property and lab equipment were the largest factors explaining the difference between earnings and cash burn. Following the end of the quarter, Heat conducted a capital raise which should add \$12.6 million in additional funds if overallocments are exercised.

Pelican PTX-35 Update

Since our previous report, Heat has made progress on its PTX-35 T-cell co-stimulator. In an October [press release](#), the company highlighted its progress on the program citing several accomplishments. These include:

- Completion of cell line development and creation of master cell bank for cGMP manufacturing
- Established chemistry, manufacturing & controls (CMC) path for the production of clinical material and toxicology studies
- Efficient binding of PTX-35 to TNFRSF25 receptor observed
- Increased expansion of T-cells in-vivo
- Primate IND-enabling dose range finding study that finds no toxicity signals
- Ongoing discussions with FDA regarding IND
- Targeted 1Q:19 IND submission

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 first quarter.

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 overallocation 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.

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 on the horizon for Heat Biologics. Over the next several quarters we anticipate the following events.

- Closing of \$20.7 million public offering – 2Q:18
- Receive \$6.9 million in CPRIT grant funds – 3Q:18
- HS-110 (NSCLC) interim data readout - 4Q:18
- Closing of \$12 million public offering – 4Q:18
- HS-130 (ComPACT) IND filing – 4Q:18
- HS-130 (ComPACT) first patient enrollment – 1Q:19
- IND for PTX-35 – 1Q:19
- Receipt of \$6.9 MM in CPRIT grant funds (PTX-35) – 1Q:19
- Enroll first patient in PTX-35 Phase I trial – 1Q:19
- Complete HS-110 Phase II NSCLC enrollment – 2Q:19
- Interim ComPACT data readout – 2Q:19
- HS-110 Phase II final readout – 2Q:19
- HS-110 End of Phase II Meeting – Mid-2019
- HS-110 NSCLC Phase III ready – 3Q:19
- Interim PTX-35 data readout – 3Q:19
- Discussion with potential partners – 2018 / 2019
- Develop Phase III / commercial manufacturing capacity for HS-110 – 2018 / 2019

Summary

Heat Biologics had a relatively quiet quarter as it prepared the ComPACT and PTX-35 candidates for IND submission to the FDA; however, we anticipate the pace to accelerate as we move into 2019. Pelican highlighted its progress with IND-enabling activities and is on track to submit its PTX-35 IND in 1Q:19. The company has a favorable cash position, having raised over \$30 million this year and receiving CPRIT funds for advancement of PTX-35, which we anticipate will avoid distractions from capital raising activities until 2020.

PROJECTED FINANCIALS

Heat Biologics, Inc. - Income Statement

Heat Biologics Inc.	2017 A	Q1 A	Q2 A	Q3 A	Q4 E	2018 E	2019 E	2020 E
Total Revenues	\$1.5	\$0.8	\$1.1	\$1.8	\$1.2	\$4.9	\$4.8	\$2.8
<i>YOY Growth</i>								
Research & Development	\$8.3	\$2.9	\$3.5	\$4.4	\$2.4	\$13.2	\$15.0	\$16.2
General & Administrative	\$6.4	\$1.8	\$1.4	\$1.6	\$2.0	\$6.7	\$8.0	\$8.2
Other	\$0.2	\$0.0	\$0.5	\$0.1	\$0.0	\$0.7		
Income from operations	(\$13.3)	(\$3.9)	(\$4.2)	(\$4.3)	(\$3.2)	(\$15.6)	(\$18.2)	(\$21.6)
<i>Operating Margin</i>	-878%	-520%	-371%	-232%	-263%	-315%	-379%	-773%
Interest Income	\$0.0	\$0.0	\$0.0	\$0.1	\$0.0	\$0.0	\$0.0	\$0.0
Other Income	\$0.1	\$0.2	(\$0.1)	\$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	(\$13.2)	(\$3.7)	(\$4.2)	(\$4.1)	(\$3.2)	(\$15.6)	(\$18.2)	(\$21.6)
Provision for Income Tax	\$0.8	\$0.0	\$0.0	\$0.2	\$0.0	\$0.2	\$0.0	\$0.0
<i>Tax Rate</i>	-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)	(\$3.2)	(\$15.3)	(\$18.2)	(\$21.6)
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)	(\$3.0)	(\$14.5)	(\$17.4)	(\$20.8)
<i>Net Margin</i>	-816%	-496%	-371%	-213%	-263%	-311%	-379%	-773%
Reported EPS	(\$3.08)	(\$0.75)	(\$0.27)	(\$0.16)	(\$0.11)	(\$0.84)	(\$0.55)	(\$0.63)
<i>YOY Growth</i>	-56.9%	-36.7%	-69.9%	-75.4%	-86.3%	-73%	-34%	
Basic Shares Outstanding	3.85	4.71	14.73	23.14	26.50	17.27	31.68	33.00

Source: Company Filing // Zacks Investment R

HISTORICAL STOCK PRICE

Heat Biologics, Inc. – Share Price Chart



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