Zacks Small-Cap Research
*Sponsored – Impartial – Comprehensive*

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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

# Heat Biologics Inc (HTBX - NASDAQ)

## *Three Assets in the Clinic*

Based on our DCF model and a 15% discount rate, Heat Biologics is valued at approximately $3.50 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 (11/16/2020) | $1.04 |
| **Valuation** | **$3.50** |

## OUTLOOK

Heat Biologics has three novel immunotherapies in clinical development: HS-110, HS-130 & PTX-35. The candidates use 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. In response to COVID-19, Heat has launched a vaccine program using the gp96 platform.

The company's lead 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 dosing HS-130 patients in a Phase I study. 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 began Phase I trial in June 2020.

The valuation assumes a 2023 FDA approval of HS-110 and a 2024 launch of the compound in the US, followed by a 2025 launch in the EU and rest of world that will be achieved through the efforts of partners. HS-130 and PTX-35 are anticipated to be launched in 2028 in the US and 2029 in other regions.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **4.30** |
| **52-Week Low** | **0.20** |
| **One-Year Return (%)** | **142** |
| **Beta** | **0.57** |
| **Average Daily Volume (sh)** | **9,240,840** |
| **Shares Outstanding (mil)** | **159.8** |
| **Market Capitalization ($mil)** | **166.2** |
| **Short Interest Ratio (days)** | **2.3** |
| **Institutional Ownership (%)** | **9.9** |
| **Insider Ownership (%)** | **3.0** |
| **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 2020 Estimate** | **N/A** |
| **P/E using 2021 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) |
|---|---|---|---|---|---|
| 2019 | $0.7 A | $0.3 A | $0.0 A | $2.0 A | $3.0 A |
| 2020 | $0.9 A | $0.6 A | $0.8 A | $0.6 E | $2.9 E |
| 2021 | | | | | $0.0 E |
| 2022 | | | | | $0.0 E |

### Earnings per Share

| | Q1 | Q2 | Q3 | Q4 | Year |
|---|---|---|---|---|---|
| 2019 | -$0.17 A | -$0.14 A | -$0.18 A | -$0.10 A | -$0.60 A |
| 2020 | -$0.11 A | -$0.05 A | -$0.06 A | -$0.04 E | -$0.22 E |
| 2021 | | | | | -$0.18 E |
| 2022 | | | | | -$0.20 E |

## WHAT'S NEW

**Third Quarter 2020 Results**

Heat Biologics, Inc. (NASDAQ: HTBX) reported third quarter 2020 results in a November 9th release concurrent with the submission of the 10-Q to the SEC. Heat now has three clinical assets under investigation as well as a preclinical program underway for a coronavirus vaccine. During the third quarter and to date, Heat has achieved several milestones related to the COVID program, announcing proof of concept data in preclinical models, demonstrating robust T cell mediated immune response against SARS-CoV-2 and publication of positive COVID vaccine results. A pair of new patents were obtained for gp96 and $77.0 million in new capital was raised which should provide sufficient runway to continue operations well into 2023.

The company is in the process of preparing a data package to share with the FDA in an End-of-Phase II meeting for HS-110 that we expect will be scheduled soon. Phase I trials for PTX-35 and HS-130 for solid tumors are now active and we expect them to wrap up in the first quarter of 2021.

Revenues for the third quarter were $0.8 million, representing the recognition of grant income from CPRIT supporting the PTX-35 T cell activation platform. Research and development expenditures totaled $3.2 million, up 1% compared with the prior year third quarter amounts. Expenditures on the COVID program, Zika program, laboratory supplies and stock compensation were mostly offset by declines in the HS-110 program and lower spending on manufacturing drug product for the PTX-35 program. General and administrative expenses rose sharply by 230% on stock compensation related to achieving a milestone. Other expenses totaled $0.2 million related to interest earned from cash and equivalents and foreign currency adjustments. Net loss for 3Q:20 was ($8.9) million or ($0.06) per share compared with ($6.2) million or ($0.18) per share in 3Q:19.

Cash and equivalents as of September 30, 2020 were $117.3 million, compared to $14.8 million at the end of 2019. Heat continues with no debt on the books. Cash burn was ($5.6) million in the third quarter compared with ($4.3) million in 3Q:19. Net cash provided by financing activities totaled $76.0 million, representing proceeds from the issuance of common stock and warrant exercise. Following the end of the reporting period, Heat raised an additional $1.0 million in capital from its at-the-market (ATM) facility.

**Coronavirus**

The global threat of coronavirus has changed the landscape for many biotechnology research and development companies. The spread of the virus may delay trial progression and the availability of drug product but it also has incentivized programs that many companies, including Heat Biologics, have developed in infectious disease. Heat's wholly-owned subsidiary, Zolovax, has been focused on developing medicines and vaccines for infectious diseases using the glycoprotein platform, gp96, for many years. Previous research has been conducted for simian immunodeficiency virus, malaria and Zika. In March 2020, Heat entered into a research agreement with the University of Miami (UM) to sponsor new research and development of a SARS-CoV-2 (COVID-19) vaccine and diagnostic test.

The vaccine incorporates multiple SARS-CoV-2 antigens using the gp96 platform. The approach is expected to induce long-term immunity and provide protection against future infections. As no viral vector is used, Heat's coronavirus vaccine avoids anti-vector immunity and viral activation while activating T and B cells with high immunogenicity. The activation of T and B cells drives induction of mucosal immunity and long-term memory response. In early March, the company filed multiple provisional patent applications for its technology that treat and prevent infection from the SARS-CoV-2 virus. Heat's approach may also be appropriate in combination with other vaccines that activate the humoral immune system on account of its complementary stimulation of the adaptive immune system.

Heat has achieved stable expression of the gp96/nCoV-S protein and identifyied a manufacturing partner in Waisman Biomanufacturing. Other milestones include completion of a cell-based vaccine containing gp96-Ig; OX40L-Ig; and SARS-CoV-2 protein S, development of proof-of-concept; animal-model data demonstrating vaccine immunogenicity and continued sourcing of funding to support the development efforts.

In late July, Heat confirmed successful pre-clinical testing of the vaccine, demonstrating immunogenicity in animal models. The vaccine was shown to expand human-HLA (human leukocyte antigen)-restricted T-cells against immunodominant epitopes of SARS-CoV-2 Spike protein. In mid-August, Heat provided an update on the coronavirus program providing additional preclinical data for Heat's gp96-based vaccine. In an animal model, the COVID-19 vaccine stimulated expansion of both killer CD8+ T cells and helper CD4+ T cells. These immune cells destroy

virally infected cells and assist in producing antibodies specific to the virus. Both the CD8+ and CD4+ cells release cytokines that augment the immune response and migrate to the lungs and airways where the SARS-CoV-2 infection resides. Heat was involved in two COVID-19 publications including a white paper on "The Importance of T-Cell Immunity in SARS-CoV-2 Infection" and the preclinical COVID-19 vaccine results in a paper entitled "Induction of SARS-CoV-2 protein S-specific CD8+ T cells in the lungs of gp96-Ig-S vaccinated mice."

The white paper concluded that protective antibody responses alone may be insufficient to successfully clear SARS-CoV-2. T-cell responses, which are critical for priming antibody-producing B cells, will likely be required for a long-term response against the virus. Some cited studies have shown that patients with higher antibody titers were associated with stronger CD4+ T cell responses. In other viral studies, patients maintain long-lasting memory T cells, while antibody responses dissipate. Heat's gp96/OX40L vaccine coordinates humoral and cellular immune response and may be an efficient approach to stimulating an effective attack against SARS-CoV-2. Heat's vaccine stimulates a cellular immune response through CD4+ and CD8+ T cells and a humoral immune response with the neutralizing IgG antibody. gp96 alerts the immune system that a strong immune response is necessary and OX40L expands CD4+ helper T cells that promote B cell differentiation and IgG/IgA antibody class switching. The paper further detailed Heat's use of its gp96 platform to deliver antigens representing the SARS-CoV-2 spike protein to induce cell-mediated immune responses. The *in vivo* work confirmed that the approach generates a spike specific CD4+ and CD8+ response in the respiratory system.

Heat has made the case for using its approach, if ultimately approved, along with other vaccines to improve resistance to COVID-19. Many other vaccines that are being developed for the virus stimulate an antibody response and if used in conjunction with Heat's gp96 approach, the combination would layer on T cell immunity to potentially provide more durable protection.

**Pipeline**

**Exhibit I – Heat Biologics Product Pipeline[1]**

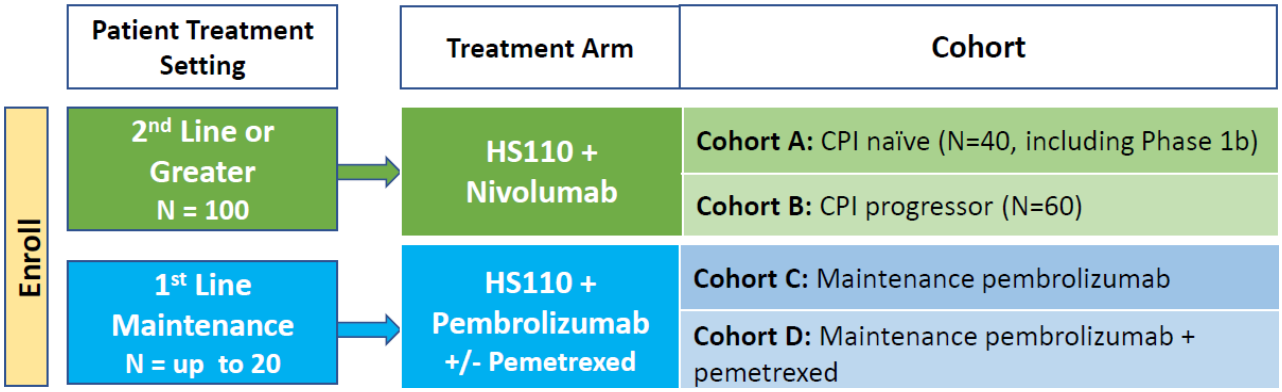
| Product | MOA (Modality) | Indication | Preclinical | Phase 1 | Phase 2 | Phase 3 |
|---|---|---|---|---|---|---|
| **HS-110** | gp96 + CTAs (Cell Therapy) | NSCLC | | | | |
| **HS-130** | OX40L (Cell Therapy) | Solid Tumors | | | | |
| **COVID-19 Vaccine** | gp96 + Viral Antigens (Cell Therapy) | COVID-19 | | | | |
| **PTX-35** | TNFRSF25 (mAb) | Solid Tumors | | | | |

[1] Source: Heat Biologics October 2020 Corporate Presentation.

**HS-110**

The HS-110 Phase II Durga trial provided the latest update to its interim data in mid-November 2019. 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, designated C and D that will examine HS-110 in combination with pembrolizumab, and pembrolizumab and chemotherapy which are intended to evaluate safety with an alternative checkpoint inhibitor. About 20 patients are expected to be enrolled in the C and D cohorts with 122 patients enrolled overall.

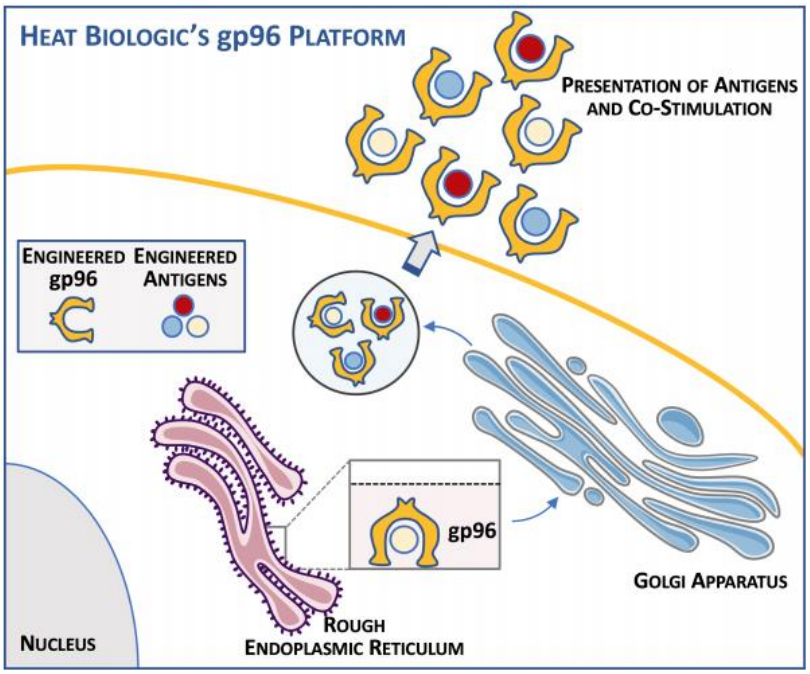
**Exhibit II – HS-110 Trial Design[2]**




**ASCO 2020 Abstract**

Heat participated in the 2020 American Society of Clinical Oncology (ASCO) meeting presenting the company's poster entitled: "Tumor antigen expression and survival of patients with previously treated advanced non-small cell lung cancer (NSCLC) receiving viagenpumatucel-L (HS-110) plus nivolumab." The abstract highlights Cohort A in the Durga trial that combines HS-110 with nivolumab in the 47-patient study. Subjects enrolled in this group exhibited an overall survival duration of 28.7 months. The cohort was divided into patients based on whether their tumor-antigens were similar to those in HS-110. (≥8 vs <8 antigens in common). Patients whose cancer testis antigen (CTA) had higher similarity to HS-110 experienced a longer median overall survival.

**Exhibit III – gp96 Platform[3]**




[2] Source: Heat Biologics Corporate Presentation. November 5, 2019.
[3] Source: Heat Biologics Corporate Presentation. May 2020.

**PTX-35**

In early June, Heat announced that the FDA had cleared its investigational new drug application (IND) for PTX-35 followed shortly after by the initiation of the first clinical site for the trial and the appointment of Anthony Tolcher, MD as lead investigator. By the end of June, the first patient had been treated in the Phase I trial to evaluate PTX-35. Up to 30 patients are expected to be enrolled with advanced solid tumors refractory to standard of care.

As a reminder, PTX-35 is being developed by 85% owned subsidiary, Pelican Therapeutics, and we allocate royalties accordingly. There is also a relatively complex royalty arrangement with Cancer Prevention and Research Institute of Texas (CPRIT) that includes a return of 4x the original grant and a 0.5% royalty in perpetuity. There are a number of milestones owed to Pelican by Heat that we also reflect in our valuation.

**HS-130**

In late 2019, Heat announced that its IND for HS-130 had been submitted and the program had received clearance from the FDA to begin a Phase I safety trial. In December, the first patient was dosed in the dose escalation trial. The combination study, which will pair HS-130 with HS-110, will enroll patients with advanced solid tumors refractory to standard of care. The candidate is in development to treat solid tumors and will employ ComPACT technology that delivers gp96 heat shock protein along with a T-cell co-stimulatory fusion protein (OX40L). The associated trial expects to enroll up to 30 patients and have primary endpoints of safety and optimal dose determination for its Phase II trial.

The Phase I trial of HS-130 suffered an enrollment pause during the months of April and May this year due to lack of personal protective equipment at a clinical site. When the equipment became available, enrollment resumed and no further delays in development milestones are expected for HS-130.

**Patents Issued**

Two new patents were recently issued to Heat, both titled “Vector co-expressing vaccine and costimulatory molecules.” The patents, numbered 10,758,611 and 10,780,161, provide details on the compositions and methods for co-expressing a secretable vaccine protein, such as gp96, from a single vector. The patents are a key support to the company’s gp96 plus OX40L T cell co-stimulation platform, with applications in cancer, infectious disease and other areas. Anticipated advantages of the work represented here include enhanced memory T cell response, limited systemic toxicity and cost advantages compared to other systemic therapies.

**Corporate Milestones**

Below we list key milestones for Heat Biologics.

- HS-110 interim data readout – November 2019
- HS-110 Phase II interim readout – 4Q:19
- First patient dosed in HS-130 Phase I – December 2019
- ASCO poster presentation – May 29, 2020
- PTX-35 IND clearance and first patient dosing – 2Q:20
- Various coronavirus vaccine milestones – 2021
    - Manufacturing
    - Investigational New Drug (IND) Application
    - Phase I launch
- Discussion with potential partners – ongoing
- Complete HS-130 Phase I trial – 1Q:21
- Complete PTX-35 Phase I trial – 1Q:21
- End of Phase II meeting for HS-110 – 1H:21

**Sources of Capital**

Heat Biologics started 2020 with $15 million in cash on the balance sheet and has raised close to $120 million in additional funds to date. For the nine months ending September 30, Heat received net proceeds of $113.4 million from the sale of 9.4 million shares and an additional $1.0 million following the end of the quarter in return for 831,000 shares. Warrant exercise also generated additional capital. At the end of the third quarter, Heat held $117.3 million in cash and equivalents and short term investments.

**Summary**

Heat Biologics has made substantial progress this year with the entry of HS-130 and PTX-35 into the clinic as well as continued advancement of the Phase II HS-110 program. Substantial preclinical work has also taken place for a coronavirus vaccine which may enter the clinic next year. Year to date, Heat has been opportunistic in raising capital and has accumulated over $117 million on the balance sheet that should sustain operations for the next several years. We reiterate our valuation opinion of $3.50 per share.

## PROJECTED FINANCIALS

**Heat Biologics, Inc. - Income Statement**

| Heat Biologics Inc. | 2019 A | Q1 A | Q2 A | Q3 A | Q4 E | 2020 E | 2021 E | 2022 E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenues** | **$3.0** | **$0.9** | **$0.6** | **$0.8** | **$0.6** | **$2.9** | **$0.0** | **$0.0** |
| Research & Development | $13.0 | $2.8 | $2.8 | $3.2 | $4.0 | $12.7 | $18.0 | $20.1 |
| General & Administrative | $9.4 | $3.3 | $1.8 | $6.6 | $2.4 | $14.1 | $10.0 | $11.2 |
| Other | $1.4 | ($0.0) | $0.8 | $0.2 | $0.0 | $0.0 | $0.0 | $0.0 |
| Income from operations | ($20.7) | ($5.1) | ($4.8) | ($9.1) | ($5.8) | ($23.9) | ($28.0) | ($32.3) |
| Interest Income | $0.4 | $0.1 | $0.1 | $0.1 | $0.1 | $0.3 | $0.0 | $0.0 |
| Other Income | ($0.0) | ($1.3) | $0.2 | $0.1 | $0.0 | ($1.0) | $0.0 | $0.0 |
| Pre-Tax Income | ($20.3) | ($6.4) | ($4.5) | ($8.9) | ($5.7) | ($24.5) | ($28.0) | ($32.3) |
| Provision for Income Tax | ($0.0) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $1.0 |
| *Tax Rate* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *100.0%* |
| **Net Income** | **($20.4)** | **($6.4)** | **($4.5)** | **($8.9)** | **($5.7)** | **($24.5)** | **($28.0)** | **($31.3)** |
| Non-controlling Interest | ($0.4) | ($0.1) | ($0.1) | ($0.1) | ($0.1) | ($0.3) | ($0.8) | |
| **Net Income After NCI** | **($20.0)** | **($6.3)** | **($4.5)** | **($8.9)** | **($5.6)** | **($24.2)** | **($27.2)** | **($31.3)** |
| *Net Margin* | *-669%* | *-707%* | *-765%* | *-1049%* | *-950%* | *-831%* | *-* | *# DIV/0!* |
| **Reported EPS** | **($0.60)** | **($0.11)** | **($0.05)** | **($0.06)** | **($0.04)** | **($0.22)** | **($0.18)** | **($0.20)** |
| *YOY Growth* | *-33%* | *-35.6%* | *-64.7%* | *-66.5%* | *-62.8%* | *-63%* | *-20%* | *11%* |
| Basic Shares Outstanding | 33.28 | 57.28 | 87.93 | 143.73 | 150.00 | 109.74 | 155.00 | 160.00 |

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

## HISTORICAL STOCK PRICE

**Heat Biologics, Inc. – Share Price Chart**

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