

November 9, 2020



Heat Biologics Provides Third Quarter 2020 Business Update

Continued progress on oncology and COVID-19 vaccine programs

Over \$117 million of cash and short-term investments

DURHAM, NC / ACCESSWIRE / November 9, 2020 /Heat Biologics, Inc. ("Heat") (NASDAQ:HTBX), a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, including multiple oncology product candidates and a novel COVID-19 vaccine, today provided financial, clinical and operational updates for the third quarter ended September 30, 2020.

Jeff Wolf, Chief Executive Officer of Heat, commented, "We continue to make progress on both our oncology and COVID-19 vaccine programs. We presented data for HS-110 in combination with Nivolumab in our Phase 2 lung cancer trial at the 2020 American Society of Clinical Oncology Annual Meeting demonstrating a strong survival benefit in a cohort of previously treated checkpoint inhibitor naïve patients with advanced non-small cell lung cancer (NSCLC). We are actively pursuing a variety of strategies to maximize value for the program."

"At the same time, we continue to advance PTX-35, our potential first-in-class T-cell co-stimulatory antibody, through clinical development. Earlier this year, we initiated the first clinical trial site for PTX-35 in multiple solid tumors and began dosing patients in the Phase 1 clinical trial. PTX-35 is designed to harness the body's natural antigen specific immune activation and tolerance mechanisms to reprogram immunity and provide a long-term, durable clinical effect. This study is expected to enroll up to 30 patients with advanced solid tumors refractory to standard of care."

"Importantly, we announced preclinical data for our gp96-based COVID-19 vaccine. The data, generated at the University of Miami Miller School of Medicine and published in [bioRxiv](#), shows robust T-cell mediated immune response directed against the spike protein of SARS-CoV-2. Our gp96-based COVID-19 vaccine induced the expansion of both "killer" CD8+ T-cells that destroy virus infected cells, as well as "helper" CD4+ T-cells that assist in producing highly specific antibodies. As a result, we believe our vaccine has the potential to be used as either a standalone vaccine, or in combination with other antibody-focused vaccine approaches to enhance prophylactic protection. These results highlight the potential utility and versatility of our vaccine platform to address SARS-CoV-2, relevant mutations and other pathogens of interest."

"We continue to strengthen our IP portfolio and were recently awarded an additional U.S. patent covering Heat's gp96 platform in combination with a T cell costimulatory agonist in a single therapy. We believe the combination of our gp96 platform in a single therapy holds

enormous promise in the prevention and treatment of cancer and infectious diseases, such as COVID-19."

"Finally, we have maintained a solid balance sheet with over \$117 million of cash and short-term investments as of September 30, 2020. We believe this capital will provide us significant runway to achieve a number of important clinical milestones that we believe will drive value for shareholders in the months and years ahead," concluded Mr. Wolf.

Third Quarter 2020 Financial Results

- Recognized \$0.8 million of grant revenue for qualified expenditures under the CPRIT and NIH grant. No grant revenue was recognized under the respective grants for the three months ended September 30, 2019. The increase in grant revenue in the current-year period primarily reflects the expected timing of completion of deliveries under the current phase of the contracts. As of September 30, 2020, we had deferred revenue of \$1.2 million for CPRIT proceeds received but for which the costs had not been incurred or the conditions of the award had not been met.
- Research and development expenses was \$3.2 million and \$3.1 million for the three months ended September 30, 2020 and 2019, respectively.
- General and administrative expense was \$6.6 million and \$2.0 million for the three months ended September 30, 2020 and 2019. General and administrative expenses primarily consist of personnel costs, including stock-based compensation expense, and consulting expenses to manage the business.
- Net loss attributable to Heat Biologics was approximately \$8.9 million, or (\$0.06) per basic and diluted share for the quarter ended September 30, 2020 compared to a net loss of approximately of \$6.2 million, or (\$0.18) per basic and diluted share for the quarter ended September 30, 2019.
- As of September 30, 2020, the Company had approximately \$117.3 million in cash, cash equivalents and short investments.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system. The company's gp96 platform is designed to activate immune responses against cancer or pathogenic antigens. The Company has multiple product candidates in development leveraging the gp96 platform, including HS-110, which has completed enrollment in its Phase 2 trial, HS-130 in Phase 1, and a COVID-19 vaccine program in preclinical development. In addition, Heat is also developing a pipeline of proprietary immunomodulatory antibodies, including PTX-35 which is enrolling in a Phase 1 trial.

For more information, please visit: www.heatbio.com, and also follow us on [Twitter](#).

Forward Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 on our current expectations and projections about future events. In some cases, forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based upon current

beliefs, expectation, and assumptions and include statements such as PTX-35 being the potential first-in-class T- cell costimulatory antibody, the expected enrollment of the Phase 1 PTX-35 study, the potential of Heat's COVID-19 vaccine to be used as either a standalone vaccine or in combination with other antibody-focused vaccine approaches to enhance prophylactic protection, the combination of Heat's gp96 platform in a single therapy holding enormous promise in the prevention and treatment of cancer and infectious diseases, such as COVID-19 and Heat's capital providing a significant runway to achieve a number of important clinical milestones that will drive value for shareholders in the months and years ahead. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's vaccine platform to provide protection against COVID-19, the ability of Heat's therapies to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, especially in light of COVID-19, Heat's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Heat's ability to promote or commercialize its product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products, Heat's ability to maintain its license agreements, the continued maintenance and growth of its patent estate, its ability to establish and maintain collaborations, its ability to obtain or maintain the capital or grants necessary to fund its research and development activities, its ability to continue to maintain its listing on the Nasdaq Capital Market and its ability to retain its key scientists or management personnel, and the other factors described in Heat's most recent annual report on Form 10-K filed with the SEC, and other subsequent filings with the SEC. The information in this release is provided only as of the date of this release, and Heat undertakes no obligation to update any forward-looking statements contained in this release based on new information, future events, or otherwise, except as required by law.

Media and Investor Relations Contact

David Waldman
+1 919 289 4017
investorrelations@heatbio.com

SOURCE: Heat Biologics, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/615362/Heat-Biologics-Provides-Third-Quarter-2020-Business-Update>