UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **March 14, 2022**

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction of incorporation)

001-35994	**26-2844103**
(Commission File Number)	*(IRS Employer Identification No.)*

627 Davis Drive, Suite 400
Morrisville, North Carolina 27560
(Address of principal executive offices and zip code)

(919) 240-7133
(Registrant's telephone number including area code)

N/A
(Former Name and Former Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0002 par value per share	HTBX	NYSE American LLC
Common Stock Purchase Rights		NYSE American LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On March 14, 2022, Heat Biologics, Inc., a Delaware corporation (the "Registrant"), issued the attached press release that included financial information for its year ended December 31, 2021. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in the press release is being furnished to the Securities and Exchange Commission (the "Commission") and shall not be deemed incorporated by reference into any of the Registrant's registration statements or other filings with the Commission.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit Number	Description
99.1	Press Release issued by Heat Biologics, Inc., dated March 14, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: March 14, 2022

HEAT BIOLOGICS, INC.

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: Chairman, President and Chief Executive Officer

EXHIBIT 99.1

Heat Biologics Provides Year-End 2021 Business Update

Durham, NC – March 14, 2022 – Heat Biologics, Inc. ("Heat") (NYSE American: HTBX), a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, today provided strategic, financial, and operational updates for the year ended December 31, 2021.

Jeff Wolf, Chief Executive Officer of Heat, commented, "2021 was a transformative year for Heat as we progress our strategic evolution to become a fully-integrated biopharmaceutical company. On the clinical front, we presented favorable survival data at The American Association of Cancer Research (AACR) of HS-110 in combination with checkpoint inhibitors for the treatment of non-small cell lung cancer (NSCLC). We recently submitted meeting requests to the FDA for separate Type B ("End of Phase 2 Meeting") and Type C (Phase 3 "CMC Readiness Meeting") meetings to receive feedback on our proposed trial design and regulatory path forward. We anticipate these meetings will be scheduled for the second quarter of 2022. Following these meetings, we should be in a better position to advance potential strategic discussions regarding this program."

"In September, based on our positive review of the Phase 1 data generated to date, we announced additional dose levels for our Phase 1 clinical trial evaluating the safety of PTX-35 monotherapy in patients with solid tumors and look forward to reporting the results of this trial later this year. We also recently announced new data demonstrating a single dose of the preclinical version of PTX-35 (mPTX-35), was able to expand regulatory T cells (Tregs) and significantly improve disease and graft survival outcome in a model of pancreatic islet allotransplantation for the treatment of diabetes."

"We continued to make great strides towards becoming a fully integrated biotech capable of driving innovations from discovery through delivery. With the formation of Skunkworx Bio, we have ramped up our in-house discovery of biologics for our preclinical and clinical development efforts."

"Our biomanufacturing and analytical team at Scorpion Biological Services broke ground on a new facility in San Antonio, Texas, designed to decrease our dependence on third-party CDMOs, reducing costs and accelerating timelines. In addition to supporting our own internal operations, we intend to offer manufacturing services to other biopharma companies on a fee-for-service basis. These efforts reinforce our goal of maximizing efficiency of drug development to expedite the delivery of novel immune activating therapies."

"At the World Vaccine Conference, we announced our new biosecurity/biodefense initiative led by RapidVax®, a novel vaccine platform designed to enable an accelerated response and long-lasting immunological memory against a wide variety of infectious agents. RapidVax is designed to utilize a common unprogrammed vaccine base that can be manufactured in bulk, stockpiled, and rapidly customized upon identification of a biological threat to enable an accelerated time to clinic that can harness shared development, clinical safety, and manufacturing synergies. Our gp96-based cellular vaccines have previously demonstrated prophylactic protection in animal models against a range of diseases, including malaria, HIV/SIV, Zika and SARS-CoV-2 in multiple DOD and NIH-funded studies. Since launching this program, we have filed patents to protect our proprietary technology and have established our new Biothreat Advisory Board, which includes highly renowned individuals in the fields of biosecurity and biodefense, to guide the development of our programs."

"In addition to our internal biodefense initiatives, we announced a definitive merger agreement to acquire Elusys Therapeutics, a commercial-stage biodefense company and the manufacturer of ANTHIM® (obiltoxaximab), which is approved for the treatment of inhalation anthrax in the U.S., Canada, Europe. Since announcing this acquisition, Elusys completed the first phase of a contract for $50 million with an option to procure up to an additional $31 million of ANTHIM by the first half of 2023. Given the growing global uncertainty, we believe the risks of anthrax and other biological threats are more present than ever. This acquisition is aligned with our strategy to take a leading role in the biodefense market."

2021 Financial Results

- Recognized $2.1 million of grant and contract revenue, primarily for qualified expenditures under the CPRIT grant for the year ended December 31, 2021 compared to $2.9 million for the year ended December 31, 2020. The decrease 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 December 31, 2021, we had a grant receivable balance of $1.3 million for CPRIT proceeds not yet received but for which the costs had been incurred or the conditions of the award had been met. We continue our efforts to secure future non-dilutive grant funding to subsidize ongoing research and development costs.
- Research and development expense was $18.8 million and $12.9 million for the years ended December 31, 2021 and 2020, respectively. The increase was primarily due to manufacturing and patient costs for PTX-35, consulting expenses in our clinical and CMC groups, and a $2.4 million impairment of IPR&D.

- General and administrative expense was $16.8 million and $14.9 million for the years ended December 31, 2021 and 2020. The increase was primarily due to the increase in salaries, D&O insurance expense, and legal fees.

- Net loss attributable to Heat Biologics was approximately $35.1 million, or ($1.41) per basic and diluted share for the year ended December 31, 2021 compared to a net loss of approximately of $26.0 million, or ($1.63) per basic and diluted share for the year ended December 31, 2021.

- As of December 31, 2021, the Company had approximately $96.4 million in cash, cash equivalents and short term investments.

About Heat Biologics, Inc.
Heat Biologics is a biopharmaceutical company focused on developing first-in-class therapies and vaccines to modulate the immune system. Heat's gp96 platform is designed to activate immune responses against cancer or infectious diseases. The Company has multiple product candidates in development leveraging the gp96 platform, including HS-110, which has completed enrollment in a Phase 2 trial, various infectious disease/biological threat programs in preclinical development and a pipeline of proprietary immunomodulatory antibodies and cell-based therapies, including PTX-35 and HS-130 in Phase 1 clinical trials.

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 regarding anticipated FDA meetings being scheduled for the second quarter of 2022 and following these meetings being in a better position to advance potential strategic discussions, reporting results of the Phase 1 clinical trial evaluating the safety of PTX-35 monotherapy in patients with solid tumors later this year, offering manufacturing capabilities to other biopharma companies, decreasing the dependence on third-party CDMOs reducing costs and accelerating timelines and maximize the efficiency of drug development to expedite the delivery of novel immune activating therapies, RapidVax® enabling an accelerated response and long-lasting immunological memory against a wide variety of infectious agents and the risks of anthrax and other biological threats being more present than ever. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including Heat's ability to offer manufacturing capabilities to other biopharma companies and decrease dependence on third-party CDMOs, reduce costs and accelerate timelines, the ability to maximize the efficiency of drug development to expedite the delivery of novel immune activating, the ability of RapidVax® to enable an accelerated response and long-lasting immunological memory against a wide variety of infectious agents, Heat's ability to leverage its gp96 platform for its new biosecurity/biodefense initiative, Heat's ability to reduce development costs, accelerate development timelines and ensure the highest levels of quality control, Heat's ability to successfully consummate the merger of Elusys, Heat's ability to provide further near-term updates on its biodefense efforts, execute on key upcoming milestones and drive shareholder value, Heat's ability to augment its clinical programs and enhance and expand its therapeutic pipeline, 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

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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 and its cash and short-term investments providing significant runway to fund Heat's current clinical programs and further expand Heat's therapeutic portfolio , 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 for the year ended December 31, 2021 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.

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