

**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): May 19, 2022

HCW BIOLOGICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

001-40591
(Commission File Number)

82-5024477
(I.R.S. Employer Identification No.)

**2929 N. Commerce Parkway
Miramar, Florida**
(Address of principal executive offices)

33025
(Zip Code)

Registrant's telephone number, including area code: (954) 842-2024

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the 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 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 240.13d-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	HCWB	The Nasdaq Stock Market 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 check mark 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 7.01. Regulation FD Disclosure.

On May 19, 2022, the Masonic Cancer Center at the University of Minnesota announced that the first patient was dosed in an investigator-sponsored Phase 1 clinical trial to evaluate HCW9218, the lead drug candidate for HCW Biologics Inc., in patients with advanced solid tumors with progressive disease after prior chemotherapies. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release by University of Minnesota dated May 19, 2022.
104	Cover Page Interactive Data File (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.

HCW BIOLOGICS INC.

Date: May 19, 2022

By: /s/ Hing C. Wong
Hing C. Wong
Founder and Chief Executive Officer

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4131-8822-6609.9

U of M begins Phase I of first-in-human clinical trial for advanced solid tumor cancers

MINNEAPOLIS, MN - May 19, 2022 - Physicians and scientists at the University of Minnesota have opened a new solid tumor cancer clinical trial and have treated their first patient with HCW9218, an injectable, bifunctional immunotherapeutic, developed by HCW Biologics Inc (NASDAQ: HCWB). This Phase I, first-in-human clinical trial is enrolling patients that have advanced solid tumors with progressive disease after prior chemotherapies.

The trial is led by University of Minnesota oncologist Melissa Geller, MD, MS, Professor, and Division Director, Gynecologic Oncology, Department of Obstetrics, Gynecology and Women's Health (OBGYN) in the Medical School and the Masonic Cancer Center's Associate Director for Clinical Research, with collaboration from Jeffrey Miller, MD, Professor of Medicine in the Medical School's [Division of Hematology, Oncology and Transplantation](#) and Deputy Director of the Masonic Cancer Center, and Manish Patel, DO, Associate Professor of Medicine, [Division of Hematology, Oncology and Transplantation](#) and Director of the Developmental Therapeutics Clinic.

"Our team is very excited to bring this clinical trial to patients who have recurrent cancer," noted Dr. Geller. "With the ease of a subcutaneous injection, this innovative compound can stimulate the immune system while at the same time inhibiting proteins that cause immunosuppression. This unique combination will provide patients with cancer a novel immune-based therapy when previous treatments have failed."

The treatment, HCW9218 has an IL-15 component that activates the immune system (NK cells and T cells) and a second component that neutralizes TGF-beta, a common protein induced by tumors to suppress the immune system. As a result, this bifunctional fusion protein complex is designed to drive anti-tumor immune activity to attack cancer cells while simultaneously blocking unwanted immunosuppressive activities.

About the Masonic Cancer Center, University of Minnesota

The Masonic Cancer Center, University of Minnesota, is the Twin Cities' only Comprehensive Cancer Center, designated 'Outstanding' by the National Cancer Institute. As Minnesota's Cancer Center, we have served the entire state for more than 25 years. Our researchers, educators, and care providers have worked to discover the causes, prevention, detection, and treatment of cancer and cancer-related diseases. Learn more at cancer.umn.edu.

About HCW Biologics

HCW Biologics is a clinical-stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation, and age-related diseases, such as cancer, cardiovascular diseases, diabetes, neurodegenerative diseases, and autoimmune diseases. The Company has combined deep understanding of disease-related immunology with its expertise in advanced protein engineering to develop the TOBI™ (Tissue factOr-Based fuslon) discovery platform. The Company uses its TOBI™ discovery platform to generate designer, novel multi-functional fusion molecules with immunotherapeutic properties. The invention of HCW Biologics' two lead molecules, HCW9218 and HCW9302, was made via the TOBI™ discovery platform. The Masonic Cancer Center, University of Minnesota, has initiated a Phase 1 clinical trial to evaluate HCW9218 in solid tumors that have progressed after prior chemotherapies. The FDA has also cleared HCW Biologics to initiate a first-in-human Phase 1b clinical trial for HCW9218 in patients with advanced pancreatic cancer. HCW9302 is currently undergoing IND-enabling studies for an autoimmune indication.

