# 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): January 24, 2022**

# HCW BIOLOGICS INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-40591** | **82-5024477** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

| **2929 N. Commerce Parkway**<br>**Miramar, Florida** | **33025** |
|---|---|
| **(Address of principal executive offices)** | **(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))

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. ☒

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** |

**Item 7.01. Regulation FD Disclosure.**

On January 24, 2022, HCW Biologics Inc. issued a press release announcing that the Masonic Cancer Center at the University of Minnesota was cleared by the U.S. Food and Drug Administration to proceed to evaluate HCW9218, the lead drug candidate for HCW Biologics Inc., in a Phase 1 clinical trial in patients with advanced solid tumors with progressive disease after prior chemotherapies.

The information furnished in this Current Report, 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

| | |
|---|---|
| 99.1 | Press Release issued January 24, 2022 |
| 104 | Cover Page Interactive Data File (embedded with 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: January 24, 2022

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

**Exhibit 99.1**

**Masonic Cancer Center at the University of Minnesota Receives FDA Clearance to Proceed with Phase 1 Clinical Trial in Solid Tumors for HCW9218, HCW Biologics' Novel Bifunctional Fusion Protein**

*UM cleared to proceed with clinical trial to evaluate HCW9218 in various advanced solid tumors, such as breast, ovarian, prostate and colorectal cancers*

**Miramar, FL** – January 24, 2022 – HCW Biologics Inc. (the "Company") (NASDAQ: HCWB), a biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between inflammation and age-related diseases, today announced that the Masonic Cancer Center, University of Minnesota was cleared by the U.S. Food and Drug Administration (FDA) to proceed to evaluate the Company's lead drug candidate, HCW9218, in a Phase 1 clinical trial in patients with advanced solid tumors with progressive disease after prior chemotherapies. HCW9218 is an injectable, bifunctional fusion protein complex designed to drive anti-tumor activity by activating desired immune responses to attack cancer cells while simultaneously blocking unwanted immunosuppressive activities.

The Principal Investigator of the clinical trial is Melissa A. Geller, M.D., M.S., Professor and Division Director of Gynecologic Oncology in the Department of Obstetrics, Gynecology and Women's Health at the University of Minnesota. Dr. Geller stated, "Because the immunosuppressive tumor microenvironment limits the success of current therapies, there is a critical need for novel immune based therapies for advanced solid tumors. The estimated percentages of patients who are eligible for and who respond to cancer treatments such as checkpoint inhibitor drugs remain modest. We are excited to be able to sponsor a clinical study for treatment-resistant solid tumors using HCW9218. This immunotherapeutic might be the answer we need to augment anti-tumor activities of existing standards of care chemotherapies."

"HCW9218 is a unique combination of a TGF-ß receptor that neutralizes a highly immunosuppressive cytokine secreted by tumors, and IL-15, a potent cytokine that stimulates the natural killer and $CD8^+$-T cell cytotoxicity. As a result, this bifunctional immunotherapeutic has the potential to drive significant anti-tumor activity," noted Jeffrey A. Miller, M.D., the Deputy Director of the Masonic Cancer Center, and co-Principal Investigator on this study. Dr. Miller continued, "HCW9218 also may define a new category of cancer treatment through modifying factors related to drug resistance and disease recurrence. We plan to conduct correlative studies to evaluate this potential in our current clinical trial."

Hing C. Wong, Ph.D., Founder and CEO of HCW Biologics, stated, “HCW Biologics is honored to have the Masonic Cancer Center as the sponsor for the second clinical trial to evaluate HCW9218 in difficult-to-treat cancers. This is an important milestone for HCW Biologics and our efforts to advance the development of potentially groundbreaking immunotherapeutic candidates for cancer and other age-related diseases. We have demonstrated that HCW9218 can augment the anti-tumor activities and lessen the side effects of chemotherapies by reducing the therapy-induced senescent cells in preclinical animal models.”

**About Masonic Cancer Center**

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, they have served the entire state for more than 25 years. Their researchers, educators, and care providers have worked to discover the causes, prevention, detection, and treatment of cancer and cancer-related diseases.

**About Advanced Solid Tumors:**

Solid tumors represent approximatively 90% of adult human cancers. In 2022, in the US alone, it is believed there will be an estimated 1.9 million new cancer cases diagnosed and over 600,000 cancer deaths, which are increasing with an aging population. Solid tumor cancer can develop in many parts of the human body — including the breast, ovary, colon, and prostate. Breast cancer is the most common cancer worldwide—surpassing lung cancer for the first time in 2020—and the most common cancer diagnosed in American women. It is a leading cause of cancer death in less developed countries and the second leading cause of cancer death in American women. Ovarian cancer ranks fifth in cancer deaths among U.S. women and eighth in cancer deaths among women worldwide. Colorectal cancer is the third most common malignancy and the second most deadly cancer worldwide. Prostate cancer is the second most commonly occurring cancer in men and the fourth most commonly occurring cancer overall. Solid tumor anatomy or tumor microenvironment does not consist of cancer cells alone. The heterogeneity of solid tumor’s microenvironment makes this cancer difficult to treat. Recent advances in anti-cancer agents have contributed significantly to the improvement of both the disease-free survival and quality of life in cancer patients. However, in many instances, a favorable initial response to treatment changes afterwards, thereby leading to cancer relapse, recurrence and resistance to further therapy.

**About the TOBI™ platform:**

HCW Biologics has combined deep understanding of disease-related immunology with its expertise in advanced protein engineering to develop the TOBI™ discovery platform. The TOBI™ platform is a proprietary immunotherapeutic drug design and discovery platform. The Company has utilized this modular, tunable technology to generate a novel pipeline of immunotherapeutic candidates capable of activating and targeting desired immune responses while blocking unwanted immunosuppressive activities. The balancing of these two activities is believed to be the key to developing immunotherapeutic agents that will be safe, well tolerated and efficacious.

**About HCW Biologics:**

HCW Biologics is a transformative immunotherapy company that focuses on inflammaging, a state of unresolved inflammatory responses and chronic inflammation. The Company is developing novel immunotherapies designed to improve 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 uses its TOBI™ discovery platform to generate designer, novel multi-functional fusion molecules with

immunotherapeutic properties for the treatment of inflammaging. The invention of HCW Biologics' two lead molecules, HCW9218 and HCW9302, was made via the TOBI™ discovery platform. The FDA has 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.

**Forward Looking Statements:**

Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "expect," "believe," "will," "may," "should," "estimate," "project," "outlook," "forecast" or other similar words and include, without limitation, statements regarding the ability of HCW9218 to drive anti-tumor activity by activating desired immune responses to attack cancer cells while simultaneously blocking unwanted immunosuppressive activities; the ability of HCW9218 to augment anti-tumor activities of existing standards of care chemotherapies and lessen the side effects of chemotherapies by reducing the therapy-induced senescent cells; the potential of HCW9218 as a cancer treatment through modification of factors related to drug resistance and disease recurrence and plans to conduct correlative studies regarding same; and immunotherapeutic candidates capable of activating and targeting desired immune responses while blocking unwanted immunosuppressive activities; the balancing of certain activities believed to be the key to developing immunotherapeutic agents that are expected to be safe, well tolerated and efficacious. Forward-looking statements are based on the Company's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. Factors that could cause actual results to differ include, but are not limited to, the risks and uncertainties that are described in the section titled "Risk Factors" in the final prospectus related to the Company's initial public offering filed with the Securities and Exchange Commission on July 21, 2021 and in other filings filed from time to time with the SEC. Forward-looking statements contained in this press release are made as of this date, and the Company undertakes no duty to update such information except as required under applicable law.

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