

**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): August 13, 2021

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 2.02 Results of Operations and Financial Condition.

On August 13, 2021, HCW Biologics Inc., (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth in this Item 2.02 (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, regardless of any general incorporation language in such filing, except as 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 dated August 13, 2021.
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: August 13, 2021

By: /s/ Hing C. Wong

Hing C. Wong

Title: Chief Executive Officer



HCW Biologics Reports Second Quarter Financial Results and Recent Business Highlights

Miramar, FL – August 13, 2021 – HCW Biologics Inc. (the “Company”) (NASDAQ: HCWB), an innovative 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, today reported financial results and recent business highlights for its second quarter ended June 30, 2021.

“HCW Biologics delivered on a milestone as we achieved our goal of closing our initial public offering on July 22 to raise capital to advance the clinical development of our lead molecules,” stated Hing C. Wong, Ph.D., founder and CEO of HCW Biologics Inc. “We started HCW Biologics three years ago with an idea to develop immunotherapeutic treatments for age-related diseases. Since that time, we applied our expertise in advanced protein engineering to internally develop our TOBIT™ (Tissue factOr-Based fusIon) discovery platform and successfully developed immunotherapeutic molecules based on TOBIT™ technology that can be administered by subcutaneous injection as well as used in adoptive cell therapy approaches. After extensive studies to assess the molecules we created, we selected two lead molecules, HCW9218 and HCW9302 for clinical development.”

“HCW Biologics’ clinical development strategy is to prove the safety and efficacy of both lead molecules individually in future clinical trials, and eventually combine them as an immunotherapeutic for some of the most difficult to treat age-related diseases. Our gateway indication for our lead molecule, HCW9218, is cancer. Several scientific studies have revealed that increased normal tissue cellular senescence can promote tumor progression, creating a link between aging and cancer. In preclinical studies, HCW9218 has shown it can reduce chemotherapy-induced tumor and normal tissue senescence and decrease senescence associated secretory phenotype (i.e., proinflammatory) factors that senescent cells secrete, in particular TGF-β. We are wrapping up IND-enabling activities and expect to submit an Investigational New Drug (IND) application for a Phase 1b/2 clinical trial to assess HCW9218 in the treatment of pancreatic cancer by the end of 2021.”

Business Highlights:

- **Initial Public Offering:** On July 22, 2021, the Company closed on its IPO with the sale of 7,000,000 shares of common stock at a public offering price of \$8.00 per share, resulting in net proceeds of approximately \$49.0 million, after deducting underwriting discounts and commissions and estimated offering-associated expenses.
- As part of the preparations of becoming a public company, HCW Biologics shareholders elected two new independent board members in May 2021. Mr. Scott Garrett serves as the Chairman of the Board and Chairman of the Compensation Committee. His experience as a Chief Executive

Officer and in other senior leadership positions with biomedical and diagnostics companies enables him to bring to the Board of Directors an operational perspective as well as valuable insights and experience. Mr. Rick Greene serves as the Chairman of the Audit Committee. His experience as a Chief Financial Officer and in other financial management and reporting, operations and business development positions in the healthcare industry enables him to bring financial expertise to the Board of Directors. The Company is committed to expanding the size of its Board of Directors to bring additional diversity and operational expertise.

- As of June 30, 2021, the Company completed good laboratory practice (GLP) toxicology studies on nonhuman primates and mice to understand the onset, degree of severity, and time length up to which a particular dose of a drug demonstrates any toxic effects. The Company will continue to complete IND-enabling activities for HCW9218 and prepare for the IND filing in the second half of 2021.
- The Company launched the execution of its strategy to use pivotal publications to establish its leadership in oncology and age-related diseases in scientific and clinical communities. The Company currently has two articles published online:
 - An article published online by *Cancer Immunology Research* describing the TOBITTM discovery platform: Becker-Hapak MK, et al. A Fusion Protein Complex Combines IL-12, IL-15, and IL-18 Signaling to Induce Memory-like NK Cells for Cancer Immunotherapy. July 9, 2021.
 - An article published online by *Molecular Therapy* on the characterization of the Company's lead molecules, HCW9218: Liu B et al. Bifunctional TGF- β Trap/IL-15 Protein Complex Elicits Potent NK Cell and CD8⁺ T Cell Immunity Against Solid Tumors. June 3, 2021.

Second Quarter Financial Results:

- **Cash and cash equivalents:** On June 30, 2021, the Company's cash balance was \$5.1 million. Together with net proceeds of \$49.0 million from the IPO, the Company estimates that it has sufficient cash to fund operations and capital expenditures for at least the next 24 months. This does not include potential sources of non-dilutive financing, which may be obtained as a result of entering out-licenses, such as upfront cash payment and shares of Wugen common stock that were received as a result of entering a license agreement with Wugen for limited rights to two of the Company's molecules.
- **Research and development expenses:** Research and development expenses were \$1.7 million in the second quarter of 2021, as compared to \$2.1 million for the second quarter of 2020. Higher costs in the second quarter of 2020 were a result of the ramp up costs required for initiation of cGMP manufacturing for five of the Company's internally developed molecules.
- **General and administrative expenses:** General and administrative expenses were \$1.1 million in the second quarter of 2021, as compared to \$0.7 million for the second quarter of 2020. The difference reflects additional general and administrative costs arising primarily from additional patent filings to broaden the protection of the Company's intellectual property and performance-based bonuses.

- **Net loss:** Net loss was \$2.8 million in the second quarter of 2021, as compared to \$2.8 million for the second quarter of 2020.

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 by disrupting the link between chronic, low-grade inflammation and age-related diseases such as cancer, cardiovascular disease, diabetes, neurodegenerative disease and autoimmune disease. HCW uses its Tissue factor-Based fusion (TOBIT™) discovery platform to generate designer, novel multi-functional fusion molecules with therapeutic properties for the treatment of inflammaging. Two of HCW's lead discoveries via the TOBIT™ platform include molecules HCW9218 and HCW9302, both currently undergoing IND-enabling studies.

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 successful submission of an IND for Phase 1b/2 clinical trial to assess HCW9218 in the treatment of pancreatic cancer by the end of 2021, reduction of chemotherapy-induced tumor and normal tumor and normal tissue senescence and decrease senescence associated secretory phenotype factors by HCW9218 and the successful combination of HCW9218 and HCW9302 as an immunotherapeutic for some of the most difficult to treat age-related diseases. 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. 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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