

**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 03, 2022

HCW Biologics Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40591
(Commission File Number)

82-5024477
(IRS 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

(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 240.13e-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, par value \$0.0001 per share	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 August 2, 2022, HCW Biologics Inc. was granted U.S. Patent No. 11,401,324 by the United States Patent and Trademark Office which contains claims for immunotherapeutic compounds comprised of a single-chain chimeric polypeptide with two target-binding domains on a scaffold made of an extracellular domain of human tissue factor.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated August 3, 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 thereunto duly authorized.

HCW BIOLOGICS INC.

Date: August 3, 2022

By: /s/ Hing C. Wong
Hing C. Wong, Founder and CEO



U.S. Patent Issued to HCW Biologics for Foundational Platform Technology

*Issued Claims for Single-Chain Chimeric Polypeptide
and Composition Claims for Lead Product Candidate, HCW9302*

Miramar, FL – August 3, 2022 – HCW Biologics Inc. (the “Company”) (NASDAQ: HCWB), a clinical-stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen healthspan by disrupting the link between chronic, low-grade inflammation and age-related diseases, was granted U.S. Patent 11,401,324 which contains claims for immunotherapeutic compounds comprised of a single-chain chimeric polypeptide with two target-binding domains on a scaffold made of an extracellular domain of human tissue factor.

This patent provides intellectual property protection for the lead drug candidate, HCW9302, a single-chain, IL-2-based fusion protein designed to activate and expand regulatory T (“T_{reg}”) cells to suppress the activity of inflammasome-bearing cells and the inflammatory factors which they secrete. Preclinical studies in mouse models have demonstrated the ability of HCW9302 to activate T_{reg} cells and reduce inflammation-related disease pathologies, supporting the potential of HCW9302 to treat a wide variety of autoimmune and proinflammatory diseases. HCW9302 is currently completing IND-enabling activities for an IND application for a clinical trial in an autoimmune disorder.

HCW Biologics has created an extensive patent portfolio with multiple families of patent applications that are directed to its internally developed TOBI™ discovery platform technology for creation of novel single-chain and multi-chain chimeric polypeptides as well as methods of use of these polypeptides alone and in combination.

Hing C. Wong, Ph.D., Founder and CEO of HCW Biologics, expressed his excitement upon reaching this milestone by stating, “We are thrilled to announce the issuance of a patent that has allowed such broad claims. The issuance of our first patent marks an important step in the evolution of our patent portfolio. This news, along with our progress in the prosecution of our other patent applications, reinforces our belief that our novel single-chain and multi-chain immunotherapeutics, as well as the proprietary approach used to create them with our TOBI™

discovery platform, are novel, valuable assets. We are pleased that this patent has been granted by the U.S. Patent and Trademark Office, providing vital recognition and protection of the intellectual property on which we based one of our lead product candidates, HCW9302.”

HCW Biologics is represented by the leading global intellectual property law firm, Fish & Richardson P.C. “From the beginning, we have worked with HCW Biologics to build a portfolio of foundational patents which will protect the Company’s technology, inventions and improvements that are commercially important to the foundation of its business,” observed Tiffany A. Reiter, Ph.D., Principal in the Boston office of Fish & Richardson P.C.

About HCW Biologics:

HCW Biologics is a clinical-stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen healthspan 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 fusIon) 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 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 HCW Biologics to protect its intellectual property through issued patents or otherwise. 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 Company’s Quarterly Report on Form 10-Q filed with the United States Securities and Exchange Commission (the “SEC”) on May 13, 2022, and the Annual Report on Form 10-K filed with the SEC on March 29, 2022, 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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