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): June 16, 2026

HCW Biologics Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40591**	**82-5024477**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2929 N. Commerce Parkway Miramar, Florida	**33025**
(Address of Principal Executive Offices)	**(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 June 16, 2026, HCW Biologics Inc. issued a press release announcing the positive preliminary human data readout for the first two dose cohorts from its dose-escalating Phase 1 clinical trial of HCW9302, an IL-2 based fusion immunotherapeutic, in patients with alopecia areata. 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

Exhibit No.	Description
99.1	Press release dated June 16, 2026.
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: June 16, 2026

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

EXHIBIT 99.1

HCW Biologics Announces Positive Results for Preliminary Human Data Readout for Phase 1 Clinical Trial Evaluating IL-2 Based Fusion Immunotherapeutic, HCW9302 Monotherapy, in Alopecia Areata

Potentially best-in-class IL-2 based treatment for autoimmune diseases by expanding and activating regulatory T cells

Readout for dose-escalating clinical study for first two dose cohorts

All participants in second dose cohort at the dose level of 3 micrograms/kg body weight showed positive clinical response after single dose administration

Well tolerated, with no dose-limiting toxicities or significant known IL-2-treatment-related adverse effects, including no reported incidence of capillary leak, cytokine release syndrome, or increase in blood eosinophil counts

HCW Biologics projects to establish the Recommended Phase 2 Dose by year end 2026

MIRAMAR, Fla., June 16, 2026 (GLOBE NEWSWIRE) — HCW Biologics Inc. ("HCWB" or the "Company") (NASDAQ: HCWB), a U.S.-based clinical-stage biopharmaceutical company developing transformative fusion immunotherapeutics to support or treat diseases promoted by chronic inflammation, focusing on autoimmune disorders and other inflammatory diseases, cancer and senescence-associated dysplasia, today announced a positive preliminary human data readout for the first two dose cohorts from its dose-escalating Phase 1 clinical trial of HCW9302, an IL-2 based fusion immunotherapeutic, in patients with alopecia areata.

In the second dose cohort, comprised of patients who received a single subcutaneous dose of HCW9302 monotherapy of three (3) micrograms/kg body weight, all three participants showed preliminary indications of improvement in Severity of Alopecia Tool ("SALT") scores. These three participants, all with mild alopecia, showed a ≥25% reduction in SALT scores compared to baseline at four and/or nine weeks after dosing. Treatment of patients in the third dose cohort (i.e., eight (8) micrograms/kg body weight) is underway and evaluation of correlative study endpoints is ongoing.

All patients, including the first dose cohort at one (1) microgram/kg body weight and the second dose cohort at three (3) micrograms/kg body weight, received a single subcutaneous dose of HCW9302 monotherapy. There were no reported incidences of capillary leak or cytokine release syndromes associated with high dose intravenous IL-2 therapy. Additionally, HCW9302 treatment did not increase blood eosinophil counts, another serious side effect commonly associated with IL-2 therapy. All reported HCW9302 treatment emergent adverse events were mild in severity and self-limiting and resolved without medical intervention. The most common side effect was temporary injection-site reaction.

These preliminary findings support the Company's belief that HCW9302 has the potential to activate and expand regulatory T (T_{reg}) cells in patients, reducing inflammation, while minimizing the risk of broad immunosuppression or unwanted side effects caused by the activation of immune effector cells. For alopecia areata, the Company believes that HCW9302 can suppress the hair-follicle killing activities of the auto-reactive immune cells by activating and expanding T_{reg} cells.

Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, commented, "The positive preliminary human data readout from the first two cohorts of the Phase 1 clinical study of HCW9302 monotherapy for alopecia areata is highly encouraging, showing potential benefit along with a well-tolerated safety profile even with a single, subcutaneous low-dose regimen. The results are consistent with our pre-clinical studies which demonstrated that HCW9302 exhibits a strong IL-2 receptor α bias, a unique and novel mechanism of action, while preferentially expanding and stimulating T_{reg} cells to reduce pro-inflammatory and autoimmune responses in animal disease models, including alopecia and atherosclerosis. This strong IL-2Rα bias highly differentiates HCW9302 from native recombinant IL-2 and other IL-2-based muteins and PEG conjugates, which typically exhibit reduced binding activity to IL-2 receptor components. HCW9302 is comprised of all human-derived components and can be produced with a cost-effective, streamlined process similar to therapeutic monoclonal antibodies."

Dr. Wong continued, "We are progressing through dose escalation in this clinical study with the objective to establish the safe recommended Phase 2 dose by year-end. Patient enrollment remains on track, and we have initiated dosing patients in the third dose escalation cohort."

Dr. Wong added further thoughts about the indications that may be considered for Phase 2 clinical studies. He stated, "Once we achieve our objective to establish the recommended Phase 2 dose, we will consider expanding clinical studies to evaluate multi-dose HCW9302 monotherapy in Phase 2 studies in patients with alopecia areata, as well as other autoimmune diseases and inflammatory dermatological conditions, such as vitiligo and atopic dermatitis. We carefully monitor other potential indications with high unmet medical needs. We are very excited that recently published clinical evidence suggests that patients with Amyotrophic Lateral Sclerosis or ALS, an autoimmune neuroinflammatory disease, are expected to respond positively to combined T_{reg} cell and IL-2 treatment. We believe HCW9302 could position the Company to explore the opportunity for treatment of patients afflicted with debilitating neurodegenerative diseases such as ALS."

About the HCW9302 Phase 1 Clinical Trial for Alopecia Areata:

The Phase 1 multi-center dose-escalation study (Clinicaltrials.gov: NCT07049328) of HCW9302 monotherapy is designed to treat up to 30 patients with alopecia areata. The primary objectives of the study are to evaluate the safety of HCW9302, injected as a single dose under the skin (subcutaneously), and to determine the recommended dose level to advance to later phase clinical studies. Secondary objectives include assessment of disease responses and the effects of HCW9302 on proliferation and function of immune cells, particularly T_{reg} cells. Depending on the results of this study, multi-dose studies of HCW9302 monotherapy in expanded cohorts of patients with alopecia areata and in patients with other inflammatory dermatological conditions are expected to be initiated. There are two active clinical sites enrolling patients, The Ohio State University Wexner Medical Center, Columbus, Ohio, and the James A. Haley Veterans' Hospital, Tampa, Florida.

About HCW9302:

HCW9302 is the Company's lead product candidate for its clinical program to develop treatments for autoimmune diseases and inflammatory conditions. HCW9302 is a subcutaneously injectable, first-in-kind IL-2 based fusion immunotherapeutic molecule constructed with a proprietary tissue factor scaffold. IL-2, the active component of HCW9302, is the cytokine in humans responsible for maintaining the proper numbers and functions of T_{reg} cells in the body which control excessive inflammation caused by other immune cells, which is the etiology of autoimmune diseases. In pre-clinical studies, HCW9302 was found to bind with high affinity to the IL-2 receptor α chain ("IL-2Rα") expressed on the surface of T_{reg} cells, resulting in preferential stimulation of T_{reg} proliferation and activation compared to $CD4^+$ and $CD8^+$ T cells and Natural Killer cells. This strong IL-2Rα bias highly differentiates HCW9302 from native recombinant IL-2 and other IL-2-based muteins and PEG conjugates, which typically exhibit reduced binding activity to IL-2 receptor components. As a result, HCW9302 treatment was found to induce T_{reg} cell accumulation and activity and reduce pro-inflammatory and autoimmune responses in animal disease models, including alopecia and atherosclerosis. HCW9302 is comprised of all human-derived components and can be produced with a cost-effective streamline process similar to therapeutic monoclonal antibodies.

About Alopecia Areata:

Alopecia areata ("AA") is one of the most prevalent autoimmune diseases in the world, affecting approximately 1 in 1,000 people, with a lifetime incidence of 2% worldwide, or 160 million people. According to the National Alopecia Areata Foundation, about 7 million people in the United States have alopecia areata. The condition primarily affects individuals under the age of 30, occurring at similar rates in both males and females. AA is characterized by hair loss in localized areas, the entire scalp, or, in some cases, the whole body. It occurs when the immune system mistakenly attacks hair follicles, leading to hair loss without causing permanent damage to the follicles. Patients often experience recurring episodes of hair loss throughout their lives. Existing treatments, such as corticosteroids, immunotherapy, Janus kinase inhibitors, and topical solutions, focus on managing the severity and duration of episodes of hair loss. However, these therapies primarily address symptoms rather than providing a cure or consistent, long-term hair regrowth. Currently, there is no cure for alopecia areata.

About HCW Biologics:

HCW Biologics Inc. (the "Company") (NASDAQ: HCWB) is a clinical-stage biopharmaceutical company developing transformative fusion immunotherapeutics to treat diseases promoted by chronic inflammation, including autoimmune diseases, cancer, and senescence-associated dysplasia. The Company's immunotherapeutics represent a new class of drugs that it believes have the potential to fundamentally change the treatment of proinflammatory and senescence-associated diseases and conditions that are promoted by chronic inflammation —and in doing so, improve patients' quality of life and possibly extend longevity. A key aspect of the Company's clinical development and financing strategy is to focus on its business development programs. See the Company Pipeline at https://hcwbiologics.com/pipeline/

Forward Looking Statements:

This press release contains "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, the safety, ability and efficacy of HCW9302 to treat autoimmune diseases and other inflammatory diseases, including the efficacy of HCW9302 in the treatment of alopecia areata from preliminary clinical safety data; the ability of HCW9302 to advance to Phase 2 clinical trials; the ability of HCW9302 to treat other autoimmune or neurodegenerative conditions; and the selection of a safe recommended Phase 2 dose for HCW9302 by year end. 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 annual report on Form 10-K filed with the United States Securities and Exchange Commission (the "SEC") on March 31, 2026, the quarterly report on Form 10-Q filed with the SEC on May 14, 2026, and in other filings filed from time to time with the SEC.

Company Contact:

Peter Rhode, PhD.
Chief Scientific Officer and Vice President Clinical Operations
HCW Biologics Inc.
peterrhode@hcwbiologics.com