

**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): September 4, 2026

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 1.01 Entry into a Material Definitive Agreement.

On September 4, 2026, HCW Biologics Inc. (the “Company”) entered into an Exclusive Distribution Agreement (the “Distribution Agreement” or “Agreement”) with Akron Biotech (“Akron”), a leading manufacturer of ancillary materials and a contract development and manufacturing organization for the distribution of the Company’s commercial-ready molecule, HCW11-006, for use as a reagent in cell therapy manufacturing and other ex vivo applications, but not for use in injectable therapies (the “Product”), throughout the world, excluding the People’s Republic of China, for a term of five years from the closing date unless terminated earlier for cause or by the Company’s exercise of its right to terminate for convenience. If the Agreement is terminated by the Company for convenience, under the terms of the Distribution Agreement, the Company has committed to continue to supply the Product to support existing Akron customers, in addition to other provisions, to ensure a seamless transition for customers.

In connection with the Distribution Agreement, the parties will enter into a Material Transfer Agreement to permit Akron to perform further due diligence and evaluate the Product. The closing is subject to the satisfactory completion of due diligence and product testing but will occur no later than November 30, 2026. Under the Distribution Agreement, the parties also agreed to negotiate in good faith to finalize and execute a Supply Agreement within 60 days of the closing date, under which the Company will (assuming the closing occurs) receive advance payments of \$200,000 at closing, \$100,000 within 30 days of execution of the Supply Agreement, and \$100,000 on each of the first and second anniversaries of the closing date. In addition, the Distribution Agreement provides that Akron will make quarterly payments for the Company’s technical support, as needed.

The foregoing description of the Distribution Agreement is qualified in its entirety by reference to the full text of the Distribution Agreement, a copy of which will be filed as an exhibit to a subsequent filing, if applicable.

Item 7.01 Regulation FD Disclosure.

On September 8, 2026, HCW Biologics Inc. issued a press release announcing its entry into an Exclusive Distribution Agreement with Akron Biotech for the commercialization and distribution of HCW11-006 for use as a reagent to support cell therapy manufacturing. 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 September 8, 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: September 8, 2026

By: /s/ Hing C. Wong

Hing C. Wong, Founder and Chief Executive Officer



HCW Biologics Entered an Exclusive Distribution Agreement with Akron Biotech to Commercialize HCW11-006 as Reagent Used to Support Production of Highly Functional Human CAR-T Cells

Agreement includes pre-payment commitments for product sales and distribution of the second-generation multi-cytokine-based HCW11-006 for use as a reagent

Akron is a leading supplier of critical ancillary materials and accessory molecules for clinical and commercial scale-up of cell, gene and regenerative therapy products

HCW Biologics supplies research and cGMP-grade HCW11-006 and Akron markets and distributes the reagent to its established network of research institutions and commercial companies

Company showed in studies that CAR-T cells manufactured using HCW11-006 as a reagent exhibited strong anti-tumor activity and enhanced antiviral potency as well as potential for lowering the cost of production of CAR-T therapies

MIRAMAR, Fla., September 8, 2026 (GLOBE NEWSWIRE) — HCW Biologics Inc. (the “Company” or “HCW Biologics”) (NASDAQ: HCWB), a U.S.-based clinical-stage biopharmaceutical company focused on developing novel fusion immunotherapeutics to treat autoimmune diseases, cancer, and senescence-associated dysplasia, announced today that the Company has entered into an Exclusive Distribution Agreement with Akron Biotech (“Akron”), a leading manufacturer of ancillary materials and a contract development and manufacturing organization for the cell, gene therapy, and regenerative medicine industries, for the commercialization of HCW11-006 for use as a reagent to support a new method of producing highly functional human CAR-T cells for treating cancer, autoimmune disease, and infectious diseases. Akron operates within a highly specialized global network of biomedical institutions, primarily catering to a customer base of advanced therapy developers, biopharmaceutical companies, and research organizations. Akron manufactures and markets cGMP-compliant ancillary materials (such as cytokines, media supplements, and plasmid DNA) necessary for bringing regenerative medicine from preclinical stages to commercialization.

HCW11-006, a first-in-class multi-cytokine fusion molecule built with our proprietary TRBC platform, enables production of more potent CAR-T-based immunotherapies by generating a CAR-T population that is highly functional and markedly enriched for long-lived T-memory stem cells (T_{scm}). Utilizing HCW11-006 as part of a manufacturing strategy may be broadly applicable to increase persistence and functionality of CAR-Ts. Functional persistence of CAR-Ts is limited by conventional and costly manufacturing methods utilizing anti-CD3/CD28 (αCD3/28)/IL-2 stimulation, which generates terminally differentiated and shorter-lived CAR-Ts.

Utilizing HCW11-006 as a reagent in the manufacture of CAR-Ts synergizes the effects of IL-7, IL-15 and IL-21 to promote the generation of a CAR-T cell product with a diverse mix of T cell subsets that exhibit a combination of T_{scm} self-renewal capacity and enhanced T cell effector function. In addition, as a reagent, HCW11-006 stimulates proliferation of CD8⁺ T cells, particularly those within the T_{scm} subset. As a result, HCW11-006 was shown to generate CAR-Ts without requiring α CD3/28/IL-2 activation that are highly enriched in long-lived T_{scm} and display potent activity across distinct disease experimental models, namely, HIV-1 and B-cell leukemia.

In preclinical studies, CAR-Ts manufactured using HCW11-006 were significantly superior compared to CAR-Ts manufactured using standard methods employing α CD3/28/IL-2 reagents for CAR lentiviral transduction and subsequent expansion and persistence of highly active human CAR-Ts. Clinical studies are planned to further confirm these findings. This research suggests that CAR-T cells produced with HCW11-006 may be a more effective and longer-lasting CAR-T cell immunotherapy than conventional CAR-T cells produced using α CD3/28/IL-2.

Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, stated, "We are thrilled that our first product, created using our proprietary TRBC platform, has reached the commercialization stage. HCW11-006 is a novel compound that enables a single molecule to deliver synergistic signals from three different immune-stimulatory cytokines. It is versatile and can be used as a novel reagent to potentially replace the current industry-standard method that relies on α CD3/28/IL-2-based approaches. An approach that employs HCW11-006 as a reagent is highly streamlined and may lower the cost of CAR-T manufacturing compared to existing approaches. Equally important, based on experimental models, HCW11-006 has shown improvement in functional activities and persistence of CAR-Ts following adoptive transfer, a goal the industry has been trying to achieve for the last decade."

Dr. Wong continued, "We are pleased to be entering into a partnership with Akron Biotech and their extensive network of customers who include leading research institutions all over the world that will include the use of CAR-T treatments produced using HCW11-006 as a reagent in clinical research and scale-up of commercialization. Recently, research laboratories and companies approached us directly seeking supply of HCW11-006 to support their cell-based research and development for their novel therapies. We decided to seek a partnership with a leading supplier to commercialize HCW11-006 for use as a reagent. We are excited to enter into this Distribution Agreement to commercialize this application of HCW11-006 as a reagent with an established firm that specializes in manufacturing and distribution of cell-based, gene and regenerative therapies."

Article Referenced in Press Release:

Cole et al., "IL-7/IL-15/IL-21 cytokine-fusion scaffold generates highly functional CAR T cells enriched in long-lived T memory stem cells," Science Advances, Vol. 12, No.11, 13 Mar 2026

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. HCW Biologics is the leader in creation of multi-valent immunotherapeutics with a unique protein-based scaffold, without the antibody Fc domain. 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, including its commercial-ready reagents to be used in the production of immunotherapeutics for cancer and infectious diseases. To date, the Company has entered into two licensing agreements in which it has licensed exclusive, worldwide rights for some of its proprietary molecules. See the Company Pipeline at <https://hcwbiologics.com/pipeline/>

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, the ability and efficacy of HCW11-006 for generating CAR-T cells for immune cell therapy with increased persistence and functionality at a lower cost; the ability of HCW11-006 preclinical studies to translate into human trials and demonstrate activation of long-lived T-memory stem cells (“T_{scm}”) in patients; the ability of HCW11-006 to improve long-term survival of disease- specific CAR-Ts following adoptive transfer and enable sustained suppression of malignancies, chronic infections and autoimmune diseases; the availability of HCW11-006 for licensing, distribution and commercial supply for certain indications; the anticipated commercialization of HCW11-006 as a reagent; the anticipated benefits, capabilities and applications of HCW11-006 in supporting the manufacture of CAR-T cell therapies; the ability of HCW11-006 to generate CAR-T cells with enhanced persistence, functionality or therapeutic activity; the ability of HCW11-006 to reduce or lower CAR-T manufacturing costs or simplify manufacturing processes; the potential adoption, evaluation or use of HCW11-006 by research institutions, biopharmaceutical companies and other customers; the anticipated benefits of the Company’s relationship with Akron Biotech, including Akron’s ability to market and distribute HCW11-006; the expected demand for HCW11-006; and the ability of HCW11-006 to support the development, commercialization or scale-up of cell-based therapies. 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 and in other filings filed from time to time with the SEC.

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