HCW Biologics Reports Second Quarter 2026 Business and Clinical Development Highlights and Financial Results

August 14, 2026

MIRAMAR, Fla., Aug. 14, 2026 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the “Company” or “HCW Biologics”) (NASDAQ: HCWB), a clinical-stage biopharmaceutical company focused on developing transformative fusion immunotherapeutics to treat autoimmune diseases, cancer and senescence-associated dysplasia, today reported financial results and recent business highlights for the three and six months ended June 30, 2026.

On June 16, 2026, the Company announced its preliminary human data readout for the first two cohorts in a dose-escalating Phase 1 clinical study to evaluate HCW9302 as a monotherapy in patients with alopecia areata. HCW9302 is a fusion immunotherapeutic which is potentially a best-in-class IL-2-based treatment for autoimmune diseases. 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.

The Company remains on track for a full Phase 1 clinical data readout in the fourth quarter of 2026. 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. The Company has not reported any dose-limiting toxicities.

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. In addition, there were no reported incidences of capillary leak or cytokine release syndromes associated with high dose intravenous IL-2 therapy. HCW9302 treatment did not increase blood eosinophil count, another serious side effect commonly associated with IL-2 therapy.

Dr. Hing C. Wong, the Company’s Founder and Chief Executive Officer, stated, “HCW9302 was selected as our lead product candidate for our autoimmune program because it has several unique features that differentiate it from other immunotherapeutic treatments for autoimmune disorders. Because our clinical study was designed to administer HCW9302 as a monotherapy, we feel confident of our findings and clear signals that indicate this drug has great potential. So far, our in-human clinical experience with HCW9302 is consistent with our preclinical results showing HCW9302’s effectiveness in alopecia areata and atopic dermatitis in relevant animal models.”

Dr. Wong continued, “HCW9302 targets CD25 directly, which we believe demonstrates activation and expansion of regulatory T cells. It has preliminarily demonstrated it has an effect on alopecia areata, even when administered as monotherapy at a low dose. Our design does not use pegylation, so we avoid anti-PEG immune responses, which account for efficacy loss and can possibly cause severe allergic symptoms. With an eye toward the future commercialization of HCW9302 for the treatment of alopecia areata and other autoimmune disorders, we developed a manufacturing process for this drug that is a simple process capable of producing large quantities with consistent quality at a relatively low cost.”

Business and Clinical Development Highlights

Commercial-Ready Molecules Used as Reagents

Since the second quarter of 2025, the AlloTera Therapeutics License (formerly the Wugen License) was in a one-year suspension period, which the Company agreed to at the request of AlloTera Therapeutics, Inc. (“AlloTera Therapeutics”). On May 21, 2026, the Company re-acquired the *ex vivo* rights to two commercial-ready molecules that had previously been licensed to AlloTera Therapeutics by exercising its right to terminate the AlloTera Therapeutics License Agreement according to the terms of the suspension letter agreement.

The Company is actively pursuing a corporate partner to commercialize HCW9206 and like molecules as reagents to support the production of cell-based immunotherapeutics, particularly CAR-T therapies. In collaboration with researchers at the Albert Einstein College of Medicine, the Company demonstrated and published in a scientific paper in Science Advances that replacing standard activation with HCW9206 during CAR-T cell manufacturing significantly increased the long-term persistence, functionality, and proportion of T memory stem cells in immunotherapies for cancer and HIV and potentially significantly lowers the production costs.

The market for reagents used in CAR-T therapy production is experiencing rapid expansion, driven by a projected increase in the global CAR-T cell therapy market, which is expected to grow from $4.0 billion in 2025 to over $15.0 billion by 2032. One of the impediments to growth is the manufacturing process, which is subject to delays and has difficult meeting target doses for commercial production.

Milestone for Company’s T-Cell Engager Program

The Company requested a Type B (pre-IND application) meeting with the U.S. Food and Drug Administration (“FDA”) to discuss the development and regulatory strategy for its investigational lead product candidate, HCW11-018b, a tetravalent T-cell engager (“TCE”) constructed with the Company’s proprietary TRBC drug development platform. The Company would like to reach agreement with the FDA on requirements for a clinical study before we submit an IND application to evaluate HCW11-018b in cancer. This clinical trial is on track to initiate in the first half of 2027, provided we secured

FDA authorization.

HCW11-018b is intended to treat solid tumors and is administered by subcutaneous injection. In preclinical studies, it has shown the ability to target tissue factor-expressing cancer cells and activate CD3-positive effector T cells, while simultaneously reducing immunosuppression in the tumor microenvironment. Immunosuppression in the tumor microenvironment can limit effector T-cell infiltration and antitumor activity in solid tumors, particularly in gynecologic and pancreatic cancers.

The Company believes that our robust, streamlined, and cost-efficient manufacturing process will produce high-quality cGMP material to support clinical development. Our manufacturing process for HCW11-018b is based on high-producing recombinant CHO cell lines and a proprietary monoclonal antibody needed for the affinity purification process. This monoclonal antibody will be manufactured under GMP standards using a top-tier CDMO.

TCEs have emerged as a potent therapeutic modality to treat cancer. First-generation TCEs represented a breakthrough in immunotherapy but they continue to face significant challenges, including limited antigen selection, poor efficacy in solid tumors, tolerability and safety concerns, and complex manufacturing processes. Extensive preclinical studies of HCW11-018b —including assessments of *in vitro* and *in vivo* potency, antigen specificity, pharmacokinetics, toxicity in nonhuman primates, and its therapeutic window — suggest that HCW11-018b may be able to overcome the limitations of earlier-generation TCEs.

$5.6 Million in Equity Financings

Pursuant to a May 2026 securities purchase agreement, in a private placement, the Company issued and sold an aggregate of 71,174 shares of Common Stock, 403,322 Pre-Funded Warrants, and Common Warrants to purchase an aggregate of up to 474,496 shares of Common Stock for aggregate gross proceeds of approximately $4.0 million at the closing, before deducting fees payable to the placement agent and other offering expenses payable by the Company. The Investors included officers, directors and significant stockholders. Scott Garrett, Chairman of the Company's Board of Directors, purchased $250,000 of securities, Hing C. Wong, the Company's Founder and Chief Executive Officer, purchased $160,000 of securities, and Rebecca Byam, the Company's Chief Financial Officer, purchased $20,000 of securities. Such purchases were made on the same terms and conditions as those offered to other investors. On June 18, 2026, the SEC declared effective a resale registration statement on Form S-1 (File No. 333-296577) covering the resale of shares of Common Stock and warrants issued in this private placement.

Pursuant to a July 2026 securities purchase agreement, in a private placement, the Company issued and sold an aggregate of 218,862 shares of Common Stock, 400,000 Pre-Funded Warrants and Common Warrants to purchase an aggregate of 618,682 shares of Common Stock for aggregate proceeds of approximately $1.6 million at closing, before deducting offering fees. The Investors included officers and directors. Scott Garrett purchased $20,000 of securities, Hing C. Wong purchased $60,000 of securities, and Lee Flowers, the Company's SVP Business Development, purchased $20,000 of securities. Under a Registration Rights Agreement, the Company is obligated to file a registration statement to register the securities sold in this offering within 15 business days from closing.

Second Quarter 2026 Financial Results

Revenues: Revenues for the three months ended June 30, 2025 and 2026 were $6,550 and $135,568, respectively. Revenues in the six months ended June 30, 2025 and 2026 were $11,615 and $6.7 million, respectively. In the three and six months ended June 30, 2026, the Company completed the closing of the exclusive, worldwide licensing agreement with Beijing Trimmune Biotech Co., Ltd. ("Trimmune") for the *in vivo* rights for HCW11-006 ("Trimmune License") and performed additional post-transfer services under the agreement.

Research and development (R&D) expenses: R&D expenses for the three months ended June 30, 2025 and 2026 were $1.2 million and $1.2 million, respectively, a decrease of $23,472, or 2%. The decrease was primarily due to decreases in salaries, benefits and related taxes and clinical trial expenses, partially offset by an increase in preclinical expenses with a focus on IND-enabling activities for the Company's lead product T-Cell Engager candidate, HCW11-018b. R&D expenses for the six months ended June 30, 2025 and 2026 were $2.7 million and $2.5 million, respectively, a decrease of $244,236, or 9%. The decrease was primarily due to a decline in manufacturing and materials expenses, partially offset by increases in taxes and salaries, benefits and related expenses.

General and administrative (G&A) expenses: G&A expenses for the three months ended June 30, 2025 and 2026 were $2.1 million and $1.9 million, respectively, a decrease of $225,646, or 11%. The decrease was primarily attributable to decreases of $242,073 in salaries and benefits related to a decline in stock-based compensation expense, $87,835 in accretion expense for the fixed bonus payable upon the maturity date of outstanding Secured Notes and a $79,518 decrease in insurance premiums, partially offset by increases in taxes and expenses related to financing activities. In May 2025, the Company restructured $7.4 million of debt related to the Secured Notes, and these Noteholders converted to equity. G&A expenses for the six months ended June 30, 2025 and 2026 were $4.3 million and $3.7 million, respectively, a decrease of $598,649, or 14%. The decrease was primarily attributable to decreases of $507,206 in salaries and benefits related to a decline in stock-based compensation expense and $346,482 in accretion expense for the fixed bonus payable upon maturity date of outstanding Secured Notes and a decrease of $175,343 in insurance premiums, partially offset by an increase in taxes and expenses related to financing activities.

Legal expenses (recoveries), net: Legal expenses and recoveries, net represent the legal fees that the Company incurred for an Arbitration, net of insurance recoveries. In the six months ended June 30, 2025, the Company received a $2.0 million insurance recovery, partially offset by $403,049 of legal expenses. The Company anticipates it will continue to incur some expenses for the costs of remaining in compliance with the terms of the Settlement and Release Agreement from the Arbitration, primarily due to requirements for patents which are necessary to protect the Company's exclusive, worldwide intellectual property rights held in perpetuity.

Nonoperating changes impacting net income (loss): The Company adopted the fair value method of accounting for its shares in AlloTera Therapeutics in the second quarter of 2025. As a result, in the three and six months ended June 30, 2025, the Company recognized a $1.7 million gain in both periods related to a change in the fair value for this investment. The Company recognized a warrant liability in connection with warrants with a contingent settlement provision which was resolved on June 15, 2026. As a result, these warrants were reclassified to permanent equity. In the three and six months ended June 30, 2026, the changes in the fair value of the warrant liability prior to reclassification were a loss of $2.4 million and $1.8 million, respectively. In addition, during the three and six months ended June 30, 2026, the Company settled a $1.7 million liability for $1.2 million, and as a result recognized a gain on extinguishment of a liability of $483,383 in both periods.

Net loss: Net loss for the three months ended June 30,2025 and 2026 was $1.9 million and $5.2 million, respectively. Net loss for the six months

ended June 30, 2025 and 2026, was $4.1 million and $1.7 million, respectively.

Financial Guidance

As of June 30, 2026, the Company believes that substantial doubt exists regarding its ability to continue as a going concern for at least 12 months from the issuance date of the audited financial statements, without additional funding or financial support. We considered future elements of our financing plan, especially business development programs. We have had early success in completing key elements of our multi-step financing plan; however, we cannot be assured that we will continue to have success with remaining elements of our plan.

On June 26, 2025, the Company announced that it received formal notice from The Nasdaq Stock Market LLC ("Nasdaq") that the Company is in compliance with Listing Rule 5550(b)(1) (the "Equity Rule"). On June 29, 2026, HCW Biologics Inc. (the "Company") received written notice form the Listing Qualifications Staff (the "Staff") of the Nasdaq Capital Market Nasdaq Stock Market LLC ("Nasdaq") that the Nasdaq Hearings Panel (the "Panel") found that the Company regained compliance with Listing Rule 5550(a)(2), the "Bid Price Rule," per the terms set forth in the Panel's decision letter dated May 29, 2026, as amended. As indicated in the Panel's decision letter, as amended, if the Company satisfies the remaining terms of the decision through September 22, 2026, the Panel also intends to impose a Discretionary Panel Monitor on the Company pursuant to Listing Rule 5815(d)(4)(A) for a one-year period from that date. On June 30, 2026, the Company effected a one-for-six reverse stock split.

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, 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. 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, including timing and efficacy in human clinical trial data for HCW9302, ability of HCW11-018b to treat solid tumors, ability to obtain U.S. Food and Drug Administration clearance to advance Phase 2 clinical trials for HCW9302, success in obtaining FDA clearance to initiate clinical trials for HCW11-018b, and effectiveness of commercial-ready reagents for production of immunotherapeutics; and the Company's ability to license or sell reagents. 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 June 30, 2026, the Form 10-Q filed with the SEC on August 14, 2026, 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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HCW Biologics Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2026**	**2025**	**2026**
Revenues:				
Revenues	$ 6,550	$ 135,568	$ 11,615	$ 6,678,569
Cost of revenues	(5,240)	(229,455)	(9,292)	(240,526)
Net revenues	1,310	(93,887)	2,323	6,438,043
Operating expenses:				
Research and development	1,226,824	1,203,352	2,705,536	2,461,300
General and administrative	2,096,021	1,870,375	4,302,301	3,703,652
Legal expenses (recoveries), net	142,542	(1,325)	(1,596,951)	5,525
Indirect tax expense	-	-	-	198,146
Total operating expenses	3,465,387	3,072,402	5,410,886	6,368,623
Operating income (loss)	(3,464,077)	(3,166,289)	(5,408,563)	69,420
Interest expense	(228,714)	(100,541)	(505,853)	(209,815)

Change in fair value of warrant liability	-	(2,443,335)	-	(1,775,992)
Change in fair value of investment, net	1,748,688	-	1,748,688	-
Gain on extinguishment of liability	-	483,383	-	483,383
Other income, net	16,373	7,551	41,122	16,439
Net loss before income taxes	$ (1,927,730)	$ (5,219,231)	$ (4,124,606)	$ (1,416,565)
Income tax expense	-	-	-	(330,186)
Net loss	$ (1,927,730)	$ (5,219,231)	$ (4,124,606)	$ (1,746,751)
Equity dividend to investor	(10,153,799)	(10,154,642)	(10,153,799)	(11,643,114)
Net loss attributable to Common Stockholders	$ (12,081,529)	$ (15,373,873)	$ (14,278,405)	$ (13,389,865)
Net loss per share, basic and diluted	$ (40.72)	$ (11.58)	$ (59.14)	$ (11.98)
Weighted average shares outstanding, basic and diluted	296,686	1,327,966	241,417	1,117,350

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2025	June 30, 2026 Unaudited
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,952,464	$ 741,324
Accounts receivable, net	32,175	18,451
Prepaid expenses	222,156	282,533
Other current assets	77,564	97,702
Total current assets	2,284,359	1,140,010
Investments	1,326,329	4,854,028
Property, plant and equipment, net	20,880,849	20,745,804
Other assets	28,476	28,476
Total assets	$ 24,520,013	$ 26,768,318
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	$ 13,143,394	$ 10,609,950
Accrued liabilities and other current liabilities	1,110,104	1,128,592
Short-term debt, net	6,809,215	6,561,361
Deferred revenue	—	348,270
Total current liabilities	21,062,713	18,648,173
Contingent liability - related party	692,531	692,531
Total liabilities	21,755,244	19,340,704
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock:		
Common, $0.0001 par value; 250,000,000 shares authorized and 546,635 shares issued at December 31, 2025; 250,000,000 shares authorized and 1,617,642 shares issued at June 30, 2026	55	161
Additional paid-in capital	111,280,560	117,690,050
Accumulated deficit	(108,515,846)	(110,262,597)
Total stockholders' equity	2,764,769	7,427,614
Total liabilities and stockholders' equity	$ 24,520,013	$ 26,768,318