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

November 16, 2026

MIRAMAR, Fla., Nov. 16, 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 nine months ended September 30, 2026.

The Company featured two of its preclinical, non-Fc TRBC molecules at the 41st Annual Meeting of the Society for Immunotherapy of Cancer (“SITC2026”) which took place from November 4 – 8, 2026 in Phoenix, Arizona. In addition, the Company showcased the uniqueness of its TRBC platform to create novel multivalent non-Fc fusion molecules for solid tumor and senescence-associated diseases therapies.

The submission for the Company’s second-generation, tetravalent immune checkpoint inhibitor, HCW11-040, was recognized by SITC2026 as one of the top 150 abstracts out of over 1,200 abstracts submitted for its scientific rigor, novelty, clarity and potential impact on cancer immunotherapy. In the Poster presentation of its T Cell Engager Program, the Company shared the newly discovered, distinctive features of its lead product candidate in this program, HCW11-018b, including capabilities to induce/promote tertiary lymphoid structure formation inside tumors, convert immunological “cold” tumors into “hot” tumors, and enhance T-cell activation and tumor infiltration while mitigating immunosuppression, using subcutaneous (“s.c.”) administration.

In the three months ended September 30, 2026, the Company activated an additional clinical site to participate in the HCW9302 Phase 1 clinical study in alopecia areata and continued patient enrollment and treatment in the third dose cohort (i.e., eight (8) micrograms/kg body weight). In patients treated to date, the s.c. administration of HCW9302 has been well-tolerated and has had no dose-limiting toxicities. With continued patient enrollment, the Phase 1 readout and determination of the Recommended Phase 2 Dose are expected in the first quarter of 2027. The Company intends to present the full results of the Phase 1 clinical trial in an invited oral presentation at the 9th Treg-Directed Therapies Summit in March 2027 in Boston, Massachusetts.

Dr. Hing C. Wong, the Company’s Founder and Chief Executive Officer, stated, “Progress continues steadily for our clinical study evaluating HCW9302 in alopecia areata, and we are encouraged by results in humans that are consistent with our preclinical studies. We have the support of strong clinical sites who share our passion for developing breakthrough immunotherapeutics. With the addition of a third clinical site, we are hopeful that patient enrollment will maintain a good momentum as we come to the end of the Phase 1 clinical study. We are also excited about the great progress we have made with the molecules we have constructed using our TRBC platform, especially our lead T-cell engager, HCW11-018b, and our lead second-generation immune-checkpoint inhibitor, HCW11-040, which have the potential of revolutionizing treatment for solid tumors and senescence-associated diseases.”

Business and Clinical Development Highlights

In the nine months ended September 30, 2026, the Company raised $8.6 million of equity financing, which allowed it to continue to support a Phase 1 clinical study to evaluate HCW9302 in an autoimmune disease and advance preclinical programs, especially the Company’s T-Cell Engager Program. On November 4, 2026, the Company secured up to $10.0 million in cash through debt financing, and received $3.0 million, less transaction costs, at closing and access to an additional $7.0 million, subject to certain conditions. With this financing, the Company believes it has funding in place to reach the milestone of completion of the Phase 1 clinical trial for HCW9302 and determining the Recommended Phase 2 Dose level, which are expected in the first quarter of 2027.

As a result of discussions at a recent Type B meeting with the U.S. Food and Drug Administration (“FDA”), the FDA provided the Company with clear guidance for the next steps to prepare its IND application to support a first-in-human clinical study to evaluate HCW11-018b in solid tumors, which the Company intends to file in the first half of 2027. In support of potential upcoming clinical trials, the Company has initiated cGMP manufacturing of HCW11-018b. HCW Biologics has created a high-expression production cell line and a streamlined GMP manufacturing process, utilizing a relatively simple manufacturing process that is similar to the process used to make therapeutic monoclonal antibodies.

Third Quarter 2026 Financial Results

Revenues: Revenues for the three months ended September 30, 2025 and 2026 were $15,606 and $55,463, respectively. Revenues in the nine months ended September 30, 2025 and 2026 were $27,222 and $6.7 million, respectively. In the three and nine months ended September 30, 2025, at the request of the licensee, the Company agreed to suspend the license with AlloTera Therapeutics, Inc. (“AlloTera Therapeutics”), thus the Company recognized revenues related only to minor ancillary services such as storage. In the nine months ended September 30, 2026, the Company elected to terminate the license with AlloTera Therapeutics and recaptured the exclusive rights to the licensed molecules. In the nine months ended September 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 September 30, 2025 and 2026 were $1.4 million and $1.2 million, respectively, a decrease of $161,670, or 12%. The decrease was primarily due to decreases in salaries, benefits and related taxes and preclinical expenses. R&D expenses for the nine months ended September 30, 2025 and 2026 were $4.1 million and $3.7 million, respectively, a decrease of $405,905, or 10%. 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 September 30, 2025 and 2026 were $1.8 million and $1.4 million, respectively, a decrease of $518,608, or 28%. The decrease was primarily attributable to decreases in stock-based compensation expense and a decline in fees paid for professional services, such as corporate legal advice, legal advice for prosecution of patents, auditing and tax services, and other professional services. G&A expenses for the nine months ended September 30, 2025 and 2026, were $6.2 million and $5.1 million, respectively, a decrease of $1.1 million, or 18%. The decrease was primarily attributable to decreases in stock-based compensation expense, professional services and insurance premiums.

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 nine months ended September 30, 2025, the Company received a $2.0 million insurance recovery, partially offset by $409,055 of legal expenses. In the nine months ended September 30, 2026, there were expenses of $14,483. 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): In the three months ended September 30, 2025, the was a decrease in fair value of $966,284 related to the change in the fair value of the Company's shares in AlloTera Therapeutics and the related contingent liability, and a loss of $182,146 on the sale of put shares through the Company's Standby Equity Purchase Agreement. In the three months ended September 30, 2026, there was a $494,683 loss on the return of equipment.

In the nine months ended September 30, 2025, there was an increase in fair value of $782,404 related to the change in fair value of the Company's shares in AlloTera Therapeutics and the related contingent liability, a loss of $182,146 on the sale of put shares through the Company's Standby Equity Purchase Agreement. In the nine months ended September 30, 2026, there was a $1.8 million nonoperating loss, primarily consisting of a $1.8 million decrease in the fair value of a warrant liability, which was reclassified to equity in this period.

Net loss: Net loss for the three months ended September 30, 2025 and 2026 was $4.6 million and $3.2 million, respectively. Net loss for the nine months ended September 30, 2025 and 2026, was $8.7 million and $5.0 million, respectively.

Financial Guidance

As of September 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, but we cannot be assured that we will continue to have success with remaining elements of our plan.

On June 26, 2025, the Company received formal notice from The Nasdaq Stock Market LLC ("Nasdaq") that the Company was in compliance with Listing Rule 5550(b)(1) (the "Equity Rule"). On October 2, 2026, the Company received formal notice from Nasdaq that the Company maintained compliance with Listing Rule 5550(a)(2) (the "Bid Price Rule," along with all of the applicable continued listing requirements until September 22, 2026, as required by the Panel decision dated May 29, 2026, as amended.

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. 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, including timing of completion of Phase 1 in the first quarter of 2027, 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 March 31, 2026, the Form 10-Q filed with the SEC on November 16, 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 September 30,		Nine Months Ended September 30,	
	2025	**2026**	**2025**	**2026**
Revenues:				
Revenues	$ 15,606	$ 55,463	$ 27,222	$ 6,734,032
Cost of revenues	(12,485)	(27,345)	(21,777)	(267,871)
Gross Profit	3,121	28,118	5,445	6,466,161
Operating expenses:				
Research and development	1,404,247	1,242,577	4,109,782	3,703,877
General and administrative	1,884,994	1,366,386	6,187,296	5,070,038
Legal expenses (recoveries), net	6,006	9,058	(1,590,945)	14,583
Indirect tax expense	-	-	-	198,146
Total operating expenses	3,295,247	2,618,021	8,706,133	8,986,644
Operating loss	(3,292,126)	(2,589,903)	(8,700,688)	(2,520,483)
Interest expense	(127,070)	(141,797)	(632,923)	(351,612)
Change in fair value of contingent liability, net	1,055,825	-	(692,531)	-
Change in fair value of investment, net	(2,022,109)	-	1,474,935	-
Change in fair value of warrant liability	-	-	-	(1,775,992)
Loss on sale of put shares	(182,146)	-	(182,146)	-
Loss on return of equipment	-	(494,683)	-	(494,683)
Gain on extinguishment of liability	-	-	-	483,383
Other income, net	13,290	3,554	54,412	19,992
Net loss before income taxes	(4,554,336)	(3,222,829)	(8,678,941)	(4,639,395)
Income tax expense	-	-	-	(330,186)
Net loss	$ (4,554,336)	$ (3,222,829)	$ (8,678,941)	$ (4,969,581)
Equity dividend to investor	-	(2,718,837)	(10,153,799)	(14,361,951)
Net loss attributable to Common Stockholders	$ (4,554,336)	$ (5,941,666)	$ (18,832,740)	$ (19,331,532)
Net loss per share, basic and diluted	$ (12.09)	$ (2.83)	$ (68.02)	$ (13.35)
Weighted average shares outstanding, basic and diluted	376,678	2,101,872	276,889	1,448,485

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2025	September 30, 2026
		Unaudited
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,952,464	$ 955,458
Accounts receivable, net	32,175	-
Prepaid expenses	222,156	239,998
Other current assets	77,564	85,202
Total current assets	2,284,359	1,280,658
Investments	1,326,329	4,854,028
Property, plant and equipment, net	20,880,849	18,963,834
Other assets	28,476	28,476
Total assets	$ 24,520,013	$ 25,126,996
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		

Accounts payable	$ 13,143,394	$ 9,435,785
Accrued liabilities and other current liabilities	1,110,104	1,046,440
Short-term debt, net	6,809,215	6,831,899
Deferred revenue	—	297,101
Total current liabilities	21,062,713	17,611,225
Contingent liability - related party	692,531	692,531
Total liabilities	21,755,244	18,303,756
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 2,236,324 shares issued at September 30, 2026	55	223
Additional paid-in capital	111,280,560	120,308,443
Accumulated deficit	(108,515,846)	(113,485,426)
Total stockholders' equity	2,764,769	6,823,240
Total liabilities and stockholders' equity	$ 24,520,013	$ 25,126,996

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