HCW Biologics Reports Third Quarter 2025 Business Highlights and Financial Results

November 14, 2025

MIRAMAR, Fla., Nov. 14, 2025 (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the “Company” or “HCW Biologics”) (NASDAQ: HCWB), a clinical-stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen healthspan by disrupting the link between inflammation and diseases, today reported financial results and recent business highlights for its third quarter ended September 30, 2025.

The Company anticipates dosing the first patient in a Phase 1 clinical study (NCT07049328) to evaluate HCW9302 in patients with an autoimmune disease in the fourth quarter of 2025. 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 interleukin 2 (“IL-2”) fusion molecule constructed using the Company’s legacy TOBI™ platform technology. IL-2, the active component of HCW9302, is the cytokine in humans and other vertebrates responsible for maintaining the proper numbers and functions of regulatory T (“T_{reg}”) cells in the body. T_{reg} cells control excessive inflammation caused by other immune cells, which is the etiology of autoimmune diseases. The breakthrough discovery of the critical function of T_{reg} cells by Drs. Mary E. Brunkow, Fred Ramsdell and Shimon Sakaguchi was recently acknowledged with the 2025 Nobel Prize in Physiology or Medicine for their groundbreaking work concerning T_{reg} cells, which discovery was that these cells are the immune system’s security guards which prevent immune cells from attacking our own body.

Dr. Hing C. Wong, the Company’s Founder and Chief Executive Officer said, “The goal of our Phase 1 clinical study for HCW9302 is to establish the safe dose that effectively increases T_{reg} cell activity in patients with an autoimmune disease. Once we achieve this objective, we hope to rapidly expand clinical development of HCW9302 in Phase 2 studies in patients with alopecia areata as well as other autoimmune diseases and inflammatory conditions.”

Business Highlights

Business Development Transactions

- The Company has launched its search for a strong commercial partner for the clinical development of its T-cell engager (“TCE”) compounds. These compounds are designed to address shortfalls in the first generation products. The Company has created TCE compounds that can target cancer antigens and CD3 activation of effector T cells while simultaneously reducing the immunosuppression in tumor microenvironment. Such immunosuppression could play a pivotal role in reducing effector T-cell infiltration and anti-tumor efficacy in solid tumors.

Financing Transactions

- During the three months ended September 30, 2025, the Company issued 475,000 shares of Common Stock for gross proceeds of $2.2 million utilizing the Company’s Standby Equity Purchase Agreement.

Preclinical and Clinical Development Results

- The Company has successfully opened two clinical sites that are actively screening patients to participate in a first-in-human Phase 1 dose escalation clinical trial to evaluate one of its lead drug candidates, HCW9302, in patients with alopecia areata. The Company expects to dose the first patient in this clinical trial in the fourth quarter of 2025. Alopecia areata is a common autoimmune disease in humans that currently has no curative FDA approved treatments. It causes sudden hair loss and can have a significant negative impact on patients’ quality of life and psychological health. The National Alopecia Areata Foundation estimates approximately 160 million people worldwide and 7 million people in the United States have alopecia areata. The condition affects about 2% of the global population at some point in their lifetime.
- HCW Biologics showcased data for its lead engager HCW11-018b highlighting the uniqueness and advantages of the Company’s second-generation TCE program over the first-generation products at SITC. HCW11-018b is a tetra-valent construct that activates tumor-infiltrated exhausted T cells while addressing the immunosuppressive tumor microenvironment. It has broad coverage for human solid tumor indications by targeting tissue factor, with high potency and precision, shown in xenograft models including the Patient-Derived Xenograft (PDX) tumor model.
- HCW Biologics also presented data for its lead product candidate in the Company’s second-generation immune checkpoint inhibitor program at SITC. HCW11-040 is a proprietary TRBC-pembrolizumab-based immune checkpoint inhibitor, which

the Company considers as its franchise immunotherapeutic compound for internal clinical development. It is a unique combination of cytokines in multi-functional fusion protein molecule that exhibits the ability to expand progenitor exhausted T cells, or TPEX cells, without inducing a cytokine storm in preclinical studies. TPEX cells, located in the draining lymph nodes and tumors of the patients, have been implicated as the primary responders to ICI therapy. HCW11-040 in undergoing IND-enabling studies to prepare for clinical trials for evaluation in the treatment of solid tumors.

Third Quarter 2025 Financial Results

Revenues: Revenues for the three months ended September 30, 2024 and 2025 were $426,423 and $15,606, respectively. Revenues for the nine months ended September 30, 2024 and 2025 were $2.2 million and $27,222, respectively. Historically, revenues have been derived exclusively from the sale of licensed molecules to the Company's licensee, Wugen. In the nine months ended September 30, 2025, the Company agreed to a one-year suspension of the Wugen License Agreement.

Research and development (R&D) expenses: R&D expenses for the three months ended September 30, 2024 and 2025 were $1.2 million and $1.4 million, respectively, an increase of $271,334, or 18%. R&D expenses for the nine months ended September 30, 2024 and 2025 were $5.3 million and $4.1 million, respectively, a decrease of $1.2 million, or 23%. R&D expenses in the nine months ended September 30, 2024 were comparatively higher than the same period in 2025 due to expenses incurred for the manufacture of a high-expressing line of HCW9101, an element needed in the manufacture of HCW9302, the Company's clinical-stage molecule. Such activities were completed in 2024.

General and administrative (G&A) expenses: G&A expenses for the three months ended September 30, 2024 and 2025 were $1.6 million and $1.9 million, respectively, an increase of $251,537, or 15%. G&A expenses for the nine months ended September 30, 2024 and 2025 were $4.8 million and $6.2 million, respectively, an increase of $1.4 million, or 29%. The increase in G&A expenses in 2025 was primarily due to salaries and benefits and professional fees related to audit services, tax and other advisory services, as well as required activities to remain in compliance with SEC regulations and Nasdaq listing rules.

Legal expenses (recoveries), net: Legal expenses and recoveries, net represent the legal fees that the Company incurred for an Arbitration which held its hearing in May 2024, was settled on July 13, 2024, and was dismissed on December 24, 2024. Legal expenses (recoveries), net for the three months ended September 30, 2024 and 2025 were $1.0 million and $6,006, respectively. Legal expenses (recoveries), net for the nine months ended September 30,2024 and 2025 were $15.8 million and a contra expense of ($1.6) million, respectively. In January 2025, the Company received a $2.0 million insurance reimbursement that was paid directly to the law firm involved in representing Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, in the Arbitration. The Company is engaged in discussions with the law firms involved with this matter to arrange a reasonable payment plan with respect to $12.1 million legal fees which remain unpaid.

Net loss: Net loss for the three months ended September 30, 2024 and 2025 was $3.9 million and $4.6 million, respectively. Net loss for the nine months ended September 30, 2024 and 2025 was $26.7 million and $8.7 million, respectively.

Financial Guidance

As of September 30, 2025, 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, that were probable and likely to be implemented within the next year to determine if financing activities currently underway are sufficient to mitigate the substantial doubt in our going concern analysis. 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.

An important part of the Company's future financing plans is the ability to access the public markets for the sale of securities. This requires the Company's compliance with all Nasdaq Listing Rules, and it is currently deficient in meeting the requirements of Listing Rule 5550(b)(1), or the Equity Rule, related to the minimum requirements to maintain a $2.5 million balance in stockholders' equity. On October 13, 2025, a Nasdaq Hearings Panel granted the Company's request for continued listing on the Exchange, subject to, among other things, that the Company is in compliance with the Equity Rule by December 31, 2025.

About HCW Biologics

HCW Biologics Inc. (NASDAQ: HCWB) is a clinical-stage biopharmaceutical company developing proprietary immunotherapies to treat diseases promoted by chronic inflammation, especially age-related and senescence-associated diseases. The Company's immunotherapeutics represent a new class of drugs that it believes have the potential to fundamentally change the treatment of cancer and many other diseases and conditions that are promoted by chronic inflammation — and in doing so, improve patients' quality of life and potentially extend longevity. Chronic inflammation, including inflammaging, is believed to be a significant contributing factor to senescence-associated diseases and conditions that diminish healthspan, including many types of cancer, autoimmune diseases, and neurodegenerative diseases, as well as many indications that impact quality-of-life that are not life-threatening. The Company's lead product candidate, HCW9302, was developed using the Company's legacy TOBI™ (Tissue factOr-Based fusIon) platform. The Company has created another drug discovery technology, the TRBC platform, which is not based on Tissue Factor. The TRBC platform has the capability to construct immunotherapeutics that not only activate and target immune responses but are also equipped with receptors that specifically target cancerous or infected cells. This platform is a versatile scaffold that enables the creation of multiple classes of immunotherapeutic compounds: Class I: Multi-Functional Immune Cell Stimulators; Class II: Second-Generation Immune Checkpoint Inhibitors; Class III: Multi-Specific Targeting Fusions and Enhanced Immune Cell Engagers. These novel immunotherapeutics are being developed for treatment of a wide range of disease indications, including oncology, autoimmune diseases, and improving quality of life conditions. The Company has constructed over 50 molecules using the TRBC platform. HCW9302 is the lead product candidate for the Company's clinical development program for autoimmune diseases and other proinflammatory conditions. The Company expects to dose the first patient in a Company-sponsored, multi-center Phase 1 clinical trial (NCT07049328) to evaluate HCW9302 in an autoimmune disease in the fourth quarter of 2025. The IND-enabling process is underway for three TRBC-based molecules which were selected as the lead product candidates for other clinical development programs in cancer and age-related diseases based on promising preclinical data. The Company has two licensing programs in which it has licensed exclusive rights for some of its proprietary molecules.

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 Company’s ability to develop new immunotherapeutic treatments for non-oncology or oncology indications; timing of initiation of studies for age-related and autoimmune diseases; the Company’s ability to continue as a going concern and that after considering the elements of the Company’s financing plan that were probable to occur within a year of the date of issuance, the Company concluded that substantial doubt was not alleviated in its going concern analysis; the Company’s cash runway; the Company’s expectations regarding future purchases of licensed molecules by Wugen; the Company’s ability to license its preclinical molecule(s); the initiation of patient enrollment for a clinical trial to evaluate HCW9302; the actual success and potency of the Company’s TCE-based TRBC fusion molecules; the ability of the Company’s TCE’s to target cancer antigens, activate effector T cells, and reduce immunosuppression in the tumor microenvironment;; effectiveness of the Company’s TCEs in treatment of solid tumors and pancreatic cancers; the actual success and potency of pembrolizumab-based TRBC fusion molecules; the ability of HCW11-040 to expand TPEX cells more effectively and expand and activate PBMCs more effectively; the Company’s future capital-raising plans and ability to continue with clinical development efforts until they are achieved, if at all; and Company’s ability to pay legal fees incurred in connection with the arbitration with ImmunityBio and its affiliates. 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 28, 2025 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.
Unaudited Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2025	2024	2025
Revenues:				
Revenues	$ 426,423	$ 15,606	$ 2,171,988	$ 27,222
Cost of revenues	(341,138)	(12,485)	(1,291,546)	(21,777)
Net revenues	85,285	3,121	880,442	5,445
Operating expenses:				
Research and development	1,186,913	1,404,247	5,339,383	4,109,782
General and administrative	1,633,457	1,884,994	4,788,558	6,187,296
Legal expenses (recoveries), net	949,455	6,006	15,761,531	(1,590,945)
Nonoperating loss	—	—	1,300,000	—
Total operating expenses	3,769,825	3,295,247	27,189,472	8,706,133
Loss from operations	(3,684,540)	(3,292,126)	(26,309,030)	(8,700,688)
Interest expense	(229,058)	(127,070)	(393,908)	(632,923)
Change in fair value of investment and contingent liability, net	—	(966,284)	—	782,404
Loss on sale of put shares	—	(182,146)	—	(182,146)
Other income, net	11,310	13,290	52,397	54,412
Net loss	$ (3,902,288)	$ (4,554,336)	$ (26,650,541)	$ (8,678,941)
Equity dividend to investor	—	—	—	(10,153,799)
Net loss attributable to Common Stockholders	$ (3,902,288)	$ (4,554,336)	$ (26,650,541)	$ (18,832,740)
Net loss per share, basic and diluted	$ (4.13)	$ (2.02)	$ (28.33)	$ (11.34)
Weighted average shares outstanding, basic and diluted	945,585	2,260,068	940,586	1,661,332

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2024	September 30, 2025

		Unaudited
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,674,572	$ 1,096,909
Accounts receivable, net	582,201	30,667
Prepaid expenses	328,181	210,661
Other current assets	113,528	250,340
Total current assets	5,698,482	1,588,577
Investments	1,599,751	1,326,329
Property, plant and equipment, net	22,909,869	22,502,158
Other assets	28,476	28,476
Total assets	$ 30,236,578	$ 25,445,540
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Liabilities		
Current liabilities:		
Accounts payable	$ 22,332,261	$ 18,968,173
Accrued liabilities and other current liabilities	981,940	1,084,602
Short-term debt, net	6,314,684	6,807,431
Total current liabilities	29,628,885	26,860,206
Debt, net	7,377,865	—
Contingent liability - related party	—	692,531
Total liabilities	37,006,750	27,552,737
Commitments and contingencies (Note 11)		
Stockholders' deficit:		
Common stock:		
Common, $0.0001 par value; 250,000,000 shares authorized and 1,113,532 shares issued at December 31, 2024; 250,000,000 shares authorized and 2,621,607 shares issued at September 30, 2025	111	262
Additional paid-in capital	93,785,854	107,127,619
Accumulated deficit	(100,556,137)	(109,235,078)
Total stockholders' deficit	(6,770,172)	(2,107,197)
Total liabilities and stockholders' deficit	$ 30,236,578	$ 25,445,540