HCW Biologics Reports First Quarter 2025 Business Highlights and Financial Results

May 15, 2025

MIRAMAR, Fla., May 15, 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 health span by disrupting the link between inflammation and age-related diseases, today reported financial results and recent business highlights for its first quarter ended March 31, 2025.

On May 15, 2025, the Company closed an equity offering with gross proceeds of $5.0 million with a single institutional investor. Dr. Hing Wong, Founder and CEO, stated, “We are pleased to have completed a successful $5.0 million equity offering in a difficult market without using a highly structured deal. This funding will be used to open clinical sites for our Phase 1 clinical trial to evaluate HCW9302 in an autoimmune disorder.” Dr. Wong continued, “Our new round of financing will provide funding for critical studies to complete the research package for our business development campaign to identify a licensing partner to commercialize our Immune-Cell Engagers, including T-Cell Engagers, which we created using our TRBC drug discovery and development platform.”

Dr. Wong explained the Company’s financing strategy, stating, “We have over 50 compounds that we have created and own. We are continually assessing our portfolio of molecules to identify strong candidates to develop and commercialize through licensing or other business development transactions. We plan to ramp up our business development efforts in the second half of 2025. One of our compounds that is ready to commercialize is HCW9206, a clinical-stage molecule. It is a promising revolutionary reagent to replace anti-CD3/anti-CD28/IL-2-based approaches to streamline and lower the costs of CAR-T manufacturing. Equally important, we believe that HCW9206 can improve the functional activities and persistence of CAR-Ts following adoptive transfer, a goal that has not been achieved for the last decade.”

Business Highlights

Business Development Transactions

- On May 13, 2025, the Company delivered its technology report to WY Biotech in accordance with the terms of the WY Biotech exclusive worldwide licensing agreement to use and apply HCW11-006 for *in vivo* applications. HCW11-006 is a preclinical drug built with our second-generation discovery and development platform -- the TRBC platform. WY Biotech has 30-days due diligence to study this report, after which the Company expects to recognize revenue for a $7.0 million upfront licensing fee.

Financing Transactions

- On May 15, 2025, the Company completed a $5.0 million offering of an aggregate of 671,140 units at a purchase price of $7.45 per unit priced at-the-market under Nasdaq rules. Each unit consisted of one share of Common Stock or one Pre-Funded Warrants to purchase one share of Common Stock, with two warrants, each of which can be exercised for one share of Common Stock for $7.45 per share. In addition, the Company entered into a privately negotiated agreement with the holder of certain existing outstanding warrants to purchase up to 167,925 shares of common stock (the “Existing Warrants”) to reduce the exercise price of such Existing Warrants from $41.20 per share to $7.45 per share.
- On May 13, 2025, the Company received a compliance letter from the Nasdaq Panel to confirm that the Company has regained compliance with the bid price requirement in Listing Rule 5550(a)(2), the public float requirement in Listing Rule 5550(a)(4), and the market value of publicly held shares requirement in Listing Rule 5550(a)(5), as required by the Nasdaq Panel decision of April 8, 2025, as amended. The Company remains subject to the remaining terms of the Panel’s April 8, 2025, decision to provide an extension to the compliance period for other Listing Rules. The Company must be in compliance with all Listing Rules by June 16, 2025.

Clinical Development Results

- On January 28, 2025, the Company received clearance of its IND from the FDA to initiate a first-in-human Phase 1 dose escalation clinical trial to evaluate one of its lead drug candidates, HCW9302, in patients with moderate-to-severe alopecia areata, a common autoimmune disease in humans that currently has no curative FDA approved treatments. This will be a multi-site, Company-sponsored trial that is expected to be initiated in the third quarter of 2025.
- The Company is launching the commercialization of its clinical-stage molecule, HCW9206. Positive results of studies presented by the Company’s research collaborator Dr. Harris Goldstein’s laboratory at the Albert Einstein College of

Medicine, Bronx, New York, at the 2025 Annual Meeting of American Association of Immunologists (AAI 2025), Honolulu, HI. The results of these studies represent an alternative novel strategy for CAR-T cell production with the advantage of generating a large population of CAR-Ts with a stem cell-like memory T cell phenotype, which should enhance the persistence of CAR-Ts in patients. We believe that this strategy will likely improve long-term survival of disease-specific CAR-Ts following adoptive transfer and enable sustained suppression of malignancies, chronic infections and autoimmune diseases, and lower the cost of CAR-T manufacturing. Also, we believe that it provides the Company with an in-road opportunity to participate in the development of "in-vivo CAR-T manufacturing technology," a highly promising emergent field.

First Quarter 2025 Financial Results

- **Revenues:** Revenues for the first quarters ended March 31, 2024 and 2025 were $1.1 million and $5,065, respectively. Revenues in both periods were derived exclusively from the sale of licensed molecules to the Company's licensee, Wugen. The licensed molecules are one of the components used by Wugen in manufacturing their immunotherapeutic products.
- **Research and development (R&D) expenses:** R&D expenses for the first quarters ended March 31, 2024 and 2025 were $2.1 million and $1.5 million, respectively, a decrease of $644,573, or 30%. R&D expenses were comparatively lower in the reporting period of the first quarter of 2025 primarily due to a decline in manufacturing and material and preclinical expenses, but all expense categories were comparatively lower in the first quarter of 2025 when compared to the first quarter of 2024.
- **General and administrative (G&A) expenses:** G&A expenses for the first quarters ended March 31, 2024 and 2025 were $1.6 million and $2.2 million, respectively, an increase of $661,505, or 42%. The increase was primarily due to the waiver of performance bonuses of $293,159 in the aggregate in the first quarter of 2024, which were earned by officers of the Company in prior periods. Expenses increased by $273,059 as a result of accretion of a fixed bonus that will be due if the Secured Notes are repaid on the Maturity Date. Subsequent to the end of the first quarter of 2025, $6.6 million of the outstanding principal for these Secured Notes elected to convert to equity and a portion of the Company's shares in Wugen common stock. Other increases in expenses were related to insurance costs and professional services, such as auditing services as well as tax and accounting advisors.
- **Legal expenses:** Legal expenses, net represent the legal fees that the Company incurred for an Arbitration. On July 13, 2024, the parties entered into a Settlement Agreement and General Release, and the Arbitration and related Complaint were dismissed on December 24, 2024. In the first quarter of 2024, while the Company was preparing for the hearings which took place in May 2024, the Company incurred $4.4 million of legal fees. 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 those legal fees.
- **Net loss:** Net loss for the first quarters ended March 31, 2024 and 2025 was $7.5 million and $2.2 million, respectively.

Financial Guidance

As of March 31, 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 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 some 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 all of the elements of our plan.

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 drug 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 possibly extend longevity. Chronic inflammation, including inflammaging, is believed to be a significant contributing factor to the cause for senescence-associated diseases and conditions that diminish healthspan, including many types of cancer, autoimmune diseases, and neurodegenerative diseases, as well as 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 such a versatile scaffold that it 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 can be used to treat 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, including HCW11-002, HCW11-018 and HCW11-027. Further preclinical evaluation studies are currently being conducted for these three molecules the Company has selected based on promising early data. The Company has two licensing programs in which it has licensed exclusive 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 Company’s ability to develop new immunotherapeutic treatments for non-oncology or oncology indications; timing of initiation of studies for age-related 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 molecules; the initiation of patient enrollment for a clinical trial to evaluate HCW9302; 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

	For the Three Months Ended March 31,	
	2024	**2025**
Revenues:		
Revenues	$ 1,126,712	$ 5,065
Cost of revenues	(511,965)	(4,052)
Net revenues	614,747	1,013
Operating expenses:		
Research and development	2,123,284	1,478,711
General and administrative	1,566,092	2,227,597
Legal expenses, net	4,419,034	(1,739,493)
Total operating expenses	8,108,410	1,966,815
Loss from operations	(7,493,663)	(1,965,802)
Interest expense	—	(255,822)
Other income, net	25,602	24,749
Net loss	$ (7,468,061)	$ (2,196,875)
Net loss per share, basic and diluted	$ (0.20)	$ (0.05)
Weighted average shares outstanding, basic and diluted	37,223,588	44,675,656

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2024	March 31, 2025 Unaudited
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,674,572	$ 1,107,613
Accounts receivable, net	582,201	87,493
Prepaid expenses	328,181	256,291
Other current assets	113,528	443,311
Total current assets	5,698,482	1,894,708
Investments	1,599,751	1,599,751
Property, plant and equipment, net	22,909,869	22,762,471
Other assets	28,476	28,476
Total assets	$ 30,236,578	$ 26,285,406

LIABILITIES AND STOCKHOLDERS' DEFICIT		
Liabilities		
Current liabilities:		
Accounts payable	$ 22,332,261	$ 19,734,057
Accrued liabilities and other current liabilities	981,940	1,173,695
Short-term debt, net	6,314,684	6,234,338
Total current liabilities	29,628,885	27,142,090
Debt, net	7,377,865	7,705,364
Total liabilities	37,006,750	34,847,454
Commitments and contingencies		
Stockholders' deficit:		
Common stock:		
Common, $0.0001 par value; 250,000,000 shares authorized and 44,541,295 shares issued at December 31, 2024; 250,000,000 shares authorized and 44,934,120 shares issued at March 31, 2025	4,454	4,493
Additional paid-in capital	93,781,511	94,186,471
Accumulated deficit	(100,556,137)	(102,753,012)
Total stockholders' deficit	(6,770,172)	(8,562,048)
Total liabilities and stockholders' deficit	$ 30,236,578	$ 26,285,406