



HCW Biologics Reports Fourth Quarter and Fiscal Year 2024 Business Highlights and Financial Results

March 28, 2025

MIRAMAR, Fla., March 28, 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 fourth quarter and fiscal year ended December 31, 2024.

Dr. Hing Wong, Founder and CEO, stated, "We are more passionate than ever about our desire to create breakthrough immunotherapeutic treatments for diseases with no known cures, especially pancreatic, ovarian cancer and other age-related diseases. We have received clearance to begin clinical trials in alopecia areata, our first-quality-of-life indication, with one of our lead molecules, HCW9302. In non-human primate studies, HCW9302 is well tolerated at the dose level of effectively expanding regulatory T ("T_{reg}") cells. Our surrogate efficacious marker for HCW9302 in treated patients is the expansion of T_{reg} cells after subcutaneous administration."

Further, Dr. Wong provided insights to the Company's preclinical programs, adding, "Our preclinical programs are also promising. In the fourth quarter of 2024, the Company revealed its new drug discovery and development platform, with a novel scaffolding or "backbone" of proteins called T-cell Receptor β Chain constant region ("TRBC"). The TRBC drug discovery and development platform leverages the Company's in-depth knowledge of T cell and natural killer ("NK") cell immunology. The Company has constructed 50 proprietary compounds with the TRBC platform for the treatment of hematologic and solid tumors, virally infected cells, and cellular senescence diseases associated with aging."

Dr. Wong explained, "Our expanded portfolio now includes constructs with immune-cell engagers targeting cell-surface antigens associated with diseased cells and multifunctional immunotherapeutic fusions which improve the performance of immune checkpoint inhibitors. They exhibit remarkably target-specific anti-tumor activity and tolerability in relevant animal models." He continued, "We believe that some of our TRBC-based molecules could be a game-changer for Cell and Gene Based Therapies ("CGTs") by significantly reducing cost and improving the clinical efficacy of engineered effector cells for CGT. Based on preclinical studies, it appears they also support the rapidly developing "in-vivo" CAR-T manufacturing approach for CGT. We are excited to share the data in future scientific publications and invited presentations. We believe that we are uniquely positioned for a strong clinical development pipeline through our own programs and with corporate partnerships."

Business Highlights

Business Development Transactions

- The Company's clinical development strategy is to select certain proprietary molecules for development through out-licensing arrangements and other business development transactions. The Company continually assesses its portfolio of molecules in order to identify potential business development opportunities.
- On November 17, 2024, the Company entered an exclusive worldwide licensing agreement with WY Biotech Co. Ltd. ("WY Biotech"), which was amended in 2025. Under the amended agreement, the Company expects to receive \$7.0 million in June 2025. The WY Biotech license agreement grants WY Biotech the exclusive, world-wide license to use and apply HCW11-006 for *in vivo* applications. HCW11-006 is a preclinical drug. Under the terms of the license agreement, the Company has opt-in rights to reclaim the Americas market, including United States, Canada, Central America, and South America, at no cost which may be exercised after WY Biotech completes a Phase 1 clinical trial.
- The next major business development program will focus on Immune-Cell Engagers, including T-Cell Engagers. In light of recent transactions demonstrating the strong interest in this class of therapeutics by larger pharmaceutical with the necessary clinical development expertise, the Company intends to develop these molecules through corporate partnering and out-licensing arrangements.

Financing Transactions

- In 2024, the Company raised \$16.3 million:
 - On February 20, 2024, it raised \$2.5 million in a private placement of common stock with officers and directors.
 - In multiple closings throughout 2024, it raised \$6.9 million in Senior Notes, which are secured by the Company's shares of Wugen common stock. The Company received shares of Wugen stock as an upfront licensing fee for the Wugen exclusive worldwide license for some of the Company's proprietary molecules.
 - On November 18, 2024, the Company entered a \$6.9 million securities purchase agreement with an institutional

investor, involving a registered direct offering and a concurrent private placement of common stock and warrants.

- On February 20, 2025, the Company entered into an Equity Purchase Agreement with Square Gate Capital Master Fund, LLC - Series 4 ("Square Gate"), pursuant to which the Company will have the right, but not the obligation, to sell to Square Gate, and Square Gate will have the obligation to purchase from the Company, up to \$20,000,000 (with a potential increase of an additional \$20,000,000) worth of the Company's shares of common stock, at the Company's sole discretion, over the next 36 months, subject to certain conditions precedent and other limitations.

Compliance with Nasdaq Listing Rules

- During 2024, the Company received three deficiency notices from the Listing Staff of The Nasdaq Stock Market (the "Exchange") related to the Company's stock price of trading shares and the market value of the Company. On March 3, 2025, the Nasdaq Hearings Panel (the "Panel") granted the Company an extension in which to regain compliance with all Nasdaq continued listing rules. As a result of the extension, the Panel granted the Company's request for continued listing on the Exchange, provided that the Company demonstrates compliance with the Bid Price Rule by April 28, 2025, and all other Exchange continued listing rules by June 15, 2025.
- On March 31, 2025, the Company will hold a Special Meeting of the Stockholders to obtain stockholder approval for three proposals critical for the success of the compliance plan presented to the Panel, including a reverse stock split, use of the full line of the Equity Line of Credit, and approval of the terms to convert the Senior Notes issued in 2024 into equity.

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.
- As of December 31, 2024, the Company was required to close the Phase 2 clinical study to evaluate HCW9218 in combination with neoadjuvant chemotherapy in ovarian cancer sponsored by the University of Pittsburgh Medical Center, as required under the Settlement Agreement, due to lack of enrollment.

Financial Results

- **Revenues:** Revenues for the fourth quarters ended December 31, 2023 and 2024 were \$1.3 million and \$394,000, respectively. Revenues for the years ended December 31, 2023 and 2024 were \$2.8 million and \$2.6 million, 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 fourth quarters ended December 31, 2023 and 2024 were \$2.1 million and \$1.0 million, respectively, a decrease of \$1.1 million, or 51%. R&D expenses for the years ended December 31, 2023 and 2024 were \$7.7 million and \$6.4 million, respectively, a decrease of \$1.3 million, or 17%. R&D expenses were comparatively higher in the reporting periods of 2023 because there were two ongoing clinical trials to evaluate HCW9218 in cancer indications, and IND-enabling studies required for the IND application for HCW9302, including toxicology studies. For the year ended December 31, 2024, the decrease in R&D expenses compared to the comparable period in 2023 was partially offset by an increase in manufacturing costs for replenishing supply of the high-expressing cell line of HCW9101.
- **General and administrative (G&A) expenses:** G&A expenses for the quarters ended December 31, 2023 and 2024 were \$1.7 million and \$2.0 million, respectively, an increase of \$367,320, or 22%. G&A expenses for the years ended December 31, 2023 and 2024 were \$6.8 million and \$6.8 million, respectively, an increase of \$60,081, or 1%. Changes in G&A expenses reflect cost cutting measures effected by the Company in the second quarter of 2024, offset by increases in professional fees, facilities and office expenses, and financing expenses.
- **Legal expenses:** Legal expenses for the quarter ended December 31, 2023 and 2024 were \$2.0 million and \$148,949, respectively, a decrease of \$1.8 million, or 92%. Legal expenses for the twelve months ended December 31, 2023 and 2024 were \$6.6 million and \$15.9 million, respectively, an increase of \$9.3 million, or 142%. The increase in legal expenses related to preparation of testimony and evidence for the hearing and the hearing itself in connection to the Arbitration with ImmunityBio and its affiliates. 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. 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.
- **Reserve for credit losses and other expenses:** In the year ended December 31, 2023, the Company recognized a reserve for credit losses related to a \$5.3 million interest reserve deposit that was not refunded as required by the lender after the Company terminated their credit agreement. In the year ended December 31, 2024, the Company recognized a \$1.3 million loss resulting from the misdirection of funds held in Company accounts to a fraudulent account controlled by a third party.
- **Net loss:** Net loss for the fourth quarters ended December 31, 2023 and 2024 was \$10.7 million and \$3.4 million, respectively. Net loss for the years ended December 31, 2023 and 2024 was \$25.0 million and \$30.0 million, respectively.

including legal fees incurred in connection with the Arbitration discussed above.

Financial Guidance

As of December 31, 2024, 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. After launching a multi-step financing plan in the third quarter of 2024, we have completed financing transactions. We have additional capital-raising activities planned for the first half of 2025, for which Maxim Group LLC will act as our Placement Agent. If the Company is not successful in raising additional capital through these activities, management may need to revise its business plan and reduce costs.

About HCW Biologics

HCW Biologics is a clinical-stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation, and age-related diseases, such as cancer, cardiovascular, diabetes, neurodegenerative, and autoimmune diseases, as well as other inflammatory conditions. The Company has combined a deep understanding of disease-related immunology with its expertise in advanced protein engineering to develop two drug discovery platforms, each with a novel backbone which is used to generate designer, novel multi-functional fusion molecules with immunotherapeutic properties. The Company's legacy drug discovery platform is its TOBI™ (Tissue factor-Based fuslon) discovery platform, which has a Tissue-Factor based backbone. It was used to create HCW Biologics' molecules: HCW9218, HCW9302, HCW9206 and HCW9201. HCW9302 is a clinical-stage molecule, cleared by the FDA to be evaluated in patients with an autoimmune disorder. The Company's second generation drug discovery and development platform, called the T-cell Receptor β Chain constant region ("TRBC") platform, uses a unique protein-based backbone. Immunotherapeutics created with the Company's two distinct drug discovery platforms have different characteristics and mechanisms of action, expanding the various pathways for treating senescence-associated disorders.

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 finalize the license of a preclinical molecule; the initiation of patient enrollment for 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.

Company Contact:

Rebecca Byam
CFO
HCW Biologics Inc.
rebeccabyam@hcwbiologics.com

HCW Biologics Inc. Statements of Operations

	For the Three Months Ended December 31,		Years Ended December 31,	
	2023	2024	2023	2024
	Unaudited		Audited	
Revenues:				
Revenues	\$ 1,324,003	\$ 394,804	\$ 2,841,794	\$ 2,566,792
Cost of revenues	(1,071,357)	(315,843)	(2,281,434)	(1,607,389)
Net revenues	<u>252,646</u>	<u>78,961</u>	<u>560,360</u>	<u>959,403</u>
Operating expenses:				
Research and development	2,136,397	1,049,611	7,676,316	6,388,994
General and administrative	1,672,840	2,040,160	6,779,515	6,839,596
Legal expenses	1,961,599	148,949	6,571,689	15,910,480
Reserve for credit losses and other expenses	5,250,000	—	5,250,000	1,300,000
Total operating expenses	<u>11,020,836</u>	<u>3,238,720</u>	<u>26,277,520</u>	<u>30,439,070</u>
Loss from operations	(10,768,190)	(3,159,759)	(25,717,160)	(29,479,667)

Interest expense	—	(248,107)	(283,042)	(631,137)
Other income, net	87,660	34,593	1,005,925	86,990
Net loss	<u>\$ (10,680,530)</u>	<u>\$ (3,373,273)</u>	<u>\$ (24,994,277)</u>	<u>\$ (30,023,814)</u>
Net loss per share, basic and diluted	\$ (0.30)	\$ (0.08)	\$ (0.70)	\$ (0.77)
Weighted average shares outstanding, basic and diluted	35,996,415	42,301,694	35,929,446	38,793,018

HCW Biologics Inc.
Audited Balance Sheets

	<u>December 31,</u> <u>2023</u>	<u>December 31,</u> <u>2024</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,595,101	\$ 4,674,572
Accounts receivable, net	1,535,757	582,201
Prepaid expenses	1,042,413	328,181
Other current assets	230,916	113,528
Total current assets	<u>6,404,187</u>	<u>5,698,482</u>
Investments	1,599,751	1,599,751
Property, plant and equipment, net	20,453,184	22,909,869
Other assets	56,538	28,476
Total assets	<u>\$ 28,513,660</u>	<u>\$ 30,236,578</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Liabilities		
Current liabilities:		
Accounts payable	\$ 6,167,223	\$ 22,332,261
Accrued liabilities and other current liabilities	2,580,402	981,940
Short-term debt, net	—	6,314,684
Total current liabilities	<u>8,747,625</u>	<u>29,628,885</u>
Debt, net	<u>6,304,318</u>	<u>7,377,865</u>
Total liabilities	15,051,943	37,006,750
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock:		
Common, \$0.0001 par value; 250,000,000 shares authorized and 36,025,104 shares issued at December 31, 2023; 250,000,000 shares authorized and 44,541,295 shares issued at December 31, 2024	3,603	4,454
Additional paid-in capital	83,990,437	93,781,511
Accumulated deficit	<u>(70,532,323)</u>	<u>(100,556,137)</u>
Total stockholders' equity (deficit)	<u>13,461,717</u>	<u>(6,770,172)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 28,513,660</u>	<u>\$ 30,236,578</u>
