HCW Biologics Reports Second Quarter 2024 Financial Results and Business Highlights

August 14, 2024

MIRAMAR, Fla., Aug. 14, 2024 (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 age-related diseases, today reported financial results and recent business highlights for its second quarter ended June 30, 2024.

Dr. Hing C. Wong, Founder and CEO of HCW Biologics, stated, “We reached a critical milestone recently that has profound implications for the future of our Company -- we successfully reached a settlement agreement for an arbitration that created an overhang that hampered our progress for nearly two years. We wasted no time in launching our multi-faceted financing plan, including a significant equity offering and a reinvigorated out-licensing program. We have a bright future ahead, as we have emerged with the TOBI™ platform and a strong portfolio of TOBI™-based molecules, as well as several development-stage ideas that we consider “next generation” immunotherapeutics which leverage what we learned from the human data readouts from the initial phases of our clinical trials. We remain committed to developing immunotherapeutic drugs that target the reduction of senescent cells and the proinflammatory factors they secrete. Our focus continues to be on senescence-associated disorders, most typical in age-related diseases, including cancer. We are also excited to bring HCW9302 to the clinic in the very near future to evaluate this drug in the treatment of autoimmune diseases by expanding regulatory T cells.”

Business Highlights

- On July 13, 2024, the Company entered into a confidential Settlement Agreement and Release (“Settlement Agreement”) to resolve arbitration brought against the Company and Dr. Hing C. Wong, the Company’s Founder and Chief Executive Officer. The Settlement Agreement includes mutual general releases by and among all the parties. There were no monetary payments or damages paid by any party under the Settlement Agreement. See “Financial Guidance.”
- Going forward, the Company retains ownership and control of the TOBI™ platform and TOBI™-based molecules, with no restrictions under the Settlement Agreement on its ability to use the TOBI™ platform for protein-fusion molecules for non-oncology indications. The Company may pursue the clinical development of treatments for cancer indications based on HCW9302, HCW9206 and HCW9201. Further, HCW Biologics retains ownership of the Wugen license and shares of Wugen common stock transferred to the Company as the upfront licensing fee from Wugen for granting the Wugen license.
- A new financing plan was launched including an equity offering, which the Company intends to close before the end of 2024. Financing plans also include out-licensing non-core assets, and there are several discussions underway with potential licensing partners.

Second Quarter 2024 Financial Results

- **Revenues:** Revenues for the quarter ended June 30, 2023 and 2024 were $622,807 and $618,854, respectively. Revenues for the six months ended June 30, 2023 and 2024 were $664,690 and $1.7 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 inputs for manufacturing Wugen’s products.
- **Research and development (R&D) expenses:** R&D expenses for the quarter ended June 30, 2023 and 2024 were $1.6 million and $2.0 million, respectively, an increase of $412,520, or 26%. R&D expenses for the six months ended June 30, 2023 and 2024 were $3.9 million and $4.2 million, respectively, an increase of $279,991, or 7%. Manufacturing costs increased in three- and six-month periods ended June 30, 2024 because the Company was replenishing its supply of a high-expressing cell line of HCW9101. Preclinical expenses declined in the three- and six-month periods ended June 30, 2024 due to a change in the types of activities being performed in connection with IND-enabling activities to prepare an IND application to obtain permission from the FDA to evaluate HCW9302 in an autoimmune indication. In the three- and six-month periods ended June 30, 2023, preclinical costs were incurred for setup costs for toxicology studies and other IND-enabling studies. In the three- and six-month periods ended June 30, 2024, costs were incurred for supplemental research studies. Clinical trial expenses were incurred in the three- and six-month period ended June 30, 2023 related to two clinical studies to evaluate HCW9218 in chemo-refractory / chemo-resistant solid tumors. Clinical trial expenses declined in the three- and six-month periods ended June 30, 2024 because these trials were fully enrolled in the first quarter of 2024.
- **General and administrative (G&A) expenses:** G&A expenses for the quarter ended June 30, 2023 and 2024 were $1.6

million and $1.6 million, respectively, an increase of $6,332, or 0%. The increase was primarily attributable to an increase in fees for auditing and tax advisory services, offset by a reduction in salaries and benefits arising from the Company's cost-cutting measures. G&A expenses for the six months ended June 30, 2023 and 2024 were $3.6 million and $3.2 million, a decrease of $436,454, or 12%. The decrease was a result of cost-cutting measures and a decrease in legal fees incurred in procuring patents and insurance-related costs, partially offset by an increase in financing costs.

- **Legal Expenses:** Legal expenses for the quarter ended June 30, 2023 and 2024 were $1.4 million and $10.4 million, respectively, an increase of $9.0 million, or 629%. Legal expenses for the six months ended June 30, 2023 and 2024 were $2.5 million and $14.8 million, an increase of $12.3 million, or 484%. The increase in legal expenses is related to the Altor/NantCell matter. See further discussion of the Altor/NantCell arbitration in "Financial Guidance."
- **Net loss:** Net loss for the quarter ended June 30, 2023 and 2024 was $4.3 million and $15.3 million, respectively, an increase of $11.0 million, or 255%. Net loss for the six months ended June 30, 2023 and 2024 was $9.4 million and $22.7 million, respectively, an increase of $13.4 million, or 143%.

Financial Guidance

The Company has raised $8.0 million to date in 2024, through a $2.5 million private placement of common stock to officers and directors and $5.5 million issuance of Secured Notes secured by the Company's Wugen shares. The Company is authorized to raise up to $10.0 million in Secured Notes and intends to have the Secured Notes offering fully subscribed.

As of June 30, 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 condensed interim financial statements, without additional funding or financial support. 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.

As reported in the Company's Form 8-K filed on July 18, 2024, as of July 13, 2024, the Company and Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, entered into the Settlement Agreement, with Altor BioScience, LLC ("Altor"), NantCell, Inc. ("NantCell"), and ImmunityBio, Inc. (the parent of Altor and NantCell, together with Altor and NantCell, "ImmunityBio"), to resolve the previously disclosed arbitration before JAMS brought by Altor and NantCell (the "Arbitration") as well as a complaint Altor filed against the Company in the Chancery Court of the State of Delaware for the contribution of legal fees and expenses advanced to Dr. Wong ("Complaint"). The parties entered into the Settlement Agreement to avoid the costs, disruption and distraction of further litigation. Under the terms of the Settlement Agreement, no party will make monetary payments to any other party or person and each party will bear its own expenses. The Company is completing procedures required to be in compliance with the terms of the Settlement Agreement. The Settlement Agreement provides that, upon completion of these procedures, the parties will stipulate that the Arbitration and Complaint should be dismissed. The Company retains rights to develop immunotherapeutic treatments based on TOBI™-based molecules as well as the TOBI™ platform, in addition to the Wugen license and Wugen equity interest. The Company reported a balance of $10.0 million for legal fees incurred but not yet paid that were included within Accounts payable and an accrual of $4.8 million for accrued legal fees within Accrued liabilities and other current liabilities in the accompany condensed balance sheet as of June 30, 2024. In order not to overwhelm the Company's resources, a reasonable payment plan will be required. The Company is engaged in discussions with the law firms involved with this matter.

As reported on the Company's Form 8-K filed on August 12, 2024, the Company received written notices from the Listing Qualifications Staff ("Staff") of the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it is not in compliance with Nasdaq Listing Rules. The notifications from Nasdaq do not impact the listing of the Company's common stock at this time. The Company received a notice that it was not in compliance with Nasdaq Listing Rules for the $50.0 million market value listed securities requirement as of June 17, 2024; the minimum bid price as of August 6, 2024; and the $15.0 million market value of publicly held shares requirement as of August 8, 2024. The Company has 180 days from the respective date of notice to address each deficiency. While the Company is exercising diligent efforts to maintain the listing of its common stock on Nasdaq, there can be no assurance that the Company will be able to regain or maintain compliance with the applicable continued listing standards set forth in the Nasdaq Listing Rules.

About HCW Biologics:

HCW Biologics is a clinical-stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen healthspan by disrupting the link between chronic, low-grade inflammation, and age-related diseases, such as cancer, cardiovascular diseases, diabetes, neurodegenerative diseases, autoimmune diseases, as well as other conditions such as long-haul COVID-19. The Company has combined a deep understanding of disease-related immunology with its expertise in advanced protein engineering to develop the TOBI™ (Tissue factOr-Based fusIon) discovery platform. The Company uses its TOBI™ discovery platform to generate designer, novel multi-functional fusion molecules with immunotherapeutic properties. The invention of HCW Biologics' lead molecules, HCW9218, HCW9302, HCW9206 and HCW9201, was made via the proprietary TOBI™ discovery platform. The University of Pittsburgh Medical Center has agreed to include HCW9218 in an Investigator-sponsored Phase 2 clinical trial to evaluate HCW9218 in patients with metastatic, advanced stage ovarian cancer in combination with neoadjuvant chemotherapy (NCT05145569).

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; the Company's cash runway; the Company's expectations regarding future purchases of licensed molecules by Wugen; 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 Altor/NantCell arbitration. 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/A filed with the United States Securities and Exchange Commission (the “SEC”) on May 15, 2024, 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
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2024	2023	2024
Revenues:				
Revenues	$ 622,807	$ 618,854	$ 664,690	$ 1,745,566
Cost of revenues	(502,402)	(438,443)	(531,752)	(950,408)
Total revenues	120,405	180,411	132,938	795,158
Operating expenses:				
Research and development	1,616,666	2,029,186	3,872,479	4,152,470
General and administrative	1,587,861	1,594,193	3,596,739	3,160,285
Legal expenses	1,426,399	10,393,042	2,534,811	14,812,076
Nonoperating loss	—	1,300,000	—	1,300,000
Total operating expenses	4,630,926	15,316,421	10,004,029	23,424,831
Loss from operations	(4,510,521)	(15,136,010)	(9,871,091)	(22,629,673)
Interest expense	(95,514)	(159,666)	(188,951)	(159,666)
Other (expense) income, net	301,615	15,485	684,936	41,086
Net loss	$ (4,304,420)	$ (15,280,191)	$ (9,375,106)	$(22,748,253)

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2023	June 30, 2024 Unaudited
ASSETS		
Current assets:		
Cash and cash equivalents	$ 95,101	$ 1,161,314
Accounts receivable, net	1,535,757	654,973
Prepaid expenses	1,042,413	404,918
Other current assets	230,916	164,607
Total current assets	6,404,187	2,385,812
Investments	1,599,751	1,599,751
Property, plant and equipment, net	20,453,184	22,806,052
Other assets	56,538	28,476
Total assets	$ 28,513,660	$ 26,820,091
LIABILITIES AND STOCKHOLDERS’ EQUITY (DEFICIT)		
Liabilities		
Current liabilities:		
Accounts payable	$ 6,167,223	$ 16,877,463
Accrued liabilities and other current liabilities	2,580,402	6,341,676
Total current liabilities	8,747,625	23,219,139
Debt, net	6,304,318	9,900,721
Total liabilities	15,051,943	33,119,860
Commitments and contingencies (Note 8)		
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 37,823,394 shares issued at June 30, 2024	3,603	3,782

Additional paid-in capital	83,990,437	86,977,024
Accumulated deficit	(70,532,323)	(93,280,575)
Total stockholders' equity (deficit)	13,461,717	(6,299,769)
Total liabilities and stockholders' equity (deficit)	$ 28,513,660	$ 26,820,091