HCW Biologics Reports Second Quarter 2023 Financial Results and Recent Business Highlights

August 11, 2023

MIRAMAR, Fla., Aug. 11, 2023 (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, 2023.

“During the period ended June 30, 2023, we have made significant progress in crystalizing our understanding of the anti-cancer mechanism of action of HCW9218, especially in relation to how it complements immune checkpoint inhibitors ("ICIs"). HCW9218 has a unique mechanism that we believe allows it to turn a ‘cold’ tumor into a ‘hot’ tumor, potentially opening up the possibility of improving the response rate for checkpoint inhibitors which has remained stubbornly low,” stated Dr. Hing C. Wong, Founder and CEO of HCW Biologics.

Dr. Wong continued, “Our excitement about the potential of HCW9218 as a combination therapy with checkpoint inhibitors is fueled by key discoveries made as a result of extensive animal testing in different cold tumor models. First, HCW9218 stimulates and expands progenitor exhausted stem-like T cells and transitory $CD8^+$ effector T cells in the tumor draining lymph nodes followed by trafficking of these cells into the tumors. This opens a pathway for enhancing the anti-tumor activity of checkpoint inhibitors. Secondly, HCW9218 also substantially lowers the TGF-β activity in the tumor microenvironment to lessen immunosuppression. This further boosts the ICI response to block the PD1/PDL1 axis and enhances the anti-tumor activity of HCW9218-activated $CD8^+$ effector T cells.”

Business Highlights:

- In a Phase 1 clinical trial to evaluate HCW9218 in the treatment of chemo-refractory/chemo-resistant solid tumors, sponsored by the Masonic Cancer Center, University of Minnesota, the first patient was dosed in the expansion phase of the trial. There has been no dose-limiting toxicity to date. The Company expects this trial to be completed in the second half of 2023 and intends to disclose human clinical data from this trial and the mechanism of action underlying HCW9218 anti-cancer activities at a major industry conference prior to the end of the year.
- In a Company-sponsored Phase 1b clinical trial to evaluate HCW9218 in the treatment of chemo-refractory/chemo-resistant pancreatic cancer, the trial has completed two dose escalation cohorts and has begun a third, with no dose-limiting toxicity to date. The Company expects this trial to be completed late in 2023 or early 2024, with a human clinical data readout in the first half of 2024.
- On April 21, 2023, the Company entered into a secured Development Line of Credit Agreement with Prime Capital Ventures, LLC, as lender, pursuant to which the Company may borrow up to $26.3 million with a scheduled maturity date of April 20, 2028. In connection with this loan, the Company established a $5.3 million deposit for interest reserve. The Company plans to refinance its existing long-term debt with some of the proceeds from this line of credit. On August 10, 2023 the Company obtained construction permits required to begin the buildout of its new headquarters. This satisfies the final condition precedent to accessing the $26.3 million line of credit.
- On June 13, 2023, the Company was granted U.S. Patent No. 11,672,826 by the United States Patent and Trademark Office which contains methods of use claims directed to administering HCW9218 to treat various forms of cancer, including colorectal cancer, breast cancer, ovarian cancer, hepatocellular carcinoma, gastric cancer, urothelial carcinoma, and melanoma.

Second Quarter 2023 Financial Results:

- **Revenues:** Revenues for the quarter ended June 30, 2022 and 2023 were $454,000 and $622,807, respectively. Revenues for the six months ended June 30, 2022 and 2023 were $3.6 million and $664,690, respectively. Revenues 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. We expect Wugen to limit its purchases in 2023, due primarily to changes in its clinical development program and delays in ramping up its manufacturing process.

- **Research and development (R&D) expenses:** R&D expenses for the quarter ended June 30, 2022 and 2023 were $2.0 million and $1.6 million, respectively, a decrease of $353,216, or 18%. R&D expenses for the six months ended June 30,

2022 and 2023 were $3.8 million and $3.9 million, respectively, an increase of $112,921, or 3%. The change is primarily attributable to a decrease in preclinical expenses and manufacturing costs and an increase in costs associated with clinical trial activities. As of June 30, 2023, the Company anticipates it has the required supplies of its lead molecules, HCW9218 and HCW9302, in place to provide for planned clinical development activities for the next 24 months. Manufacturing costs in 2023 primarily reflect ancillary costs of shipping, storage and insurance. Preclinical costs were incurred to complete IND-enabling activities for HCW9302. In first half of 2023, IND-enabling activities focused on additional research studies required for the Company's IND submission. The Company expects to submit an IND application for permission to conduct a clinical trial to evaluate HCW9302 in an autoimmune disorder by the end of 2023.

- **General and administrative (G&A) expenses:** G&A expenses for the quarter ended June 30, 2022 and 2023 were $1.7 million and $3.0 million, respectively, an increase of $1.3 million, or 76%. G&A expenses for the six months ended June 30, 2022 and 2023 were $3.6 million and $6.1 million, an increase of $2.5 million, or 71%. The increase was primarily attributable to increases in professional fees, which include legal fees associated with legal proceedings brought against the Company by Altor BioScience, LLC and NantCell, Inc., or Altor/NantCell.

- **Net loss:** Net loss for the quarter ended June 30, 2022 and 2023 was $3.5 million and $4.3 million, respectively, an increase of $793,859, or 23%. Net loss for the six months ended June 30, 2022 and 2023 was $5.6 million and $9.4 million, an increase of $3.8 million, or 68%.

Financial Guidance

As of June 30, 2023, the Company held $17.4 million in cash, cash equivalents and U.S. Treasury bills of short duration. In addition, there were prepaid expenses of $6.6 million, including the $5.3 million deposit for interest reserve. The Company funded $3.2 million toward the new lab and manufacturing facilities while awaiting permits to begin construction and activating access to project financing. Funds for this project will be provided from financing in the future. With the current cash, cash equivalents and U.S. Treasury bills on hand, the Company has adequate capital to fund operations and other commitments to Q4 2024.

On April 27, 2023, in connection with the Altor/NantCell matter, the U.S. District Court for the Southern District of Florida (the "Court") approved the parties' stipulation and ordered the parties to arbitration. On May 1, 2023, Altor/NantCell filed a demand against the Company before JAMS. On May 3, 2023, Altor/NantCell dismissed the federal court action without prejudice and the Court ordered the case dismissed without prejudice and closed the case. Altor/NantCell's proceeding against the Company is now proceeding in arbitration before JAMS. Although adverse decisions (or settlements) may occur in arbitration, it is not possible to reasonably estimate the possible loss or range of loss, if any, associated therewith at this time. As such, no accrual for these matters has been recorded within the Company's financial statements. In the year ahead, the Company expects to continue to incur legal expenses on its own behalf in connection with the legal proceedings brought against it by Altor/NantCell. However, legal expenses incurred by Dr. Wong in connection with the arbitration against him that was initiated by Altor/NantCell, are covered through advancement of expenses from Altor/NantCell.

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' two lead molecules, HCW9218 and HCW9302, was made via the TOBI™ discovery platform. The Masonic Cancer Center, University of Minnesota, has initiated a Phase 1 clinical trial to evaluate HCW9218 in chemo-refractory/chemo-resistant solid tumors that have progressed after prior chemotherapies (Clinicaltrials.gov: NCT05322408). The Company is also enrolling patients in a Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in chemo-refractory/chemo-resistant advanced pancreatic cancer (Clinicaltrials.gov: NCT05304936). The Company's lead molecule for its regulatory T cell expansion program, HCW9302, is currently undergoing IND-enabling studies for an autoimmune indication.

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, without limitation, statements regarding completion of Phase 1/1b clinical studies in cancer; potential of HCW9218 to treat other aging-associated diseases beyond cancer; potential of HCW9218 as a combination therapy with checkpoint inhibitors and of HCW9218's mechanism of action; timing of completion and expected data readout for trials; duration of the supply of the Company's lead molecules; and timing and outcome of the Altor/NantCell arbitration and the Company's liability related thereto. 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, 2023, the Form 10-Q filed with the SEC on August 11, 2023, 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

Condensed Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2023	2022	2023
Revenues:				
Revenues	$ 454,000	$ 622,807	$ 3,571,545	$ 664,690
Cost of revenues	(287,200)	(502,402)	(1,615,276)	(531,752)
Net revenues	166,800	120,405	1,956,269	132,938
Operating expenses:				
Research and development	1,969,882	1,616,666	3,759,558	3,872,479
General and administrative	1,707,995	3,014,260	3,588,597	6,131,550
Total operating expenses	3,677,877	4,630,926	7,348,155	10,004,029
Loss from operations	(3,511,077)	(4,510,521)	(5,391,886)	(9,871,091)
Interest expense	—	(95,514)	—	(188,951)
Other (expense) income, net	516	301,615	(175,882)	684,936
Net loss	$ (3,510,561)	$ (4,304,420)	$ (5,567,768)	$ (9,375,106)

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2022	June 30, 2023 Unaudited
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,326,356	$ 7,449,010
Short-term investments	9,735,930	9,959,370
Accounts receivable, net	417,695	707,211
Prepaid expenses	1,394,923	1,356,520
Other current assets	196,015	327,055
Total current assets	34,070,919	19,799,166
Investments	1,599,751	1,599,751
Property, plant and equipment, net	10,804,610	12,623,308
Deposit for interest reserve	—	5,250,000
Other assets	333,875	211,019
Total assets	$ 46,809,155	$ 39,483,244
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	$ 1,226,156	$ 2,116,216
Accrued liabilities and other current liabilities	1,730,325	2,421,682
Total current liabilities	2,956,481	4,537,898
Debt, net	6,409,893	6,359,704
Other liabilities	14,275	—
Total liabilities	9,380,649	10,897,602
Commitments and contingencies		
Stockholders' equity:		
Common stock:		
Common, $0.0001 par value; 250,000,000 shares authorized and 35,876,440 shares issued at December 31, 2022; 250,000,000 shares authorized and 35,926,721 shares issued at June 30, 2023	3,588	3,593
Additional paid-in capital	82,962,964	83,495,201
Accumulated deficit	(45,538,046)	(54,913,152)
Total stockholders' equity	37,428,506	28,585,642
Total liabilities and stockholders' equity	$ 46,809,155	$ 39,483,244