HCW Biologics Reports Third Quarter 2023 Financial Results And Recent Business Highlights

November 14, 2023

MIRAMAR, Fla., Nov. 14, 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 third quarter ended September 30, 2023.

A human data readout from the ongoing Phase 1 clinical trial to evaluate HCW9218 in patients with chemo-refractory/chemo-resistant solid tumors was presented at the 38th Annual Meeting of the Society for Immunotherapy of Cancer (“SITC”) by Melissa A. Geller, M.D., M.S., Professor and Division Director of Gynecologic Oncology in the Department of Obstetrics, Gynecology and Women’s Health at the University of Minnesota, who serves as a Principal Investigator of this trial, which is sponsored by the University of Minnesota.

Dr. Hing C. Wong, Founder and CEO of HCW Biologics, stated, “We believe the findings we shared in the preliminary human data readout at SITC provide support for future Phase 2 studies of HCW9218 in combination with chemotherapy and/or immune checkpoint inhibitors against solid tumors in patients with ovarian cancer. We are pleased to see the consistency of results in humans with those that we saw in our preclinical animal studies. Together, we believe these findings verify the balanced bifunctional activities of HCW9218 in stimulating effector immune cells and reducing TGF-β-mediated responses.”

Business Highlights:

- The Company expects to complete the initial phase of both of its ongoing clinical studies in cancer indications in late 2023 or early 2024.
- Highlights of the human data readout from the Phase 1 clinical trial presented at SITC include:
    - HCW9218 was administered subcutaneously once every three weeks for up to six cycles at dose levels 0.25 mg/kg (DL1), 0.5 mg/kg (DL2), 0.8 mg/kg (DL3) or 1.2 mg/kg (DL4). The median number of cycles was three.
    - 87% (13/15) had >4 lines of prior therapy. Tumor types included: Ovarian (n=6), Colorectal (n=4), Rectal (n=3), and Liver (n=2).
    - 53% (8/15) patients treated with HCW9218 were evaluated in a post-treatment assessment, including biopsies and scanning. Tumor types included: Ovarian (n=3), Colorectal (n=3), Rectal (n= 1) and Liver (n=1).
    - 50% (4/8) patients evaluated in post-treatment assessments exhibited stable disease following HCW9218 treatment. Patients showed stable disease lasting over 6 months. Clinical benefit was observed from DL2, DL3 and DL4.
    - 66% (2/3) patients with ovarian cancer who underwent post-treatment assessments showed stable disease.
    - HCW9218 significantly reduced blood levels of TGF-β in cancer patients in a dose-dependent manner, without causing treatment-emergent skin lesions and bleeding events previously reported with TGF-β antagonists in clinic.
    - Based on the ability of HCW9218 to activate, expand and induce tumor trafficking of progenitor exhausted stem-like and transitory CD8+ T cells, HCW9218 treatment presents a promising approach to enhancing the antitumor activity of immune checkpoint inhibitors in patients with solid tumors.
    - Repeated HCW9218 administration up to the highest planned dose level was well tolerated by patients with chemotherapy-refractory advanced solid tumors, which has provided support for the Recommended Phase 2 Dose level for future Phase 2 studies of HCW9218.

Third Quarter 2023 Financial Results:

- **Revenues:** Revenues for the quarter ended September 30, 2022 and 2023 were $1.8 million and $853,102, respectively. Revenues for the nine months ended September 30, 2022 and 2023 were $5.4 million and $1.5 million, 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. The Company expects Wugen to limit its purchases for the remainder of 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 September 30, 2022 and 2023 were $2.6 million and $1.7 million, respectively, a decrease of $981,352, or 37%. R&D expenses for the nine months ended

September 30, 2022 and 2023 were $6.4 million and $5.5 million, respectively, a decrease of $868,434, or 14%. 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 September 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 20-24 months. In the three months ended September 30, 2023, costs were incurred primarily for master cell bank characterization for HCW9101H, a high-producing cell line of a key component of the manufacturing process for the Company's proprietary molecules including those licensed to Wugen, as well as ancillary activities such as shipping, insurance and storage. During this period, all preclinical costs were incurred to complete IND-enabling activities for HCW9302. 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 September 30, 2022 and 2023 were $1.7 million and $3.6 million, respectively, an increase of $1.9 million, or 107%. G&A expenses for the nine months ended September 30, 2022 and 2023 were $5.3 million and $9.7 million, respectively, an increase of $4.4 million, or 83%. 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, which is discussed further below.
- **Net loss:** Net loss for the quarter ended September 30, 2022 and 2023 was $3.9 million and $4.9 million, respectively, an increase of $1.0 million, or 26%. Net loss for the nine months ended September 30, 2022 and 2023 was $9.5 million and $14.3 million, respectively, an increase of $4.8 million, or 51%.

Financial Guidance

As of September 30, 2023, the Company held $11.2 million in cash and cash equivalents. In addition, the Company recognized prepaid expenses of $1.7 million, and a deposit for interest reserve of $5.3 million. The Company advanced $4.4 million toward its new lab and manufacturing facilities prior to drawing funds available under the 2023 Loan Agreement. With the current cash and cash equivalents and funds available to the Company under the 2023 Loan Agreement, including recouping the amounts advanced toward its new lab and manufacturing facilities, the Company believes it has adequate capital to fund operations and other commitments to the end of 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. Further, while 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, under certain circumstances, the Company may be required to advance his legal fees. The Company incurred legal expenses on its own behalf in the period ended September 30, 2023, and it expects to continue to incur material costs and expenses in connection with defending itself in the foregoing legal matters through the end of 2023 and into 2024.

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 TOBITM 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 Company currently has two ongoing clinical trials to evaluate HCW9218 in cancer indications. The Masonic Cancer Center, University of Minnesota, is the sponsor of 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 the sponsored of a 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 for trials; the Company’s cash runway; the Company’s expectations regarding future purchases by Wugen; timing of submission of INDs; 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 November 14, 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.

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HCW Biologics Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2023**	**2022**	**2023**
Revenues:				
Revenues	$ 1,809,025	$ 853,102	$ 5,380,570	$ 1,517,792
Cost of revenues	(1,447,220)	(678,325)	(3,062,496)	(1,210,077)
Net revenues	361,805	174,777	2,318,074	307,715
Operating expenses:				
Research and development	2,648,794	1,667,442	6,408,353	5,539,919
General and administrative	1,732,666	3,585,215	5,321,262	9,716,765
Total operating expenses	4,381,460	5,252,657	11,729,615	15,256,684
Loss from operations	(4,019,655)	(5,077,880)	(9,411,541)	(14,948,969)
Interest expense	(32,184)	(95,514)	(32,184)	(284,465)
Other (expense) income, net	137,645	234,753	(38,237)	919,688
Net loss	$ (3,914,194)	$ (4,938,641)	$ (9,481,962)	$ (14,313,746)
Net loss per share, basic and diluted	$ (0.11)	$ (0.14)	$ (0.26)	$ (0.40)
Weighted average shares outstanding, basic and diluted	35,835,135	35,926,921	35,809,216	35,907,123

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2022	**September 30, 2023 Unaudited**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,326,356	$ 11,220,793
Short-term investments	9,735,930	—
Accounts receivable, net	417,695	710,078
Prepaid expenses	1,394,923	1,742,341
Other current assets	196,015	174,881
Total current assets	34,070,919	13,848,093
Investments	1,599,751	1,599,751
Property, plant and equipment, net	10,804,610	14,780,872
Deposit for interest reserve	—	5,250,000
Other assets	333,875	137,626
Total assets	$ 46,809,155	$ 35,616,342
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	$ 1,226,156	$ 3,153,834
Accrued liabilities and other current liabilities	1,730,325	2,262,839
Total current liabilities	2,956,481	5,416,673
Debt, net	6,409,893	6,332,736
Other liabilities	14,275	—
Total liabilities	9,380,649	11,749,409
Commitments and contingencies (Note 8)		

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 35,927,321 shares issued at September 30, 2023	3,588	3,593
Additional paid-in capital	82,962,964	83,715,133
Accumulated deficit	(45,538,046)	(59,851,793)
Total stockholders' equity	37,428,506	23,866,933
Total liabilities and stockholders' equity	$ 46,809,155	$ 35,616,342