HCW Biologics Reports Fourth Quarter 2023 and Fiscal Year End Financial Results And Business Highlights

April 1, 2024

MIRAMAR, Fla., April 01, 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 fourth quarter and fiscal year ended December 31, 2023.

Dr. Hing C. Wong, Founder and CEO of HCW Biologics, stated, “These are exciting times at HCW Biologics. We achieved two major clinical milestones, with the completion of the Phase 1 clinical study to evaluate HCW9218 in solid tumors and the Phase 1b study to evaluate HCW9218 in pancreatic cancer. While it is still quite early in the clinical development process and we have only seen data when HCW9218 is administered as a monotherapy, we believe there are signs that HCW9218 provides clinical benefits to some patients who have previously failed multiple lines of standard-of-care therapies. We believe that HCW9218 shows the potential to be a first in class immunotherapeutic cancer treatment.”

Dr. Wong continued, “Now we are on the verge of initiating multiple Phase 2 clinical studies, including randomized trials, to evaluate HCW9218 as a treatment in combination with standard-of-care therapies in patients with cancer. We intend to focus on ovarian and pancreatic cancer, and we hope to opportunistically join studies with investigators who want to add an arm to their study using HCW9218 in combination with their therapy. This approach could give us an opportunity to assess HCW9218 in more cancer indications that we believe will provide valuable data to inform us of the most appropriate indications and regimens for future registration trials.”

“Another piece of exciting news for 2024 is that we are planning on the initiation of investigative studies for age-related diseases using HCW9218. We are planning on using the Recommended Phase 2 Dose level of HCW9218 identified in our two now completed Phase 1/1b cancer trials,” Dr. Wong added. “We believe age-associated dermatological conditions and diseases, such as senile lentigo and deep wrinkles, will be the first age-related indications we investigate beyond cancer.”

Business Highlights

- The Phase 1 clinical trial to evaluate HCW9218 in solid tumors and the Phase 1b clinical trial to evaluate HCW9218 in pancreatic cancer were completed in February 2024. In the Phase 1 study, over 70% of patients with ovarian cancer (5/7) showed evidence of stable disease. In the Phase 1b study, 13% (2/15) of patients who participated in the study showed evidence of stable disease.
- The first Phase 2 clinical study to evaluate HCW9218 in patients with ovarian cancer will be sponsored by the University of Pittsburgh Medical Center. This fully randomized trial will have one arm of the study treating patients with HCW9218 with a neoadjuvant chemotherapy.
- The Company’s investment in its patent portfolio is beginning to result in new patent awards from the USPTO. Most importantly, among the patents the Company was awarded are the fundamental patents which protect the technology on which the Company’s lead molecules are based.
- On January 10, 2024, the Company terminated the credit agreement with Prime Capital Ventures, whereupon the Company was entitled to receive a refund of $5.3 million that was funded to establish an interest reserve account under the terms of the credit agreement. Due to the probability of default, the Company recognized a reserve for credit losses of $5.3 million as of December 31, 2023. However, the Company intends to pursue available remedies to recover these funds.
- On February 20, 2024, the Company completed a $2.5 million private placement of its common stock, at a price of $1.40 per share, which was a 25% premium over the market price on the closing date. Investors included certain officers and directors of the Company.
- As of March 31, 2024, the Company entered into legally binding agreements to issue $10.0 million of secured notes from investors, including certain of our officers and directors as well as other investors, $2.0 million of which was funded by the issuance date of the audited financial statements.

Fourth Quarter 2023 and Year End Financial Results

- **Revenues:** Revenues for the fourth quarters ended December 31, 2022 and 2023 were $1.3 million and $1.3 million, respectively. Revenues for the years ended December 31, 2022 and 2023 were $6.7 million and $2.8 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. In 2023, revenues were negatively impacted by changes in Wugen's clinical development program. In addition, Wugen suffered delays in ramping up its manufacturing process which also limited purchases of molecules licensed by the Company.
- **Research and development (R&D) expenses:** R&D expenses for the fourth quarters ended December 31, 2022 and 2023 were $2.9 million and $2.1 million, respectively. The $793,616 decrease, or 27%, resulted from a decline in manufacturing and materials expense. R&D expenses for the years ended December 31, 2022 and 2023 were $9.4 million and $7.7 million, respectively. The $1.7 million decrease, or 18%, resulted from a decline in expenses related to manufacturing and materials expense, preclinical expenses and performance-based bonuses. Manufacturing costs declined in 2023 because the Company had already made the necessary supplies of its lead molecules, HCW9218 and HCW9302, to fulfill the requirements for planned clinical development activities in 2024-2025. Preclinical costs in 2022 and 2023 are related to IND-enabling activities required to prepare an IND application to evaluate HCW9302 in a Phase 1b/2 clinical trial. A change in preclinical activities from 2022 to 2023 was the underlying reason for a decline in preclinical expenses. Setup costs were incurred for toxicology studies and other IND-enabling studies in 2022. Costs declined in 2023, as the Company was focused on additional research studies required for the Company's IND submission.
- **General and administrative (G&A) expenses:** G&A expenses for the fourth quarters ended December 31, 2022 and 2023 were $3.0 million and $3.6 million, respectively. The $628,910 increase, or 20%, was attributable to an increase in legal expenses related to the Altor/NantCell matter. G&A expenses for the years ended December 31, 2022 and 2023 were $8.3 million and $13.3 million, respectively. The $5.0 million increase, or 60%, was attributable to an increase in legal expenses associated with the Company's ongoing arbitration with Altor/NantCell. See further discussion of the Altor/NantCell arbitration in "Financial Guidance."
- **Reserve for Credit Losses.** In the period ended December 31, 2023, the Company recognized a reserve for credit losses related to a $5.3 million interest reserve deposit established in connection with a credit agreement the Company terminated. While the Company is entitled to recover these funds, facts available as of December 31, 2023 indicate it is not probable.
- **Net loss:** Net loss for the fourth quarters ended December 31, 2022 and 2023 were $5.4 million and $10.7 million, respectively. Net loss for the years ended December 31, 2022 and 2023 was $14.9 million and $25.0 million, respectively.

Financial Guidance

As of December 31, 2023, there was substantial doubt about our ability to continue as a going concern. Since that time, we had successful financings of $12.5 million, for which we received funds or have a legally binding commitment to so. And, we continue with other fundraising efforts that we are targeting to complete in the next three to six months. Under the guidance of Topic 205-40 for going concern assessment, we evaluated whether we mitigated the substantial doubt over our ability to remain a going concern for the next 12 months from the issuance date of the financial statements. If no additional financings occur after the date of issuance, we believe the relevant conditions that brought about substantial doubt can be alleviated if we implement a plan that includes certain adjustments to our strategic and operating plans, such as cutting back on the number of investigative studies and Phase 2 clinical trials we initiate; reducing salaries and other spending, and limiting the amount of cash used to reduce accounts payable, as well as other adjustments to alleviate substantial doubt.

On December 23, 2022, Claimants Altor and NantCell ("Altor/NantCell") filed a complaint against the Company in the U.S. District Court for the Southern District of Florida (the "Court"), alleging claims of misappropriation of trade secrets, tortious interference with contractual relations, inducement of breach of fiduciary duty, and specific performance/injunction for assignment of patents and patent applications, among other claims. That same day, Altor/NantCell also initiated an arbitration against the Company's CEO and Founder, Dr. Wong, based on early identical allegations and alleging breach of contract, breach of fiduciary duty, and fraudulent concealment, among other claims. The Company moved to compel arbitration and the parties ultimately stipulated to the same. On April 27, 2023, in connection with the Altor/NantCell matter, 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, with an arbitration hearing scheduled for May 20, 2024. In addition, on March 26, 2024, Altor/NantCell gave notice that they are filing a complaint (the "Complaint") against the Company in the Chancery Court of the State of Delaware for the contribution of legal fees and expenses advanced to Dr. Wong in connection with the arbitration discussed above. Prior to the filing of the Complaint, Altor/NantCell had previously sought advancement from the Company and the Company agreed to advance 50% of Dr. Wong's legal fees going forward from December 2023. On January 8, 2024, Altor/NantCell reserved their right to pursue contribution against the Company for 50% of the amount Altor/NantCell sent for advancement of expenses for Dr. Wong. In the Complaint, Altor/NantCell seek 50% of the fees they have already advanced to Dr. Wong, a declaration that the Company has an obligation to contribute 50% of the advancement of Dr. Wong's expenses including 50% of Dr. Wong's expenses incurred in connection with the arbitration through final resolution of the matter, and costs and fees in bringing this action. 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. The Company incurred significant legal expenses in connection with this matter in the period ended December 31, 2023, and expects to continue to incur material costs and expenses in the first half of 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 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 Company completed the initial stages of two clinical trials to evaluate HCW9218 in cancer indications in February 2024. One is the Phase 1 study sponsored by The Masonic Cancer Center, University of Minnesota, to evaluate HCW9218 in chemo-refractory/chemo-resistant solid tumors that have progressed after prior chemotherapies (Clinicaltrials.gov: NCT05322408). The other is a Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in chemo-refractory/chemo-resistant advanced pancreatic cancer (Clinicaltrials.gov: NCT05304936). The Company is preparing an IND application for its lead molecule for its regulatory T cell expansion program, HCW9302, expected to be submitted in the first half of 2024.

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 potential of HCW9218 to be a first in class immunotherapeutic cancer treatment. initiation of Phase 2 clinical studies in cancer indications; potential to join other studies so HCW9218 can be assessed in more cancer indications; timing of initiation of studies for age-related diseases; the Company's cash runway; the Company's expectations regarding future purchases by Wugen; 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 April 1, 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.
Statements of Operations

	For the Three Months Ended December 31,		Years Ended December 31,	
	2022	2023	2022	2023
Revenues:	Unaudited		Audited	
Revenues	$ 1,341,520	$ 1,324,003	$ 6,722,090	$ 2,841,794
Cost of revenues	(1,073,216)	(1,071,357)	(4,135,712)	(2,281,434)
Total revenues	268,304	252,646	2,586,378	560,360
Operating expenses:				
Research and development	2,930,013	2,136,397	9,338,366	7,676,316
General and administrative	3,005,529	3,634,439	8,326,790	13,351,204
Reserve for credit losses	—	5,250,000	—	5,250,000
Total operating expenses	5,935,542	11,020,836	17,665,156	26,277,520
Loss from operations	(5,667,238)	(10,768,190)	(15,078,778)	(25,717,160)
Interest expense	(94,476)	—	(126,660)	(283,042)
Other (expense) income, net	342,973	87,660	304,735	1,005,925
Net loss	$ (5,418,741)	$ (10,680,530)	$ (14,900,703)	$ (24,994,277)
Net loss per share, basic and diluted	$ (0.15)	$ (0.30)	$ (0.42)	$ (0.70)
Weighted average shares outstanding, basic and diluted	35,861,348	35,996,415	35,822,249	35,929,446

HCW Biologics Inc.
Audited Balance Sheets

	December 31, 2022	December 31, 2023

ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,326,356	$ 3,595,101
Short-term investments	9,735,930	—
Accounts receivable, net	417,695	1,535,757
Prepaid expenses	1,394,923	1,042,413
Other current assets	196,015	230,916
Total current assets	34,070,919	6,404,187
Investments	1,599,751	1,599,751
Property, plant and equipment, net	10,804,610	20,453,184
Other assets	333,875	56,538
Total assets	$ 46,809,155	$ 28,513,660
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	$ 1,226,156	$ 6,167,223
Accrued liabilities and other current liabilities	1,730,325	2,580,402
Total current liabilities	2,956,481	8,747,625
Debt, net	6,409,893	6,304,318
Other liabilities	14,275	—
Total liabilities	9,380,649	15,051,943
Commitments and contingencies (Note 15)		
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 36,025,104 shares issued at December 31, 2023	3,588	3,603
Additional paid-in capital	82,962,964	83,990,437
Accumulated deficit	(45,538,046)	(70,532,323)
Total stockholders' equity	37,428,506	13,461,717
Total liabilities and stockholders' equity	$ 46,809,155	$ 28,513,660