HCW Biologics Reports First Quarter 2024 Financial Results and Business Highlights

May 15, 2024

MIRAMAR, Fla., May 15, 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 first quarter ended March 31, 2024.

Dr. Hing C. Wong, Founder and CEO of HCW Biologics, stated, “We reached an important clinical development milestone in the first quarter of 2024. Enrollment was completed in two ongoing clinical trials to evaluate HCW9218 in solid tumors. We are encouraged by the number of patients with evidence of stable disease, even though it is difficult of generalize from Phase 1 and Phase 1b results. We are following our strategy to participate in fully randomized Phase 2 clinical trials in difficult-to-treat cancer indications, working with leading clinical sites. Using this strategy, we believe we can cost effectively evaluate HCW9218 as a single arm in a larger study. We intend to advance our cancer studies in ovarian and pancreatic cancer, while seeking to opportunistically participate in other cancer trials that have strong sponsors with financial support.”

He added, “With the recommended Phase 2 dose established in our early studies, we plan to expand into age-related indications in skin diseases and conditions associated with senescence. These studies will be designed as investigative studies, and we anticipate that it will be quicker to see human data read outs from this type of indication than would be possible in a cancer study. We are interested to see the aesthetic effects with the deep wrinkles and senile lentigo, perhaps as secondary endpoints.”

Business Highlights

- The Company raised $6.1 million to date in 2024, from private placement of common stock and issuance of senior secured notes.
- Management financing plans are to raise a bridge financing through the issuance of up to an aggregate of $10.0 million of Secured Notes, of which $3.6 million have been issued to date in 2024. If we succeed, we expect the bridge financing will enable the Company to continue with its clinical development plans, until such time as it can complete planned business development transactions such as license for non-core assets and capital raising transactions.
- 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. The studies met the primary objective to determine a recommended Phase 2 dose (“RP2D”).
- In February 2024, we entered into an agreement with University of Pittsburgh Medical Center (“UPMC”) to conduct an Investigator-sponsored Phase 2 clinical trial to evaluate HCW9218 in patients with metastatic advanced stage ovarian cancer in combination with neoadjuvant chemotherapy. Patient enrollment is expected to begin in the second half of 2024.
- We are preparing an IND application to evaluate our IL-2 based product candidate designed to activate and expand T_{reg} cells, HCW9302, in an autoimmune disease, which we plan to submit in the third quarter of 2024.

First Quarter 2024 Financial Results

- **Revenues:** Revenues for the first quarters ended March 31, 2023 and 2024 were $41,883 and $1.1 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. 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 in 2023.
- **Research and development (R&D) expenses:** R&D expenses for the first quarters ended March 31, 2023 and 2024 were $2.3 million and $2.1 million, respectively. The $132,529 decrease, or 6%, resulted primarily from a decline in preclinical expenses, partially offset by an increase in manufacturing and material costs. Manufacturing costs increased in three-month period ended March 31, 2024 because the Company replenished supply of a high-expressing cell line of HCW9101. Preclinical expenses declined primarily due to a change in the preclinical activities in March 31, 2024 versus the comparable period one year earlier. In the three-month period ended March 31, 2023, preclinical costs were incurred for setup costs for toxicology studies and other IND-enabling studies to prepare an IND application to obtain permission from the FDA to evaluate HCW9302 in an autoimmune indication. In the three-month period ended March 31, 2024, costs were incurred for supplemental research studies required for this IND application. Clinical trial expenses were incurred in the three-month periods ended March 31, 2023 and 2024 related to two ongoing clinical studies to evaluate HCW9218 in

chemo-refractory / chemo-resistant solid tumors, including a Phase 1 study in patients with various types of solid tumors and a Phase 1b study in pancreatic cancer.

- **General and administrative (G&A) expenses:** G&A expenses for the first quarters ended March 31, 2023 and 2024 were $3.1 million and $6.0 million, respectively, a $2.9 million increase, or 94%. The increase was primarily attributable to an increase in legal expenses related to the Altor/NantCell matter. See further discussion of the Altor/NantCell arbitration in "Financial Guidance."
- **Net loss:** Net loss for the three-month periods ended March 31, 2023 and 2024 was $5.1 million and $7.5 million, respectively.

Financial Guidance

As of March 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 condensed financial statements, without additional funding or financial support. After giving consideration to 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.

Management has made some reductions in costs, but in order to continue the clinical development for the Company's lead product candidates, the Company must maintain a core group of scientists. The Company continues to pursue a plan to obtain bridge financing through the issuance of up to $10.0 million in Secured Notes, $3.6 million of which have been issued to date in 2024. The Company anticipates that this bridge financing, if fully subscribed, will allow the Company to reach such time as it can execute plans for business development transactions such as licenses for non-core assets and capital-raising transactions, although there can be no assurance of this outcome for many reasons, including the uncertainties regarding the Company's ongoing arbitration proceedings with Altor/NantCell, as described below. In addition to the bridge financing in the form of the issuance of additional Secured Notes, other potential near-term financing plans may include cooperative agreements for clinical trials and third-party collaboration funding. If the Company is not successful in raising additional capital, management has the intent and ability to revise its business plan and reduce costs. If such revisions are insufficient, the Company may have to curtail or cease operations.

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 nearly 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 and is consolidated with the arbitration Altor/NantCell initiated against Dr. Wong. The arbitration hearing scheduled to begin on May 20, 2024. In addition, on March 26, 2024, Altor/NantCell filed 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 March 31, 2024, and expects to continue to incur material costs and expenses through the third quarter 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. The Masonic Cancer Center, University of Minnesota, was 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 sponsor of a Phase 1b/2 clinical trial to evaluate HCW9218 in chemo-refractory/chemo-resistant advanced pancreatic cancer (Clinicaltrials.gov: NCT05304936). The University of Pittsburgh Medical Center has agreed to include HCW9218 in combination with neoadjuvant chemotherapy in a fully randomized trial. 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 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 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/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

	Three Months Ended March 31,	
	2023	**2024**
Revenues:		
Revenues	$ 41,883	$ 1,126,712
Cost of revenues	(29,350)	(511,965)
Net revenues	12,533	614,747
Operating expenses:		
Research and development	2,255,813	2,123,284
General and administrative	3,117,290	5,985,126
Total operating expenses	5,373,103	8,108,410
Loss from operations	(5,360,570)	(7,493,663)
Interest expense	(93,438)	—
Other (expense) income, net	383,322	25,602
Net loss	$ (5,070,686)	$ (7,468,061)
Net loss per share, basic and diluted	$ (0.14)	$ (0.20)
Weighted average shares outstanding, basic and diluted	35,883,779	37,223,588

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2023	March 31, 2024 Unaudited
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,595,101	$ 4,084,076
Accounts receivable, net	1,535,757	903,884
Secured note receivable	—	250,000
Prepaid expenses	1,042,413	783,423
Other current assets	230,916	187,267
Total current assets	6,404,187	6,208,650
Investments	1,599,751	1,599,751
Property, plant and equipment, net	20,453,184	22,590,779
Other assets	56,538	28,476
Total assets	$ 28,513,660	$ 30,427,656
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	$ 6,167,223	$ 10,493,416
Accrued liabilities and other current liabilities	2,580,402	2,919,190

Total current liabilities	8,747,625	13,412,606
Debt, net	6,304,318	8,274,449
Total liabilities	15,051,943	21,687,055
Commitments and contingencies (Note 8)		
Stockholders' equity:		
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 March 31, 2024	3,603	3,782
Additional paid-in capital	83,990,437	86,737,203
Accumulated deficit	(70,532,323)	(78,000,384)
Total stockholders' equity	13,461,717	8,740,601
Total liabilities and stockholders' equity	$ 28,513,660	$ 30,427,656