UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 28, 2023

HCW Biologics Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40591**	**82-5024477**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2929 N. Commerce Parkway Miramar, Florida	**33025**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 954 842-2024

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	HCWB	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 28, 2023, HCW Biologics Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2022. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth in this Item 2.02 (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated March 28, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HCW BIOLOGICS INC.

Date: March 28, 2023

By: /s/ Hing C. Wong,
Hing C. Wong, Founder and CEO

HCW Biologics Reports Fourth Quarter and Full Year 2022 Financial Results And Recent Business Highlights

Miramar, FL – March 28, 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 chronic, low-grade inflammation and age-related diseases, today reported financial results and recent business highlights for its fourth quarter ended December 31, 2022.

Hing C. Wong, Ph.D., Founder and CEO of HCW Biologics, stated, "We had a productive year in 2022, and our cancer program met or exceeded key milestones. In the fall, a preliminary first-in-human clinical data readout was presented at the SITC annual conference by Dr. Melissa Geller, the principal investigator for the University of Minnesota ("UMN") sponsored Phase 1 clinical trial to evaluate HCW9218 in solid tumors. We are encouraged by data gathered in this study and believe that it shows the potential of HCW9218 in the treatment of solid tumors, especially ovarian cancer. Our data indicates that HCW9218 is functioning as it was intended – activating the immune system and capturing TGF-β 1, 2 and 3 with no evidence of mucosal bleeding."

Dr. Wong continued, "UMN has been a terrific sponsor and partner for the Phase 1 solid tumor clinical study. With Dr. Geller's expertise and focus, along with the support of the co-principal investigator, Dr. Jeff Miller, the Phase 1 portion of this trial is on track to be completed within a year of its initiation, which is fortunate in the times of prolonged COVID-related delays. Because of this, we are poised to complete the Phase 1 study in 2023 and, if our studies are successful, potentially advance into Phase 2 clinical trials in 2023."

In the fourth quarter of 2022, the Company also initiated a Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in advanced pancreatic cancer. Dr. Wong stated, "With respect to HCW9218, we believe cancer is our gateway indication to other age-related diseases. As and to the extent we advance the clinical development to evaluate HCW9218 in cancer indications, we intend to focus on two of the most difficult-to-treat cancers that have no therapeutic remedy today: ovarian cancer and pancreatic cancer." He added, "If we can establish safety and dosage of HCW9218 in cancer indications, we plan to expand to other age-related diseases promoted by inflammaging."

One of the pillars of the Company's strategy is its commitment to documenting its work in high-impact scientific journals. Two scientific papers were submitted in 2022, one has been published, and the other has been accepted for publication. Dr. Wong stated, "We devote significant resources to publishing scientific papers, because we believe in the value of sharing our discoveries and inventions with the broader scientific community."

Dr. Wong continued, “Our most recent paper published in *Frontiers in Immunology* illustrates the potential for HCW9302 as a therapeutic agent to expand and activate T_{reg} cells indicating it might be effective in treating inflammatory and autoimmune diseases. HCW9302 is a unique fusion protein with two IL-2 domains linked by an extracellular tissue factor domain that has been shown in preclinical research to exhibit a more favorable pharmacokinetic profile than recombinant IL-2, with longer half-life, greater affinity to IL-2 receptor α and no toxicity. The results of our research included in this publication show the potential of HCW9302 in the treatment of age-related inflammatory diseases, such as atherosclerosis.”

Fourth Quarter and Other Recent Business Highlights:

- On November 11, 2022, there was a preliminary human data readout at the 37th Annual Meeting of the Society for Immunotherapy of Cancer from an ongoing Phase 1 clinical trial to evaluate HCW9218 in patients with chemo-refractory/chemo-resistant solid tumors, sponsored by the Masonic Cancer Center, University of Minnesota. The poster was presented by Melissa A. Geller, M.D., M.S., Principal Investigator, who is a Professor and Division Director of Gynecologic Oncology in the Department of Obstetrics, Gynecology and Women’s Health at the University of Minnesota.
- On December 3, 2022, under a Cooperative Research and Development Agreement (“CRADA”), the National Cancer Institute and HCW Biologics agreed to collaborate to perform a Phase 1b/2 clinical study to evaluate the safety and tolerability of HCW Biologics’ lead product candidate, HCW9218, in patients with advanced/metastatic pancreatic cancer. The CRADA is entitled, “A Phase 1b/2 Study of HCW9218, a Bifunctional TGF-β Antagonist/IL-15 Protein Complex, for Advanced Pancreatic Cancer.”
- HCW Biologics initiated a Company-sponsored Phase 1b/2 clinical study to evaluate HCW9218 in patients with advanced pancreatic cancer. With four clinical sites up and running, if patient enrollment continues at the current pace, the Company expects to complete the Phase 1b portion of this study in 2023.
- In January 2023, a pivotal scientific paper authored by members of the Company’s scientific research team was published in the high-impact, peer-reviewed journal, *Frontiers in Immunology*, entitled, “A Novel Interleukin-2-Based Fusion Molecule, HCW9302, Differentially Promotes Regulatory T Cell Expansion to Treat Atherosclerosis in Mice.”
- The Company has been invited to present a poster at the American Association of Cancer Research to be held from April 14-19, 2023. Dr. Varghese George, one of the Company's scientists, will be presenting a poster entitled, "Bifunctional Immunotherapeutic HCW9218 Facilitates Recruitment of Immune Cells from Tumor Draining Lymph Nodes to Promote Antitumor Activity and Enhance Checkpoint Blockade Efficacy in Solid Tumors." This research is intended to support the understanding of the mechanism of action for HCW9218 for solid tumors.

Fourth Quarter and Full Year 2022 Financial Results:

- **Cash and cash equivalents:** As of December 31, 2022, the Company held $22.3 million in cash and cash equivalents, including money market investments, and $9.7 million in U.S. government backed securities presented as short-term investments. Money market investments are held in a federal money market fund with an investment focus on liquidity and stability.

- **Revenues:** Revenues for the fourth quarter ended December 31, 2021 and 2022 were nil and $1.3 million, respectively. Revenues for the year ended December 31, 2021 and 2022 were nil and $6.7 million, respectively. Revenues were derived exclusively from the sale of licensed molecules to the Company's licensee, Wugen.

- **Research and development (R&D) expenses:** R&D expenses for the fourth quarter ended December 31, 2021 and 2022 were $1.5 million and $2.9 million, respectively. The $1.4 million increase, or 98%, resulted from increased clinical trial expenses and manufacturing costs. R&D expenses for the year ended December 31, 2021 and 2022 were $8.2 million and $9.3 million, respectively. The $1.1 million increase, or 14%, resulted from increases in salaries, performance-based bonuses, and clinical trial expenses.

- **General and administrative (G&A) expenses:** G&A expenses for the fourth quarter ended December 31, 2021 and 2022 were $1.6 million and $3.0 million, respectively. The $1.4 million increase, or 84%, was attributable to increases in salaries and stock-based compensation and professional fees related primarily to legal fees. G&A expenses for the year ended December 31, 2021 and 2022 were $5.2 million and $8.3 million, respectively. The $3.1 million increase, or 60%, resulted from increases in stock-based compensation expense for officers and directors, legal fees, and additional costs of operating as a public company.

- **Net loss:** Net loss for the fourth quarter ended December 31, 2021 and 2022 was $3.2 million and $5.4 million, respectively. Net loss for the year ended December 31, 2021 and 2022 was $12.9 million and $14.9 million, respectively.

Financial Guidance

HCW Biologics believes its cash and cash equivalents and investments will be sufficient to fund its operations through at least the next 12 months. This cash runway guidance is based on the Company's current operational plans and buildout of its new headquarters building, and it excludes any additional capital infusion resulting from bank loans, joint ventures, out-licenses, or other business development transactions. Relocation to the new headquarters is anticipated during 2024, although the Company may choose to delay the completion date to extend its cash runway. In the year ended December 31, 2022, the Company incurred significant legal expenses on its own behalf and on behalf of Dr. Wong, as required by the indemnification agreement between the Company and Dr. Wong. In the year ahead, the Company expect to continue to incur legal expenses on its own behalf in connection with the legal proceedings brought against it by Altor/NantCell. However, now that the arbitration against Dr. Wong was initiated by Altor/NantCell, Dr. Wong's legal expenses will be covered by the provisions of his advancement agreement with Altor/NantCell in connection with the arbitration.

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, and autoimmune diseases. The Company has combined 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. The Company has initiated a Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in chemo-refractory/chemo-resistant advanced pancreatic cancer. 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; initiation of Phase 2 clinical trials; the ability to meet a proposed timeframe to provide preliminary clinical results from the Phase 1 clinical study to evaluate HCW9218 in pancreatic cancer; the ability to protect our intellectual property through issued patents or otherwise; and the ability to project that cash and cash equivalents and investments are sufficient to fund operations for at least the next 12 months, and the impact of any indemnification or advancement of expenses obligations may have on such projections. 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, potential delays in clinical and pre-clinical trials and IND-enabling studies; other potential adverse impacts due to the COVID-19 pandemic, geopolitical or macroeconomic factors such as delays in regulatory review, market volatility, manufacturing and supply chain interruptions, staffing shortages, and our ability to enroll patients in our ongoing and future clinical trials; the success of our current and future licensing arrangements; our reliance on third parties for the manufacture and supply of our product candidates for clinical trials; our reliance on third parties to conduct our clinical trials; adverse impacts of litigation or other proceedings, including expenses incurred to defend against third-party claims as well as to indemnify or advance expenses of our officers and directors in connection therewith; the possibility that the Company may be required to advance legal fees of Dr. Wong despite his agreement with Altor/NantCell; and those other 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 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,	
	2021	2022	2021	2022
Revenues:	Unaudited		Audited	
Revenues	$ —	$ 1,341,520	$ —	$ 6,722,090
Cost of revenues	—	(1,073,216)	—	(4,135,712)
Net revenues	—	268,304	—	2,586,378
Operating expenses:				
Research and development	$ 1,483,307	$ 2,930,013	$ 8,173,624	$ 9,338,365
General and administrative	1,629,197	3,005,529	5,194,210	8,326,791
Total operating expenses	3,112,504	5,935,542	13,367,834	17,665,156
Loss from operations	(3,112,504)	(5,667,238)	(13,367,834)	(15,078,778)
Interest expense	(60,902)	248,496	—	(126,660)
Other income	—	—	505,366	304,735
Net loss	$ (3,173,406)	$ (5,418,742)	$(12,862,468)	$(14,900,703)
Net loss per share, basic and diluted	$ (0.09)	$ (0.15)	$ (0.69)	$ (0.42)
Weighted average shares outstanding, basic and diluted	35,750,496	35,861,348	18,770,935	35,822,249

HCW Biologics Inc.
Audited Balance Sheets

	December 31, 2021	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,730,677	$ 22,326,356
Short-term investments	24,983,520	9,735,930
Accounts receivable, net	133,000	417,695
Prepaid expenses	2,196,557	1,394,923
Other current assets	1,436,617	196,015
Total current assets	40,480,371	34,070,919
Investments	11,522,050	1,599,751
Property, plant and equipment, net	1,119,090	10,804,610
Other assets	393,318	333,875
Total assets	$ 53,514,829	$ 46,809,155
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	$ 223,664	$ 1,226,156
Accrued liabilities and other current liabilities	2,097,925	1,730,325
Total current liabilities	2,321,589	2,956,481
Debt, net	—	6,409,893
Other liabilities	—	14,275
Total liabilities	2,321,589	9,380,649
Stockholders' equity:		
Common stock:		
Common, $0.0001 par value; 250,000,000 shares authorized and 35,768,264 shares issued at December 31, 2021; 250,000,000 shares authorized and 35,876,440 shares issued at December 31, 2022	3,577	3,588
Additional paid-in capital	81,827,006	82,962,964
Accumulated deficit	(30,637,343)	(45,538,046)
Total stockholders' equity	51,193,240	37,428,506
Total liabilities and stockholders' equity	$ 53,514,829	$ 46,809,155