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): November 07, 2022

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

(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 November 7, 2022, HCW Biologics Inc. issued a press release announcing its financial results for the quarter ended September 30, 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 November 7, 2022.
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: November 7, 2022

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

HCW Biologics Reports Third Quarter 2022 Financial Results
And Recent Business Highlights

Miramar, FL – November 7, 2022 – (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 third quarter ended September 30, 2022.

Hing C. Wong, Ph.D., Founder and CEO of HCW Biologics, stated, "We are pleased to report that during the third quarter we opened three clinical sites for our second clinical trial to evaluate HCW9218 in patients with advanced pancreatic cancer. HonorHealth Research Institute was the first clinical site to dose a patient in our Company-sponsored pancreatic cancer trial. HCW Biologics is proud to have HonorHealth Research Institute as a participant in our Phase 1b/2 clinical trial to evaluate HCW9218 in one of the most difficult-to-treat cancers. HonorHealth Research Institute has a passion and commitment to bringing novel immunotherapeutics to patients with this disease." The Principal Investigator of the Phase 1b/2 clinical trial to evaluate HCW9218 in pancreatic cancer at HonorHealth Research Institute is Erkut Borazanci, MD, MS, a leading pancreatic cancer researcher who is a medical oncologist and deputy director of oncology at HonorHealth Research Institute. He also holds an adjunct appointment as Clinical Associate Professor at the Translational Genomics Research Institute.

The Company selected solid tumors for its first clinical indications because solid tumor cancers are characterized by a dense fibrotic stroma or desmoplasia that allows a tumor to shield itself from standard-of-care treatment such as chemotherapy and immune-checkpoint inhibitors, in which TGF-β plays a major role in the formation of desmoplasia and promoting metastasis. HCW9218 is an injectable, bifunctional fusion protein complex designed to simultaneously stimulate effector T cell and natural killer cell responses and inhibit the activity of TGF-ß and its immunosuppressive effect. Dr. Wong added, "HCW9218 innovatively combines a TGF-β receptor to neutralize a highly immunosuppressive cytokine secreted by tumors, and IL-15, a potent cytokine, to stimulate the natural killer and $CD8^{+}$T cell cytotoxicity. As a result, we believe this bifunctional immunotherapeutic has the potential to drive significant anti-tumor activity."

Business Highlights:

- On August 15, 2022, the Company purchased a building located in Miramar, Florida for approximately $10.0 million, as our new headquarters. The Company received a $6.5 million five-year loan to finance the purchase of the new property. The loan bears a fixed interest of 5.75% per annum with interest only payment due in the first year.
- The multi-center, Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in patients with chemo-refractory/chemo-resistant advanced pancreatic cancer has initiated. HonorHealth Research Institute dosed its first patient on October 17, 2022, and a second patient on October 31, 2022. We are in the process of activating other clinical sites at NCI-designated Comprehensive Cancer Centers.
- As of September 30, 2022, there were no reports of dose-limited toxicity in the Phase 1 clinical trial to evaluate HCW9218 in patients with chemo-refractory/chemo-resistant solid tumors with disease progression after prior treatment with standard of care therapies, being conducted at the Masonic Cancer Center. Patients have been enrolled and dosed for two levels of dose escalation in this trial.
- On August 26, 2022, the Company's $100.0 million shelf registration statement on Form S-3, including a prospectus for the issuance and sale of up to $15.5 million of shares of the Company's common stock through an at-the-market program, was declared effective by the SEC.
- The 37th Annual Meeting of the Society for Immunotherapy of Cancer ("SITC") accepted an abstract submitted by the Masonic Cancer Center, University of Minnesota, entitled: A phase 1 study of HCW9218, a bifunctional TGF-β Antagonist/IL-15 protein complex, in advanced solid tumors. Preliminary clinical results from the Phase 1 clinical study to evaluate HCW9218 in chemo-refractory/chemo-resistant solid tumors will be presented in a poster at the SITC 2022 conference by Dr. Melissa Geller, Principal Investigator.

Third Quarter 2022 Financial Results:

- **Cash and cash equivalents:** As of September 30, 2022, the Company had cash and cash equivalents and investments of $35.9 million, consisting of $26.2 million in cash and cash equivalents and $9.7 million in long-term investments held in U.S.-government backed securities. The Company estimates that the current cash balance is sufficient to fund operations and capital expenditures through the end of 2023.
- **Revenues:** Revenues were $1.8 million for the three-month period ended September 30, 2022, and there were no revenues in the three-month period ended September 30, 2021. Revenues were $5.4 million for the nine-month period ended September 30, 2022, and there were no revenues in the nine-month period ended September 30, 2021. Revenues were derived exclusively from the sale of clinical development material to the Company's licensee, Wugen.
- **Research and development (R&D) expenses:** R&D expenses were $2.7 million for each of the three-month periods ended September 30, 2021 and September 30, 2022. R&D expenses were $6.7 million for the nine-month period ended September 30, 2021, as compared to $6.4 million for the nine-month period ended September 30, 2022, a 4% decrease, due primarily to a decrease in manufacturing and materials expenses partially offset by an increase in preclinical expenses for IND-enabling activities and clinical trial expenses.

- **General and administrative (G&A) expenses:** G&A expenses were $1.4 million for the three-month period ended September 30, 2021, as compared to $1.7 million for the three-month period ended September 30, 2022, a 23% increase. G&A expenses were $3.6 million for the nine-month period ended September 30, 2021, as compared to $5.3 million for the nine-month period ended September 30, 2022, a 49% increase. These increases reflect higher salaries, benefits and related expenses primarily as a result of stock-based compensation expense associated with an equity award to the Company's CEO upon completion of the Company's IPO, expensing the offering costs incurred for the shelf registration statement on Form S-3, an increase for the Company's Board of Directors compensation under the non-employee director compensation program put in place by the Company post-IPO, and an increase in insurance costs and other expenses related to operating as a public company. During the period ended September 30, 2022, allegations were made by a former employer of Dr. Wong against Dr. Wong and the Company related to certain of the Company's core intellectual property assets. Although no claims have been filed, the Company began incurring legal expenses on its own behalf as well as on behalf of Dr. Wong, as required under the Company's indemnification agreement with its officers and directors.

- **Net loss:** Net loss was $4.1 million for the three-month period ended September 30, 2021, compared to $3.9 million for the three-month period ended September 30, 2022, a 5% decrease. Net loss was $9.7 million for the nine-month period ended September 30, 2021, compared to $9.5 million for the nine-month period ended September 30, 2022, a 2% decrease.

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 the initiation and completion of our pancreatic cancer study; our ability and proposed timeframe to provide preliminary clinical results from the Phase 1 clinical study to evaluate HCW9218, the ability to protect our intellectual property through issued patents or otherwise; cash balance being sufficient to fund operations through the end of 2023 and the impact of any indemnification or advancement of expenses obligations of the Company 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, 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; and those other risks and uncertainties that are described in the section titled "Risk Factors" in the quarterly report on Form 10-Q filed with the United States Securities and Exchange Commission (the "SEC") on November 7, 2022 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 September 30,		Nine Months Ended September 30,	
	2021	2022	2021	2022
Revenues:				
Revenues	$ —	$ 1,809,025	$ —	$ 5,380,570
Cost of revenues	—	(1,447,220)	—	(3,062,496)
Net revenues	—	361,805	—	2,318,074
Operating expenses:				
Research and development	2,687,341	2,648,794	6,690,317	6,408,353
General and administrative	1,404,823	1,732,666	3,565,013	5,321,262
Total operating expenses	4,092,164	4,381,460	10,255,330	11,729,615
Loss from operations	(4,092,164)	(4,019,655)	(10,255,330)	(9,411,541)
Interest and other income (loss), net	(2,540)	105,461	566,268	(70,421)
Net loss	$ (4,094,704)	$ (3,914,194)	$ (9,689,062)	$ (9,481,962)
Net loss per share, basic and diluted	$ (0.14)	$ (0.11)	$ (0.74)	$ (0.26)
Weighted average shares outstanding, basic and diluted	29,572,267	35,835,135	13,111,087	35,809,216

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2021	September 30, 2022 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,730,677	$ 26,224,260
Short-term investments	24,983,520	—
Accounts receivable, net	133,000	355,555
Prepaid expenses	2,196,557	1,921,993
Other current assets	1,436,616	205,921
Total current assets	40,480,370	28,707,729
Investments	11,522,050	11,268,500
Property and equipment, net	1,119,091	10,957,946
Other assets	393,318	419,027
Total assets	$ 53,514,829	$ 51,353,202
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	$ 223,664	$ 1,410,357
Accrued liabilities and other current liabilities	2,097,925	882,775
Total current liabilities	2,321,589	2,293,132
Debt	—	6,448,166
Other liabilities	—	56,676
Total liabilities	2,321,589	8,797,974
Commitments and contingencies (Note 7)		
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 35,836,135 shares issued at September 30, 2022	3,577	3,584
Additional paid-in capital	81,827,006	82,670,949
Accumulated deficit	(30,637,343)	(40,119,305)
Total stockholders' equity	51,193,240	42,555,228
Total liabilities and stockholders' equity	$ 53,514,829	$ 51,353,202