

**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): August 12, 2022**

**HCW Biologics Inc.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-40591**  
(Commission File Number)

**82-5024477**  
(IRS Employer  
Identification No.)

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

**33025**  
(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 August 12, 2022, HCW Biologics Inc. issued a press release announcing its financial results for the quarter ended June 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	<a href="#">Press release dated August 12, 2022.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**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: August 12, 2022

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

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**HCW Biologics Reports Second Quarter 2022 Financial Results  
And Recent Business Highlights**

**Miramar, FL – August 12, 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 second quarter ended June 30, 2022.

“We have achieved several milestones in the first half of 2022, and some important pieces of our strategic plan have fallen into place. First, we are now a clinical-stage company, with the entry of our lead product candidate, HCW9218, into the clinic in a solid tumor cancer trial. Our pancreatic study is not far behind, and we expect to initiate this clinical trial in the third quarter. Next, we have produced promising data in preclinical studies for our lead product candidate, HCW9302, in the treatment of proinflammatory diseases driven by activated inflammasomes. We used this data as a basis for a pivotal scientific paper for HCW9302 that we expect to be published in a high-impact, peer-reviewed journal by the end of the year,” stated Hing C. Wong, Ph.D., Founder and CEO of the Company. Dr. Wong continued, “By working with preeminent National Cancer Institute designated Comprehensive Cancer Centers, it appears that we have mitigated some of the risk for maintaining our expected rate of patient enrollment. At our current pace, we expect to be in a position to provide an early human-experience data readout from the clinical trials for HCW9218 by the end of 2022. While it is very early, we are encouraged by how patients are responding to HCW9218.”

Dr. Wong reported, “HCW Biologics has advanced one of our key strategic initiatives – establishing our own domestic manufacturing capability. We have committed to purchase a 36,000 square foot building in Miramar, Florida that will be the new headquarters for our offices, research labs, and manufacturing facility. To buildout our new facilities, our team will leverage their past experience in constructing similar facilities. We expect to complete the project by the end of 2023, and to move into our new facility shortly thereafter. Currently, contract manufacturers are experiencing backlogs of up to two years. With our own manufacturing facility, we believe we will have better control over our supply chain as we advance to later-stage clinical trials requiring additional clinical materials, as well as fulfilling our obligations to our licensee, Wugen.”

## Business Highlights:

- On May 19, 2022, the Masonic Cancer Center, University of Minnesota, announced that they opened a new Phase 1 solid tumor cancer clinical trial and treated their first patient with HCW9218, an injectable, bifunctional immunotherapeutic, developed by HCW Biologics Inc. This Phase 1, first-in-human clinical trial is enrolling patients that have advanced solid tumors with progressive disease after prior chemotherapies.
- On August 2, 2022, HCW Biologics was granted U.S. Patent No. 11,401,324 which contains claims for immunotherapeutic compounds comprised of a single-chain chimeric polypeptide with two target-binding domains on a scaffold made of an extracellular domain of human tissue factor. This patent provides protection for the underlying intellectual property on which the Company has based its lead product candidate, HCW9302. The issuance of the Company's first patent with such broad claims marks an important step in the evolution of its patent portfolio.
- On August 10, 2022, HCW Biologics committed to purchase a building located in Miramar, Florida for approximately \$10.0 million, as the Company's new headquarters. The Company received a commitment for a five-year term facility to finance the purchase, expansion, and improvement of the new property. An initial takedown equal to 65% of the purchase price will be funded on the closing date which is expected to be on August 15, 2022. The term facility may be increased to provide additional funding for expansion and improvements of the property; however, future borrowings will be subject to full credit approval and due diligence by the lender.

## Second Quarter 2022 Financial Results:

- **Cash and cash equivalents:** On June 30, 2022, the Company's cash balance was \$42.1 million, consisting of \$15.4 million in cash and cash equivalents, \$17.0 million in short-term investments, and \$9.7 million in long-term investments. Investments are all U.S. Treasury bills or notes. The Company estimates that the current cash balance, along with a commitment for a term facility for the purchase of the Company's new headquarters, is sufficient to fund operations and capital expenditures through the end of 2023.
- **Revenues:** Revenues were \$454,000 for the three-month period ended June 30, 2022, and there were no revenues in the three-month period ended June 30, 2021. Revenues were \$3.6 million for the six-month period ended June 30, 2022, and there were no revenues in the six-month period ended June 30, 2021. Revenues were derived exclusively from the sale of clinical development material to our licensee, Wugen.
- **Research and development (R&D) expenses:** R&D expenses were \$1.7 million for the three-month period ended June 30, 2021, as compared to \$2.0 million for the three-month period ended June 30, 2022, an 18% increase, due primarily to an increase in preclinical expenses. R&D expenses were \$4.0 million for the six-month period ended June 30, 2021, as compared to \$3.8 million for the six-month period ended June 30, 2022, a 5% decrease, due primarily to a decrease in manufacturing and materials expenses partially offset by an increase in preclinical expenses.

- **General and administrative (G&A) expenses:** G&A expenses were \$1.1 million for the three-month period ended June 30, 2021, as compared to \$1.7 million for the three-month period ended June 30, 2022, a 55% increase. G&A expenses were \$2.2 million for the six-month period ended June 30, 2021, as compared to \$3.6 million for the six-month period ended June 30, 2022, a 64% increase. These increases reflect higher salaries, benefits and related expenses 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, an increase for Board compensation under our non-employee director compensation program, and an increase in insurance costs and other expenses related to operating as a public company.
- **Net loss:** Net loss was \$2.8 million for the three-month period ended June 30, 2021, compared to \$3.5 million for the three-month period ended June 30, 2022. Net loss was \$5.6 million for in each of the six-month periods ended June 30, 2021 and June 30, 2022. Net loss for the six-month period ended June 30, 2021 included the impact of forgiveness of the Company's PPP loan. Net loss for the six-month period ended June 30, 2022 included the impact of unrealized loss on investments resulting from changes in interest rates.

**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 solid tumors that have progressed after prior chemotherapies. The FDA has also cleared HCW Biologics to initiate a Phase 1b clinical trial for HCW9218 in patients with advanced pancreatic cancer. 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 of our pancreatic study; the publication of a scientific paper; our ability and plan to provide an early human data readout; the build out of our new facilities; and our ability to reduce the risk of supply-related delays; the ability of HCW Biologics to protect its intellectual property through issued patents or otherwise; and cash balance and commitment for a term loan facility being sufficient to fund operations through the end of 2023. 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 Company’s annual report on Form 10-K filed with the United States Securities and Exchange Commission (the “SEC”) on March 29, 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:**

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**Condensed Statements of Operations**  
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2022	2021	2022
<b>Revenues:</b>				
Revenues	\$ —	\$ 454,000	\$ —	\$ 3,571,545
Cost of revenues	—	(287,200)	—	(1,615,276)
Net revenues	—	166,800	—	1,956,269
<b>Operating expenses:</b>				
Research and development	\$ 1,673,163	\$ 1,969,882	\$ 4,002,976	\$ 3,759,558
General and administrative	1,077,830	1,707,995	2,160,190	3,588,597
Total operating expenses	2,750,993	3,677,877	6,163,166	7,348,155
Loss from operations	(2,750,993)	(3,511,077)	(6,163,166)	(5,391,886)
Interest and other income (loss), net	631	516	568,808	(175,882)
Net loss	\$ (2,750,362)	\$ (3,510,561)	\$ (5,594,358)	\$ (5,567,768)
Less: cumulative preferred dividends earned in the period	(482,662)	—	(960,020)	—
Net loss available for distribution to common stockholders	\$ (3,233,024)	\$ (3,510,561)	\$ (6,554,378)	\$ (5,567,768)
Net loss per share, basic and diluted	\$ (0.66)	\$ (0.10)	\$ (1.34)	\$ (0.16)
Weighted average shares outstanding, basic and diluted	4,921,121	35,814,482	4,880,496	35,796,257



**HCW Biologics Inc.**  
**Condensed Balance Sheets**

	<u>December 31,</u> <u>2021</u>	<u>June 30,</u> <u>2022</u> <u>(unaudited)</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,730,677	\$ 15,420,331
Short-term investments	24,983,520	16,993,523
Accounts receivable, net	133,000	346,934
Prepaid expenses	2,196,557	1,397,497
Other current assets	1,436,616	470,021
Total current assets	40,480,370	34,628,306
Investments	11,522,050	11,302,870
Property and equipment, net	1,119,091	913,734
Other assets	393,318	563,512
Total assets	<u>\$ 53,514,829</u>	<u>\$ 47,408,422</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Liabilities		
Current liabilities:		
Accounts payable	\$ 223,664	\$ 296,207
Accrued liabilities and other current liabilities	2,097,925	848,340
Total current liabilities	2,321,589	1,144,547
Other liabilities	—	98,447
Total liabilities	2,321,589	1,242,994
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 35,823,923 shares issued at June 30, 2022	3,577	3,582
Additional paid-in capital	81,827,006	82,366,957
Accumulated deficit	(30,637,343)	(36,205,111)
Total stockholders' equity	51,193,240	46,165,428
Total liabilities and stockholders' equity	<u>\$ 53,514,829</u>	<u>\$ 47,408,422</u>

