

**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): May 13, 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 May 13, 2022, HCW Biologics Inc. issued a press release announcing its financial results for the quarter ended March 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated May 13, 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: May 13, 2022

By: /s/ Hing C. Wong
Hing C. Wong
Founder and Chief Executive Officer



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

Miramar, FL – May 13, 2022 – (GLOBE NEWSWIRE) -- HCW Biologics Inc. (the “Company” or “HCW Biologics”) (NASDAQ: HCWB), a biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation and age-related diseases, today reported financial results and recent business highlights for its first quarter ended March 31, 2022.

“We continue to successfully execute our clinical development strategy which is based on our unique approach toward inflammaging,” stated Hing C. Wong, Founder and CEO of HCW Biologics Inc. “HCW Biologics is developing immunotherapeutics that do not treat a single indication or symptom. Our approach is to treat a patient systemically to remove the underlying problems causing a condition.”

Dr. Wong continued, “Our plan is to use difficult-to-treat cancer indications as the gateway for clinical development of our lead product candidate, HCW9218. In preclinical studies, we have demonstrated that HCW9218 can effectively reduce therapy-induced cancer and normal tissue cellular senescence to augment the anti-tumor activities of chemotherapies and alleviate their side effects. In addition, HCW9218 has been shown to significantly enhance anti-tumor activity of immune checkpoint therapies in a preclinical setting.”

Dr. Wong further stated, “We believe that HCW9218 also has potential as a treatment for a broad range of age-related pathologies beyond cancer, through our discovery that HCW9218 can reduce accumulated senescent cells due to the naturally aging process or metabolic dysfunction, leading to the improvement of health span of experimental animals.”

Business Highlights:

- At the 105th Annual Meeting of the American Association of Immunologists held on May 6 -10, 2022, HCW Biologics showcased two novel groups of fusion molecules invented with the Company’s proprietary and versatile TOBI™ discovery platform. Two posters were presented which are available on the Company’s website:
 - A “kick and expand” strategy to generate large numbers of CIML NK cells for adoptive cell therapy for the treatment of cancer using novel fusion proteins HCW9201 and HCW9206.

- Robust human regulatory T cell expansion with fusion proteins HCW9302 and HCW9213 circumvents need for magnetic-bead or feeder cell approaches for adoptive cell therapy.
- On April 19, 2022, Dr. Hing Wong presented, “Bifunctional Immunotherapeutic HCW9218 for Cancer and Inflammation,” at the Third Annual International Conference on Cell and Experimental Biology. Dr. Wong presented preclinical data for the first time that showed results of the Company's investigational work related to the treatment of inflammation indications in naturally-aged mice. The Company believes these results demonstrate the potential of HCW9218 to fundamentally change the treatment of a broad range of diseases and conditions associated with aging, even aging itself, by enhancing health span that has been diminished with aging.

First Quarter 2022 Financial Results:

- Cash and cash equivalents: On March 31, 2022, the Company's cash balance was \$18.1 million, short-term investments were \$17.0 million and long-term investments were \$9.8 million. Investments are all U.S. Treasury bills or notes. The Company estimates that the current cash balance is sufficient to fund operations through the end of 2023.
- Revenues: Revenues were \$3.1 million for the three-month period ended March 31, 2022, and there were no revenues in the three-month period ended March 31, 2021. Revenues were derived from the sale of clinical development material to our licensee, Wugen.
- Research and development (R&D) expenses: R&D expenses were \$1.8 million for the three-month period ended March 31, 2022, as compared to \$2.3 million for the three-month period ended March 31, 2021. The 22% decrease in R&D expenses was driven primarily by a decrease in manufacturing and materials expenses and preclinical expenses.
- General and administrative expenses (G&A): G&A expenses were \$1.9 million for the three-month period ended March 31, 2022, as compared to \$1.1 million for the three-month period ended March 31, 2021. The 73% increase reflects 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 and an increase for Board compensation under our non-employee director compensation program, with a partial offset resulting from a decrease in performance-related bonuses.
- Net loss: Net loss was \$2.1 million for the three-month period ended March 31, 2022, compared to \$2.8 million for the three-month period ended March 31, 2021.

About HCW Biologics:

HCW Biologics is a biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span 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 FDA has cleared HCW Biologics to initiate a first-in-human Phase 1b clinical trial for HCW9218 in patients with advanced pancreatic cancer. The FDA has cleared the Masonic Cancer Center at the University of Minnesota to initiate a Phase 1 clinical trial for HCW9218 in patients with advanced solid tumors with progressive disease after prior chemotherapies. 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 ability of HCW9218 to treat a broad range of age-related pathologies beyond cancer, leading to the improvement of health span; ability of HCW9218 to fundamentally change the treatment of a broad range of diseases and conditions associated with aging by enhancing health span; and cash balance 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 March 31,	
	2021	2022
Revenues:		
Revenues	\$ —	\$ 3,117,545
Cost of revenues	—	(1,328,076)
Net revenues	—	1,789,469
Operating expenses:		
Research and development	\$ 2,329,812	\$ 1,789,678
General and administrative	1,082,360	1,880,601
Total operating expenses	3,412,172	3,670,279
Loss from operations	(3,412,172)	(1,880,810)
Interest and other income (loss), net	568,176	(176,397)
Net loss	\$ (2,843,996)	\$ (2,057,207)
Less: cumulative preferred dividends earned in the period	(477,358)	—
Net loss available for distribution to common stockholders	\$ (3,321,354)	\$ (2,057,207)
Net loss per share, basic and diluted	\$ (0.69)	\$ (0.06)
Weighted average shares outstanding, basic and diluted	4,839,871	35,778,032

HCW Biologics Inc.
Condensed Balance Sheets

	<u>December 31,</u> <u>2021</u>	<u>March 31,</u> <u>2022</u> (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,730,677	\$ 18,117,074
Short-term investments	24,983,520	16,969,298
Accounts receivable, net	133,000	553,007
Prepaid expenses	2,196,557	2,020,545
Other current assets	1,436,616	245,617
Total current assets	<u>40,480,370</u>	<u>37,905,541</u>
Investments	11,522,050	11,351,310
Property and equipment, net	1,119,091	1,012,402
Other assets	393,318	686,414
Total assets	<u>\$ 53,514,829</u>	<u>\$ 50,955,667</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	\$ 223,664	\$ 743,120
Accrued liabilities and other current liabilities	2,097,925	674,296
Total current liabilities	<u>2,321,589</u>	<u>1,417,416</u>
Other liabilities	—	139,597
Total liabilities	<u>2,321,589</u>	<u>1,557,013</u>
Commitments and contingencies		
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 35,779,489 shares issued at March 31, 2022	3,577	3,578
Additional paid-in capital	81,827,006	82,089,626
Accumulated deficit	<u>(30,637,343)</u>	<u>(32,694,550)</u>
Total stockholders' equity	<u>51,193,240</u>	<u>49,398,654</u>
Total liabilities and stockholders' equity	<u>\$ 53,514,829</u>	<u>\$ 50,955,667</u>

