

**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 09, 2023

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

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 May 9, 2023, HCW Biologics Inc. issued a press release announcing its financial results for the quarter ended March 31, 2023. 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 9, 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: May 9, 2023

By: /s/ Hing C. Wong

Hing C. Wong

Founder and Chief Executive Officer



HCW Biologics Reports First Quarter 2023 Financial Results And Recent Business Highlights

Miramar, FL – May 9, 2023 – 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, 2023.

“We measure our progress over the past year by the achievement of significant milestones: Initiating multiple clinical trials. Realizing the dream of establishing our own manufacturing facility. Publishing ground-breaking scientific papers,” stated Dr. Hing C. Wong, Founder and CEO of HCW Biologics.

Dr. Wong continued, “Our primary premise is our belief that rejuvenating the immune system creates a systemic change that reduces senescent cells and the proinflammatory factors they secrete. We have seen that HCW9218 can do both in relevant animal models. As we progress in our investigation of the underlying mechanism of HCW9218, we are also gaining a deeper understanding of how this drug works against solid tumors and how it augments anti-tumor activities of immune-checkpoint inhibitors.”

He added, “Our focus is to develop a treatment based on HCW9218 for some of the most difficult-to-treat cancers. But through our research, we believe we are seeing signs that point to its potential to treat other aging-associated diseases beyond cancer by reducing senescent cells. We believe this opens the door for using an immunotherapeutic approach to enhance healthspan.”

Business Highlights:

- On April 21, 2023, the Company entered into a \$26.25 million development line of credit to refinance an existing \$6.5 million mortgage and provide financing for the buildout of the Company's new headquarters and manufacturing facility. The five-year loan bears a fixed interest of 7.0% per annum with interest only payments for the full term.
- On March 26, 2023, the Company published a pivotal scientific paper in *Aging Cell* entitled, “Immunotherapeutic Approach to Reduce Senescent Cells and Alleviate Senescence-Associated Secretory Phenotype in Mice,” with Dr. Hing C. Wong as lead and corresponding author.

First Quarter 2023 Financial Results:

- **Revenues:** Revenues for the first quarter ended March 31, 2022 and 2023 were \$3.1 million and \$41,883, respectively. In the first quarter of 2022, deferred revenues related to historic transactions were recognized as revenue upon meeting all requirements for revenue recognition. 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 first quarter ended March 31, 2022 and 2023 were \$1.8 million and \$2.3 million, respectively. The \$466,135 increase, or 26%, resulted primarily from increased preclinical and clinical trial expenses.
- **General and administrative (G&A) expenses:** G&A expenses for the first quarter ended March 31, 2022 and 2023 were \$1.9 million and \$3.1 million, respectively. The \$1.2 million increase, or 66%, was primarily attributable to increases in professional fees, which includes legal fees associated with legal proceedings brought against the Company by Altor BioScience, LLC and NantCell, Inc., or Altor/NantCell.
- **Net loss:** Net loss for the first quarter ended March 31, 2022 and 2023 was \$2.1 million and \$5.1 million, respectively.

Financial Guidance

As disclosed above, the Company entered into a development line of credit agreement for the buildout of the Company's new headquarters and manufacturing facility. Funds formerly earmarked for this purpose will be redeployed for clinical development. The Company estimates that the cash and cash equivalents, short-term investments and the proceeds of the development line of credit extends the Company's cash runway into 2025.

On April 27, 2023, in connection with the Altor/NantCell matter, the U.S. District Court for the Southern District of Florida (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 will now proceed in arbitration before JAMS. 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. 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, legal expenses incurred by Dr. Wong in connection with the arbitration against him that was initiated by Altor/NantCell, will be covered through advancement of expenses from Altor/NantCell.

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 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 (Clinicaltrials.gov: NCT05322408). The Company is also enrolling patients in a Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in chemo-refractory/chemo-resistant advanced pancreatic cancer (Clinicaltrials.gov: NCT05304936). 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; timing and completion of the Company's manufacturing facility; ability of HCW9218 to rejuvenate the immune system to create systemic changes that reduce senescent cells and the proinflammatory factors they secrete; potential of HCW9218 to treat other aging-associated diseases beyond cancer; redeployment of funds to support clinical trials; timing and outcome of the Altor/NantCell arbitration and the Company's liability related thereto; the ability to project that cash and cash equivalents and investments are sufficient to fund operations into 2025; 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, the 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.

Company Contact:

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Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2022	2023
Revenues:		
Revenues	\$ 3,117,545	\$ 41,883
Cost of revenues	(1,328,076)	(29,350)
Net revenues	1,789,469	12,533
Operating expenses:		
Research and development	1,789,678	2,255,813
General and administrative	1,880,601	3,117,290
Total operating expenses	3,670,279	5,373,103
Loss from operations	(1,880,810)	(5,360,570)
Interest expense	—	(93,438)
Other (expense) income, net	(176,397)	383,322
Net loss	\$ (2,057,207)	\$ (5,070,686)
Net loss per share, basic and diluted	\$ (0.06)	\$ (0.14)
Weighted average shares outstanding, basic and diluted	35,778,032	35,883,779

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2022	March 31, 2023 Unaudited
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 22,326,356	\$ 18,389,659
Short-term investments	9,735,930	9,848,430
Accounts receivable, net	417,695	252,728
Prepaid expenses	1,394,923	1,132,694
Other current assets	196,015	316,963
Total current assets	34,070,919	29,940,474
Investments	1,599,751	1,599,751
Property, plant and equipment, net	10,804,610	11,741,176
Other assets	333,875	253,144
Total assets	\$ 46,809,155	\$ 43,534,545
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	\$ 1,226,156	\$ 1,164,562
Accrued liabilities and other current liabilities	1,730,325	3,357,346
Total current liabilities	2,956,481	4,521,908
Debt, net	6,409,893	6,386,234
Other liabilities	14,275	7,476
Total liabilities	9,380,649	10,915,618
Commitments and contingencies		
Stockholders' equity:		
Common stock:		
Common, \$0.0001 par value; 250,000,000 shares authorized and 35,876,440 shares issued at December 31, 2022; 250,000,000 shares authorized and 35,886,635 shares issued at March 31, 2023	3,588	3,589
Additional paid-in capital	82,962,964	83,224,070
Accumulated deficit	(45,538,046)	(50,608,732)
Total stockholders' equity	37,428,506	32,618,927
Total liabilities and stockholders' equity	\$ 46,809,155	\$ 43,534,545

