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 14, 2024

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 November 14, 2024, HCW Biologics Inc. issued a press release announcing its financial results for the quarter ended September 30, 2024. 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 14, 2024.
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 14, 2024

By: /s/ Hing C. Wong

Hing C. Wong
Founder and Chief Executive Officer

Exhibit 99.1

HCW Biologics Reports Third Quarter 2024
Financial Results and Business Highlights

Miramar, FL– November 14, 2024 – 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 third quarter ended September 30, 2024.

Dr. Hing C. Wong, Founder and CEO of HCW Biologics, stated, "In the third quarter 2024, the Company expanded our product portfolio and possible disease indications that may be treated with our immunotherapeutic compounds, consisting of compounds constructed using two different platforms. Our expanded portfolio now includes constructs with immune-cell engagers targeting tissue factor and other cell-surface antigens associated with diseased cells and multifunctional immunotherapeutic fusions which improve the performance of immune checkpoint inhibitors."

Business Highlights

- We filed the IND application to obtain approval from the FDA to evaluate HCW9302 in an autoimmune indication and we are currently progressing through the review process. HCW9302 is a category-defining immunotherapeutic designed to activate and expand regulatory T cells, which deactivate inflammasomes. The novel design results in an immunotherapeutic with the therapeutic advantages of IL-2 but that is well tolerated. We believe that these studies support the clinical development of HCW9302 as a potential therapeutic agent for treatment of a broad range of proinflammatory diseases. Our clinical development focus is autoimmune diseases, including alopecia areata, and neurodegenerative diseases.
- We launched our financing plan in the third quarter of 2024 with the conclusion of an arbitration that has hampered our ability to raise capital and complete business development transactions. In addition to equity financings, the Company has a strategic focus on business development transactions and establishing commercialization partnerships with innovative leaders in the immunotherapy field. On November 13, 2024, the Company engaged Maxim Group to act as the exclusive placement agent to execute a multi-step equity financing strategy.
- On September 25, 2024, the Company entered into a nonbinding term sheet with a well-known leader in immunology. Definitive agreements are being finalized with a closing expected in the fourth quarter of 2024. The proposed license agreement includes substantial guaranteed minimum payments which are expected within the first year of the term. The license is for a preclinical molecule created with our novel protein platform, and we consider this a validation of the potential and value of this preclinical molecule for human therapy.

- The Company has developed a new drug discovery platform with a novel protein-based scaffold. It has already used this novel protein scaffold to construct several immunotherapeutic fusions, for development by HCW Biologics or others. The clinical development plan assumes one or more molecules constructed with this novel platform to be in clinical development in 2026, either through a Company-owned program or through the clinical program of one of the Company's licensees.

Third Quarter 2024 Financial Results

- **Revenues:** Revenues for the quarter ended September 30, 2023 and 2024 were $853,102 and $426,423, respectively. Revenues for the nine months ended September 30, 2023 and 2024 were $1.5 million and $2.2 million, respectively. Revenues in both periods were derived exclusively from the sale of licensed molecules to the Company's licensee, Wugen. The licensed molecules are one of the components used in manufacturing Wugen's products.
- **Research and development (R&D) expenses:** R&D expenses for the quarter ended September 30, 2023 and 2024 were $1.7 million and $1.2 million, respectively, a decrease of $480,529, or 29%. In the three and nine months ended September 30, 2023, the Company incurred comparatively higher clinical expenses than it did in the comparable period in 2024, due to two ongoing clinical trials to evaluate HCW9218 in cancer. Similarly, in the three and nine months ended September 30, 2023, the Company incurred comparatively higher preclinical expenses that it did in the comparable period in 2024, due to costs incurred for the IND-enabling studies required for the IND application for HCW9302 including setup costs and toxicology studies. Manufacturing costs incurred in the nine months ended September 30, 2024 reflect costs incurred replenishing supply of the high-expressing cell line of HCW9101.
- **General and administrative (G&A) expenses:** G&A expenses for the quarter ended September 30, 2023 and 2024 were $1.5 million and $1.6 million, respectively, an increase of $129,216, or 9%. G&A expenses for the nine months ended September 30, 2023 and 2024 were $5.1 million and $4.8 million, respectively, a decrease of $307,237, or 6%. Changes in G&A expenses reflect cost cutting measures, offset by increases in professional fees, facilities and office expenses, and financing expenses.
- **Legal Expenses:** Legal expenses for the quarter ended September 30, 2023 and 2024 were $2.1 million and $1.0 million, respectively, a decrease of $1.1 million, or 54%. Legal expenses for the nine months ended September 30, 2023 and 2024 were $4.6 million and $15.8 million, respectively, an increase of $11.2 million, or 242%. The increase in legal expenses related to preparation of testimony and evidence for the hearing and the hearing itself in connection to the arbitration with ImmunityBio and its affiliates. There has since been a Settlement Agreement and parties have agreed to a stipulation to have the arbitration dismissed along with mutual general releases. See "Financial Guidance" below.
- **Net loss:** Net loss for the quarter ended September 30, 2023 and 2024 was $4.9 million and $3.9 million, respectively, a decrease of $1.0 million, or 21%. Net loss for the nine months ended September 30, 2023 and 2024 was $14.3 million and $26.7 million, respectively, an increase of $12.3 million, or 86%.

Financial Guidance

ImmunityBio and its affiliates initiated legal proceedings against the Company and Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, on December 31, 2022. Ultimately, legal proceedings against Company and Dr. Wong were consolidated in the arbitration before JAMS ("Arbitration"). As reported in the Company's Form 8-K filed on July 18, 2024, the parties entered into a confidential Settlement Agreement and Release (the "Settlement Agreement"). The Settlement Agreement includes mutual general releases by and among the parties thereto. No party is required to make any monetary payments to any other party or person under the Settlement Agreement and each party agreed to bear its own expenses incurred in connection with the matter. Remediation activities are substantially complete, and the parties agreed to the stipulation and dismissal of the Arbitration. With the execution of the Settlement Agreement, the Company resolved the attendant uncertainties for the outcome of the arbitration and additional complexities. However, the Company incurred substantial legal fees in its defense and for the defense of Dr. Wong. As of September 30, 2024, the Company reported $14.4 million in obligations for legal fees within accounts payable on its condensed balance sheet. The Company is engaged in discussions with the law firms involved with this matter to arrange a reasonable payment plan with respect to those legal fees.

As of September 30, 2024, the Company believes that substantial doubt exists regarding its ability to continue as a going concern for at least 12 months from the issuance date of the condensed interim financial statements, without additional funding or financial support. The Company launched a multi-faceted financing plan in the third quarter of 2024 to raise the capital required through equity financings and business development transactions to fund the future product development and operations of the Company.

A major objective of the financing strategy is to regain compliance with Listing Rules of the Nasdaq Stock Market LLC ("Nasdaq"). We were notified by Nasdaq staff that we are not in compliance with continued listing requirements on the Nasdaq Global Market. The Company was granted a period of 180 calendar days by Nasdaq in which to comply. The first deadline is currently scheduled for December 16, 2024. The Company intends to take all reasonable measures available to regain compliance with the continued listing requirements for the Nasdaq Global Market, and will utilize our right to appeal to Nasdaq to extend our deadline to regain compliance based on a solid financial plan to do so.

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, diabetes, neurodegenerative, and autoimmune diseases, as well as other inflammatory 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 two drug discovery platforms, each with a novel backbone which is used to generate designer, novel multi-functional fusion molecules with immunotherapeutic properties. The Company's legacy drug discovery platform is its TOBI™ (Tissue factOr-Based fusIon) discovery platform, has a Tissue-Factor based backbone. It was used to create HCW Biologics' molecules, HCW9218, HCW9302, HCW9206 and HCW9201. The Company's second drug discovery platform uses a unique protein-based backbone differentiated from Tissue Factor. Immunotherapeutics created with the Company's two distinct drug discovery platforms have different characteristics and mechanisms of action, expanding the various pathways for treating senescence-associated disorders. The University of Pittsburgh Medical Center has agreed to include HCW9218 in an Investigator-sponsored Phase 2 clinical trial in patients with metastatic, advanced stage ovarian cancer in combination with neoadjuvant chemotherapy (NCT05145569).

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: the Company's ability to develop new immunotherapeutic treatments for non-oncology or oncology indications; timing of initiation of studies for age-related diseases; the Company's ability to continue as a going concern and that after considering the elements of the Company's financing plan that were probable to occur within a year of the date of issuance, the Company concluded that substantial doubt was not alleviated in its going concern analysis; the Company's cash runway; the Company's expectations regarding future purchases of licensed molecules by Wugen; the Company's ability to finalize the license of a preclinical molecule; the issuance of the IND for HCW9302; the Company's future capital-raising plans and ability to continue with clinical development efforts until they are achieved, if at all; that the Company may receive feedback from the FDA on the IND application for HCW9302 which may not be given on a timely basis, or the Company may be required to change the design of the clinical protocol in order to address the feedback, potentially resulting in delays and increased costs; and Company's ability to pay legal fees incurred in connection with the arbitration with ImmunityBio and its affiliates. 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/A filed with the United States Securities and Exchange Commission (the "SEC") on May 15, 2024, the latest Form 10-Q filed with the SEC on August 14, 2024, 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.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2024**	**2023**	**2024**
Revenues:				
Revenues	$ 853,102	$ 426,423	$ 1,517,792	$ 2,171,988
Cost of revenues	(678,325)	(341,138)	(1,210,077)	(1,291,546)
Total revenues	174,777	85,285	307,715	880,442
Operating expenses:				
Research and development	1,667,442	1,186,913	5,539,919	5,339,383
General and administrative	1,509,936	1,639,152	5,106,674	4,799,437
Legal Expenses	2,075,279	949,455	4,610,091	15,761,531
Reserve for credit losses	—	—	—	1,300,000
Total operating expenses	5,252,657	3,775,520	15,256,684	27,200,351
Loss from operations	(5,077,880)	(3,690,235)	(14,948,969)	(26,319,909)
Interest expense	(95,514)	(223,363)	(284,465)	(383,029)
Other income, net	234,753	11,310	919,688	52,397
Net loss	$ (4,938,641)	$ (3,902,288)	$ (14,313,746)	$(26,650,541)

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2023	September 30, 2024 Unaudited
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,595,101	$ 998,221
Accounts receivable, net	1,535,757	651,840
Prepaid expenses	1,042,413	356,156
Other current assets	230,916	88,131
Total current assets	6,404,187	2,094,348
Investments	1,599,751	1,599,751
Property, plant and equipment, net	20,453,184	22,833,904
Other assets	56,538	28,476
Total assets	$ 28,513,660	$ 26,556,479
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Liabilities		
Current liabilities:		
Accounts payable	$ 6,167,223	$ 22,666,107
Accrued liabilities and other current liabilities	2,580,402	1,182,502
Total current liabilities	8,747,625	23,848,609
Debt, net	6,304,318	12,677,494
Total liabilities	15,051,943	36,526,103
Stockholders' equity (deficit):		
Common stock:		
Common, $0.0001 par value; 250,000,000 shares authorized and 36,025,104 shares issued at December 31, 2023; 250,000,000 shares authorized and 37,823,394 shares issued at September 30, 2024	3,603	3,782
Additional paid-in capital	83,990,437	87,209,457
Accumulated deficit	(70,532,323)	(97,182,863)
Total stockholders' equity (deficit)	13,461,717	(9,969,624)
Total liabilities and stockholders' equity (deficit)	$ 28,513,660	$ 26,556,479