UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from __________ to

Commission File Number: 001-40591

HCW Biologics Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-5024477**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. 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

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 8, 2023, the registrant had 35,888,135 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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 (Note 8)		
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

See accompanying notes to the unaudited condensed interim financial statements.

HCW Biologics Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31, 2022	Three Months Ended March 31, 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

See accompanying notes to the unaudited condensed interim financial statements.

HCW Biologics Inc.
Condensed Statements of Changes in Stockholders' Equity
For the Three Months Ended March 31, 2022 and 2023
(Unaudited)

	Stockholders' Equity				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance, December 31, 2021	35,768,264	$ 3,577	$ 81,827,006	$ (30,637,343)	$ 51,193,240
Issuance of Common Stock upon exercise of stock options	11,225	1	2,272	—	2,273
Stock-based compensation	—	—	260,348	—	260,348
Net loss	—	—	—	(2,057,207)	(2,057,207)
Balance, March 31, 2022	**35,779,489**	**$ 3,578**	**$ 82,089,626**	**$ (32,694,550)**	**$ 49,398,654**

	Stockholders' Equity				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance, December 31, 2022	35,876,440	$ 3,588	$ 82,962,964	$ (45,538,046)	$ 37,428,506
Issuance of Common Stock upon exercise of stock options	10,195	1	1,900	—	1,901
Stock-based compensation	—	—	259,206	—	259,206
Net loss	—	—	—	(5,070,686)	(5,070,686)
Balance, March 31, 2023	**35,886,635**	**$ 3,589**	**$ 83,224,070**	**$ (50,608,732)**	**$ 32,618,927**

See accompanying notes to the unaudited condensed interim financial statements.

HCW Biologics Inc.
Condensed Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2022	2023
Cash flows from operating activities:		
Net loss	$ (2,057,207)	$ (5,070,686)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	142,785	298,847
Stock-based compensation	260,348	259,206
Unrealized loss on investments, net	185,122	(112,500)
Reduction in the carrying amount of right-of-use asset	209	209
Changes in operating assets and liabilities:	—	
Accounts receivable	(420,007)	164,967
Prepaid expenses and other assets	1,380,215	182,294
Accounts payable and other liabilities	(1,071,084)	718,675
Operating lease liability	(12,543)	(79,225)
Net cash used in operating activities	(1,592,162)	(3,638,213)
Cash flows from investing activities:		
Purchases of property and equipment	(23,554)	(300,385)
Proceeds for sale or maturities of short-term investments	7,999,840	—
Net cash provided by (used in) investing activities	7,976,286	(300,385)
Cash flows from financing activities:		
Proceeds from issuance of common stock	2,273	1,901
Net cash provided by financing activities	2,273	1,901
Net changes in cash and cash equivalents	6,386,397	(3,936,697)
Cash and cash equivalents at the beginning of the period	11,730,677	22,326,356
Cash and cash equivalents at the end of the period	$ 18,117,074	$ 18,389,659
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ —	$ 93,438
Noncash operating, investing and financing activities:		
Operating lease liabilities arising from obtaining right-of-use assets	$ 306,509	$ —
Purchases of property and equipment included in accounts payable and other liabilities	$ —	$ 849,755

See accompanying notes to the unaudited condensed interim financial statements.

1. Organization and Summary of Significant Accounting Policies

Organization

HCW Biologics Inc. (the "Company") is a 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. The Company believes age-related low-grade chronic inflammation, or "inflammaging," is a significant contributing factor to several chronic diseases and conditions, such as cancer, cardiovascular disease, diabetes, neurodegenerative diseases, and autoimmune diseases. The Company is located in Miramar, Florida and was incorporated in the state of Delaware in April 2018.

Liquidity

As of March 31, 2023, the Company had not generated any revenue from commercial product sales of its internally-developed immunotherapeutic products for the treatment of cancer and other age-related diseases. In the course of its development activities, the Company has sustained operating losses and expects to continue to incur operating losses for the foreseeable future. Since inception, substantially all the Company's activities have consisted of research, development, establishing large-scale cGMP production for clinical trials, and raising capital. The Company's total revenues to date have been generated solely from the Wugen License and manufacturing and supply arrangement with Wugen. In the three months ended March 31, 2023, the Company recognized revenues of $41,883 from manufacturing and supply of materials for Wugen.

As of March 31, 2023, the Company had cash and cash equivalents of $18.4 million, and short-term investments of $9.8 million held in U.S. government-backed securities. Since inception to March 31, 2023, the Company incurred cumulative net losses of $47.5 million. Management expects to incur additional losses in the future to conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan. The Company intends to raise capital from non-dilutive funding sources such as bank financing, out-licensing rights to technology or markets, third-party collaboration funding, cooperative agreements for clinical trials, or other business development transactions, which may include additional debt or equity financing. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of some of its products.

Summary of Significant Accounting Policies

Basis of Presentation

Unaudited Interim Financial Information

The accompanying unaudited condensed interim financial statements as of March 31, 2023 and for the three months ended March 31, 2022 and 2023 have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Act of 1933, as amended (the “Securities Act”). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed interim financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company’s financial position and the results of its operations and cash flows. The results for the three months ended March 31, 2023 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The condensed balance sheet at December 31, 2022 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed interim financial statements and the notes accompanying them should be read in conjunction with the Company’s audited financial statements for the year ended December 31, 2022 which appear in the Company’s Annual Report on Form 10-K (No. 001-40591) filed for the year ended December 31, 2022 with the Securities and Exchange Commission (the “SEC”) on March 28, 2023 and in other filings with the SEC.

Revenue Recognition

The Company accounts for revenues in accordance with Accounting Standards Codification Topic 606, Revenue from Contracts with Customers (“Topic 606”). To determine revenue recognition for arrangements that fall within the scope of Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration it is entitled to in exchange for the goods or services transferred to the customer.

At contract inception, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. To date, the Company's revenues have been generated solely from transactions with Wugen. The Wugen License includes licenses of intellectual property, cost reimbursements, upfront signing fees, milestone payments and royalties on future licensee’s product sales. In addition, the Company and Wugen have an agreement for supply of materials, from which the Company also recognizes revenues.

License Grants:

For out-licensing arrangements that include a grant of a license to the Company’s intellectual property, the Company considers whether the license grant is distinct from the other performance obligations included in the arrangement. For licenses that are distinct, the Company recognizes revenues from nonrefundable, upfront payments and other consideration allocated to the license when the license term has begun and the Company has provided all necessary information regarding the underlying intellectual property to the customer, which generally occurs at or near the inception of the arrangement.

Milestone and Contingent Payments:

At the inception of the arrangement and at each reporting date thereafter, the Company assesses whether it should include any milestone and contingent payments or other forms of variable consideration in the transaction price using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur upon resolution of the uncertainty, the associated milestone value is included in the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of each such milestone and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Since milestone and contingent payments may become payable to the Company upon the initiation of a clinical study or filing for or receipt of regulatory approval, the Company reviews the relevant facts and circumstances to determine when the Company should update the transaction price, which may occur before the triggering event. When the Company updates the transaction price for milestone and contingent payments, the Company allocates the changes in the total transaction price to each performance obligation in the agreement on the same basis as the initial allocation. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment, which may result in recognizing revenue for previously satisfied performance obligations in such period. The Company’s licensees will generally pay milestones payments subsequent to achievement of the triggering event.

Materials Supply:

The Company provides clinical and research grade materials so that licensees may develop products based on the licensed molecules. The Company plans to enter into commercialization supply agreements when licensees enter the commercial stage of their company. The amounts billed are recognized as revenue as the performance obligations are satisfied by the Company, once the Company determines that a contract exists.

On June 18, 2021, the Company entered into a master services agreement ("MSA") for the supply of materials for clinical development of licensed products. On March 14, 2022, the Company entered into statements-of-work ("SOWs") contemplated under the MSA for all current and historical purchases of clinical and research grade materials. The Company determined that upon entering into the SOWs all requirements were met to qualify as a contract under Topic 606. The manufacturing of the clinical and research materials supplied by the Company each represents a single performance obligation that is satisfied over time. The Company recognizes revenue using an input method based on the costs incurred relative to the total expected cost, which determines the extent of the Company's progress toward completion. As part of the accounting for these arrangements, the Company must develop estimates and assumptions that require judgement to determine the progress towards completion. The Company reviews its estimate of the progress toward completion based on the best information available to recognize the cumulative progress toward completion as of the end of each reporting period, and makes revisions to such estimates, if facts and circumstances change during each reporting period.

For the three months ended March 31, 2023, the Company recognized $41,883 in revenue related to sale of development supply materials.

Investments

The Company holds a minority interest in Wugen which is accounted for using the measurement alternative whereby the investment is recorded at cost less impairment, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same investee. No impairment has been recognized. As of December 31, 2022 and March 31, 2023, the Company included $1.6 million for the investment in Wugen in Investments in the accompanying condensed balance sheets.

The Company invests net proceeds of its IPO in bills and notes issued by the U.S. Treasury which are classified as trading securities. As of March 31, 2023, the Company held $9.8 million in U.S. Treasury bills included in Short-term investments in the accompanying condensed balance sheet.

Operating Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in Other assets, Accrued liabilities and other current liabilities, and Other liabilities on its balance sheets. Operating lease Right of Use ("ROU") assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The Company has a lease agreement with lease and non-lease components, which are accounted for separately.

Net Loss Per Share

Basic loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during each period. Diluted loss per share of common stock includes the effect, if any, from the potential exercise of stock options and unvested shares of restricted stock, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.

2. Accrued Liabilities and Other Current Liabilities

As of December 31, 2022, the Company had a balance of $1.7 million included in Accrued liabilities and other current liabilities in the accompanying condensed balance sheet, consisting of $416,000 for legal expenses, $277,500 for clinical expenses, $524,000 for bonus expenses, $134,000 for salary and benefits, and $178,000 for a lease liability.

As of March 31, 2023, the Company had a balance of $3.4 million in Accrued liabilities and other current liabilities in the accompanying condensed balance sheet, consisting of $1.3 million for legal fees, $850,000 for construction in progress, $459,000 for clinical expenses, $365,000 for bonus payable, $146,000 for short-term lease liability, and $53,000 for salary and benefits.

3. Debt, Net

On August 15, 2022, the Company entered into a loan and security agreement (the “2022 Loan Agreement”) with Cogent Bank (“Cogent”), pursuant to which it received $6.5 million in gross proceeds to purchase a building that will become the Company's new headquarters. The loan is secured by a first priority lien on the building.

As of March 31, 2023, the Company had $6.5 million in gross principal outstanding in a loan under the 2022 Loan Agreement. The interest-only period is one year followed by 48 months of equal payments of principal and interest beginning on September 15, 2023 based on a 25-year amortization rate. The unamortized balance is due on August 15, 2027 (the “Maturity Date”), and bears interest at a fixed per annum rate equal to 5.75%. Upon the Maturity Date, a final payment of unamortized principal will be due. The Company is in compliance with all covenants as of March 31, 2023. The Company has the option to prepay the outstanding balance of the loan prior to the Maturity Date without penalty.

As of March 31, 2023, the current portion of $67,979 is included in Accrued liabilities and other current liabilities, and the noncurrent portion of $6.4 million is included in Debt, net in the accompanying condensed balance sheet.

4. Preferred Stock

At December 31, 2022 and March 31, 2023, the Company has 10,000,000 shares of preferred stock authorized and no shares issued.

5. Net Loss Per Share

The following table summarizes the computation of the basic and diluted net loss per share:

	Three Months Ended March 31,	
	2022	2023
Numerator:		
Net loss	$ (2,057,207)	$ (5,070,686)
Denominator:		
Weighted-average common shares outstanding	35,778,032	35,883,779
Net loss per share, basic and diluted	$ (0.06)	$ (0.14)

The following table summarizes the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive:

	At March 31,	
	2022	2023
Common stock options	1,745,630	1,856,463
Potentially diluted securities	1,745,630	1,856,463

6. Fair Value of Financial Instruments

The carrying amount of the Company's financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, U.S. government-backed securities with maturity dates up to one year, accounts payable and accrued liabilities, approximate fair value due to their short-term maturities.

Money market funds included in cash and cash equivalents and U.S. government-backed securities are measured at fair value based on quoted prices in active markets, which are considered Level 1 inputs. No transfers between levels occurred during the periods presented. The following table presents the Company's assets which were measured at fair value at December 31, 2022 and March 31, 2023:

	At December 31, 2022:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 19,458,020	$ —	$ —	$ 19,458,020
Treasury notes	9,735,930	—	—	9,735,930
Total	$ 29,193,950	$ —	$ —	$ 29,193,950

	At March 31, 2023:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 16,949,263	$ —	$ —	$ 16,949,263
Treasury notes	9,848,430	—	—	9,848,430
Total	$ 26,797,693	$ —	$ —	$ 26,797,693

7. Income Taxes

The Company computes its quarterly income tax expense/(benefit) by using a forecasted annual effective tax rate and adjusts for any discrete items arising during the quarter. The Company did not have a provision for income taxes (current or deferred tax expense) as of December 31, 2022 and March 31, 2023. The Company will continue to maintain a 100% valuation allowance on total deferred tax assets. The Company believes it is more likely than not that the related deferred tax assets will not be realized. As a result, the Company's effective tax rate will remain at 0.00% because no items either estimated or discrete items would impact the tax provision.

8. Commitments and Contingencies

Operating Leases

The Company has operating leases for approximately 12,250 square feet of space located in Miramar, Florida. The leases have a two-year term which commenced on March 1, 2022 and will terminate on February 29, 2024. Upon the commencement of the leases, the Company used its incremental borrowing rate of 6.0% to determine the amounts to recognize for a ROU asset and a lease liability. There are no obligations under finance leases.

The components of the lease expense for the three months ended March 31, 2023 were as follows:

	For the Three Months Ended March 31, 2023
Operating lease cost	$ 42,413

Supplemental cash flow information related to lease was as follows:

	For the Three Months Ended March 31, 2023
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows	$ 42,254
Right-of-use assets obtained in exchange for lease obligations:	
Operating lease	$ 39,717

As of March 31, 2023, the supplemental balance sheet information related to leases in the accompanying condensed balance sheet included a Right-of-Use Asset of $150,880 in Other assets; the current portion of a lease liability of $145,702 in Accrued liabilities and other current liabilities; and the noncurrent lease liability of $7,476 in Other liabilities, as follows:

	As of March 31, 2023
Operating lease right-of-use assets	$ 150,880
Operating lease liabilities, current	$ 145,702
Operating lease liabilities, net of current portion	7,476
Total operating lease liabilities	$ 153,178

For the three months ended March 31, 2022 and 2023, rent expense recognized by the Company was $38,883 and $43,950, respectively, of which $19,207 and $22,212, respectively, are included in research and development in the accompanying condensed statements of operations.

Contractual Commitments

The Company entered into an agreement with a third-party global contract development and manufacturer of biologics for the manufacture of the Company's proprietary molecules for use in clinical trials. At December 31, 2022 and March 31, 2023 , future payment obligations under such agreements were $406,000 and $1.5 million, respectively. In addition, as of December 31, 2022, the Company committed to purchase upstream processing and fluid management equipment for $1.6 million, and it advanced $495,000 for this purchase as of March 31, 2023.

Legal

From time to time, the Company is a party to or otherwise involved in legal proceedings, including suits, assessments, regulatory actions and investigations generally arising out of the normal course of business. In addition, the Company enters into agreements that may include indemnification provisions, pursuant to which the Company agrees to indemnify, hold harmless and defend the indemnified parties for losses suffered or incurred by the indemnified party. When the Company believes that the outcome of such a matter will result in a liability that is probable to be incurred and result in a potential loss, or range of loss, that can be reasonably estimated, the Company will accrue a liability and make the appropriate disclosure in the footnotes to the financial statements.

On December 23, 2022, Altor BioScience, LLC and NantCell, Inc. (“Altor/NantCell”) initiated an arbitration against Dr. Hing C. Wong, the Company’s Founder and Chief Executive Officer, in California alleging breach of contract and fiduciary duty, among other claims. On that same date, Altor/NantCell filed a lawsuit against the Company in federal court alleging misappropriation of trade secrets, inducement of breach of contract and breach of fiduciary duty, among other claims against the Company. On January 31, 2023, the Company filed a motion to compel arbitration, a motion for the stay of the litigation, and a motion to dismiss the complaint (“motion to compel”). On April 18, 2023, the U.S. District Court for the Southern District of Florida (the “Court”) heard oral argument on the Company’s motion to compel and ordered the parties to provide supplemental briefing by April 28, 2023. Before the Court ruled on the Company’s motion to compel, on April 26, 2023, the parties stipulated that Altor/NantCell’s action against the Company would be consolidated with the Altor/NantCell arbitration demand against Dr. Wong. On April 27, 2023, 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.

Inflationary Cost Environment, Banking Crisis, Supply Chain Disruption and the Macroeconomic Environment

Our operations have been affected by many headwinds, including inflationary pressures, rising interest rates, ongoing global supply chain disruptions resulting from increased geopolitical tensions such as the war between Russia and Ukraine, Chinese aggression towards Taiwan, financial market volatility and currency movements. These headwinds, specifically the supply chain disruptions, have adversely impacted our ability to procure certain services and materials, which in some cases impacts the cost and timing of clinical trials and IND-enabling activities. In addition, the Company may be impacted by inflation when procuring materials required for the buildout of our new headquarters, the costs for recruiting and retaining employees and other employee-related costs. Further, rising interest rates would also increase borrowing costs to the extent that the Company takes on any additional debt. The Company uses a number of strategies to effectively navigate these issues, including product redesign, alternate sourcing, and establishing contingencies in budgeting and timelines. However, the extent and duration of such events and conditions, and resulting disruptions to our operations, are highly unpredictable.

The Company had no exposure to a failed bank. The Company averts risks associated with such a crisis by holding minimum cash balances required for uninterrupted operations, federal funds money market fund, and U.S. government-backed securities. As of March 31, 2023, the Company held $16.9 million in a federal money market fund (the “Fund”) with an investment objective to seek to provide current income while maintaining liquidity and a stable share price of $1. The Fund invests at least 99.5% of its total assets in cash, U.S. government securities, and/or repurchase agreements that are collateralized solely by U.S. government securities or cash (collectively, government securities). As such , the Fund is considered one of the most conservative investment options available to safeguard cash and cash equivalents.

Lost-Lasting Effects of COVID-19

The length of time and full extent to which the COVID-19 pandemic directly or indirectly impacts the Company's business, results of operations and financial condition, including but not limited to the supply chain, manufacturing, clinical trials, research and development costs and employee-related costs, depends on future developments that are highly uncertain, subject to change and are difficult to predict. Additionally, the ongoing geopolitical tensions related to Chinese aggression toward Taiwan, the conflict in Ukraine, and the related sanctions and other penalties imposed, in addition to other financial pressures from inflation and higher interest rates, are creating substantial uncertainty in the global economy. The Company encountered some delays in the commencement of clinical trials as a result of clinical sites experiencing COVID-related delays due to staffing shortages and supply chain issues. In addition, the Company encountered some delays in the completion of studies required by the U.S. Federal Drug Administration to support Investigational New Drug Applications ("IND") due to government-mandated measures taken as a result of COVID outbreaks. The Company expects to be impacted by inflation, especially for materials required for the buildout of the Company's new headquarters and employee-related costs. These headwinds may have an adverse impact on the Company's ability to conduct clinical trials as well as IND-enabling activities, causing delays in our clinical development timeline. The Company uses a number of strategies to effectively navigate these issues, but the extent and duration of such events and conditions, and resulting disruptions to the Company's operations, are highly unpredictable.

9. Subsequent Events

Subsequent events have been evaluated through the date the financial statements were issued. As of such date, there were no material subsequent events identified that required recognition or disclosure other than as disclosed below or in the footnotes herein.

On April 21, 2023, the Company entered into a secured Development Line of Credit Agreement (the "Agreement") with Prime Capital Ventures, LLC, as lender (the "Lender"), pursuant to which the Lender shall advance loans to the Company in an aggregate principal amount not to exceed $26.3 million and a scheduled maturity date of April 20, 2028 (the "Maturity Date"). The note issued pursuant to the Agreement bears interest at a fixed rate of 7 percent per annum, due monthly in arrears on the first day of each month, and the outstanding principal on the note shall be due and payable in full on the Maturity Date.

On April 27, 2023 in legal proceedings brought against the Company by Altor/NantCell, 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 the lawsuit described above, 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 financial statements. See Note 8 to the accompanying notes to these unaudited condensed interim financial statements for more information about the legal proceedings with Altor/NantCell.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (i) our unaudited condensed interim financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and (ii) our audited financial statements and related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the fiscal year ended December 31, 2022 included in the Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 28, 2023. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to the "Company," "HCW Biologics," "HCWB", "we," "us" and "our" refer to HCW Biologics Inc.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this quarterly report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, adequacy of our cash resources and working capital, impact of COVID-19 pandemic on our research and development activities and business operations, and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A -"Risk Factors," in this Quarterly Report on Form 10-Q and in other filings we make with the SEC from time to time. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. These forward-looking statements speak only as of the date hereof. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Overview

HCW Biologics Inc. 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. We believe age-related, chronic, low-grade inflammation, or "inflammaging," is a significant contributing factor to several diseases and conditions, such as cancer, cardiovascular disease, diabetes, neurodegenerative diseases, and autoimmune diseases.

The induction and retention of low-grade inflammation in an aging human body is mainly the result of the accumulation of non-proliferative but metabolically active senescent cells, which can also be caused by persistent activation of protein complexes, known as inflammasomes, in innate immune cells. These two elements share common mechanisms in promoting secretion of pro-inflammatory proteins and in many cases interact to drive senescence, and thus, inflammaging. Our novel approach is to reduce senescent cells and eliminate the pro-inflammatory factors they secrete systemically through multiple pathways. We believe our approach has the potential to fundamentally change the treatment of age-related diseases. Our lead product candidates address the two primary processes that promote chronic inflammation.

HCW9218. Subcutaneous administration of our clinical-stage, lead drug candidate, HCW9218, activates NK cells, innate lymphoid group-1, and $CD8^+$ T cells, and neutralizes TGF-β. This bifunctionality gives HCW9218 the ability to reduce senescent cells as well as function as a senomorphic that eliminates senescence-associated pro-inflammatory factors. As a result, we believe HCW9218 has the ability to lower chronic inflammation and restore tissue homeostasis. This lead product candidate is currently being evaluated in two Phase 1/1b clinical trials for chemo-refractory/chemo-resistant solid tumor cancers.

HCW9302. Subcutaneous administration of our preclinical-stage, lead drug candidate, HCW9302, is designed to activate and expand T_{reg} cells to reduce senescence by suppressing the activity of inflammasome-bearing cells and the inflammatory factors which they secrete. This molecule is a single-chain, IL-2-based fusion protein. Preclinical studies in mouse models have demonstrated the ability of HCW9302 to expand and activate T_{reg} cells and reduce inflammation-related diseases, supporting the potential of HCW9302 to treat a wide variety of autoimmune and pro-inflammatory diseases, such as atherosclerosis. We are in the process of completing IND-enabling studies and intend to prepare and submit an Investigational New Drug ("IND") application to the FDA in 2023.

Recent Developments

- On April 27, 2023, in the legal proceedings brought by Altor BioScience, LLC and NantCell, Inc., or Altor/NantCell, the Court approved the parties' stipulation to move to arbitration and ordered the parties to proceed in arbitration before JAMS.
- 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.
- 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 Secretary Phenotype in Mice," with Dr. Hing C. Wong, the Company's Founder and CEO, as lead and corresponding author.

Trends and Uncertainties

Inflationary Cost Environment, Banking Crisis, Supply Chain Disruption and the Macroeconomic Environment

Our operations have been affected by many headwinds, including inflationary pressures, rising interest rates, ongoing global supply chain disruptions resulting from increased geopolitical tensions such as the war between Russia and Ukraine, Chinese aggression towards Taiwan, financial market volatility and currency movements. These headwinds, specifically the supply chain disruptions, have adversely impacted our ability to procure certain services and materials, which in some cases impacts the cost and timing of clinical trials and IND-enabling activities. In addition, the Company may be impacted by inflation when procuring materials required for the buildout of our new headquarters, the costs for recruiting and retaining employees and other employee-related costs. Further, rising interest rates would also increase borrowing costs to the extent that the Company takes on any additional debt. The Company uses a number of strategies to effectively navigate these issues, including product redesign, alternate sourcing, and establishing contingencies in budgeting and timelines. However, the extent and duration of such events and conditions, and resulting disruptions to our operations, are highly unpredictable.

On March 12, 2023, the U.S. government took extraordinary steps to stop a potential banking crisis after the historic failure of Silicon Valley Bank, assuring all depositors at the failed institution that they could access all their money quickly, even as another major bank was shut down. The Company had no exposure to a failed bank. The Company averts risks associated with such a crisis by holding minimum cash balances required for uninterrupted operations, federal funds money market fund, and U.S. government-backed securities. As of March 31, 2023, the Company held $17.0 million in a federal money market fund (the "Fund") with an investment objective is to seek to provide current income while maintaining liquidity and a stable share price of $1. The Fund invests at least 99.5% of its total assets in cash, U.S. government securities, and/or repurchase agreements that are collateralized solely by U.S. government securities or cash (collectively, government securities). As such it is considered one of the most conservative investment options offered.

Long-Lasting Effects of COVID-19

The spread of COVID-19, including the resurgence of cases related to the spread of new variants, has caused significant volatility in the U.S. and international markets since March 2020. The continuing direct and indirect impacts of the pandemic are significant and broad-based, including supply chain disruptions, and continue to represent business and financial risks. As such, the Company is continually coordinating with third-party contract manufacturing organizations ("CMOs"), service providers and vendors that constitute the Company's supply chain, with respect to risks and mitigating actions. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, IND-enabling activities, buildout of our new headquarters, business, financial condition, and results of operations.

Components of our Results of Operation

Revenues

We have no products approved for commercial sale and have not generated any revenue from commercial product sales of internally-developed immunotherapeutic products for the treatment of cancer and other age-related diseases. The principal source of our revenues to date have been generated from our Wugen License and Master Services Agreement (the "MSA") with Wugen. See Note 1 to our condensed financial statements included elsewhere in this Quarterly Report for these definitions and more information.

We derive revenue from a license agreement granting rights to Wugen to further develop and commercialize products based on two of our internally-developed molecules. Consideration under our contract included a nonrefundable upfront payment, development, regulatory and commercial milestones, and royalties based on net sales of approved products. Additionally, HCW Biologics retained manufacturing rights and has agreed to provide Wugen with clinical and research grade materials for clinical development and commercialization of licensed products under separate agreements. We assessed which activities in the Wugen License should be considered distinct performance obligations that should be accounted for separately. We develop assumptions that require judgement to determine whether the license to our intellectual property is distinct from the research and development services or participation in activities under the Wugen License.

Performance obligations relating to the granting a license and delivery of licensed product and R&D know-how were satisfied when transferred upon the execution of the Wugen License on December 24, 2020. The Company recognized revenue for the related consideration at a point in time. The revenue recognized from a transaction to supply clinical and research grade materials entered into under the MSA and covered by a Statement of Work ("SOW"), represents one performance obligation that is satisfied over time. The Company recognizes revenue generated for supply of material for clinical development using an input method based on the costs incurred relative to the total expected cost, which determines the extent of the Company's progress toward completion.

Operating Expenses

Our operating expenses are reported as research and development expenses and general and administrative expenses.

Research and Development

Our research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- Employee-related expenses, including salaries, benefits, and stock-based compensation expense;
- Expenses related to manufacturing and materials, consisting primarily of expenses incurred primarily in connection with CMOs, which produce cGMP materials for clinical trials on our behalf;
- Expenses associated with preclinical activities, including research and development and other IND-enabling activities;
- Expenses incurred in connection with clinical trials; and
- Other expenses, such as facilities-related expenses, direct depreciation costs for capitalized scientific equipment, and allocation for overhead.

We expense research and development costs as they are incurred. Costs for contract manufacturing are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the agreement, and the pattern of payments for goods and services will change depending on the material. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed.

We expect research and development expenses to increase substantially for the foreseeable future as we continue the development of our product candidates. We cannot reasonably determine the nature, timing, and costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. Product candidates in later stages of development generally have higher development costs than those in earlier stages. See "Risk Factors -- Risks Related to the Development and Clinical Testing of Our Product Candidates," in our Annual Report for the year ended December 31, 2022 filed with the SEC on March 28, 2023 for a discussion of some of the risks and uncertainties associated with the development and commercialization of our product candidates. Any changes in the outcome of any of these risks and uncertainties with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries, related benefits, and stock-based compensation expense for employees in the executive, legal, finance and accounting, human resources, and other administrative functions. General and administrative expenses also include third-party costs such as insurance costs, fees for professional services, such as legal, auditing and tax services, facilities administrative costs, and other expenses.

During the period ended December 31, 2022, Altor/NantCell, a former employer of Dr. Hing C. Wong, our Founder and Chief Executive Officer, initiated legal proceedings against Dr. Wong and the Company. On April 26, 2023, the parties stipulated that Altor/NantCell's action against the Company would be consolidated with the Altor/NantCell arbitration demand against Dr. Wong. On April 27, 2023, the U.S. District Court for the Southern District of Florida (the "Court") with jurisdiction over lawsuit against the Company 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. In connection with claims brought against Dr. Wong, Altor/NantCell has advancement obligations to him for claims brought against him. Thus, legal expenses incurred by him in connection with his arbitration will be advanced by Altor/NantCell; however, under certain circumstances, the Company may be required to advance his legal fees. The Company incurred legal expenses on its own behalf in the period ended March 31, 2023, and we expect to continue to incur material costs and expenses in connection with defending the Company in the foregoing legal matters for the remainder of the year.

We expect general and administrative expenses incurred in the normal course of business for other purposes, such as costs for recruitment and retention of personnel, service fees for consultants, advisors and accountants, as well as costs to comply with government regulations, corporate governance, internal control over financial reporting, insurance and other requirements for a public company, are expected to continue to increase for the foreseeable future as we scale our operations.

Interest and Other Income (Loss), Net

Interest and other income, net consists of interest earned on our cash, cash equivalents, unrealized gains and losses related to our investments in U.S. government-backed securities, other income related to non-operating activities, and other non-operating expenses.

On August 15, 2022, the Company entered into a short-term, market-rate lease with the former owner of the building purchased by the Company on the same date. The lease provides the former owner (tenant) with the right to occupy offices that comprise approximately 15,000 square feet of the building for a period of one year, ending August 14, 2023. The lease may be terminated at any time by the tenant with 60 days' written notice. During the three months ended March 31, 2023, the Company reported $59,453 in rental income, which is included within Interest and other income (loss), net in the unaudited statement of operations for the three months ended March 31, 2023, included elsewhere in this Quarterly Report.

Results of Operations

	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)**

Comparison of the Three Months ended March 31, 2022 and March 31, 2023

Revenues

The Company recognized $3.1 million and $41,883 of revenues in the unaudited statements of operations that appear elsewhere is this Quarterly Report for the three months ended March 31, 2022 and 2023, respectively. The difference in revenues for the comparative periods is primarily attributable to the recognition of deferred revenues as revenue in the three months ended March 31, 2022, upon meeting requirements for revenue recognition when the Company entered into SOWs with Wugen for current and historical purchases on March 14, 2022. For those transactions for which revenue was not recognized because one or more of the criteria for revenue recognition had not been met, the Company records deferred revenue. There were no deferred revenues as of March 31, 2022 and as of March 31, 2023.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2022 and March 31, 2023:

	Three Months Ended March 31,			
	2022	2023	$ Change	% Change
Salaries, benefits and related expenses	$ 772,949	$ 744,465	$ (28,484)	(4)%
Manufacturing and materials	219,038	284,905	65,867	30%
Preclinical expenses	513,117	737,686	224,569	44%
Clinical trials	109,367	246,358	136,991	125%
Other expenses	175,207	242,399	67,192	38%
Total research and development expenses	**$ 1,789,678**	**$ 2,255,813**	**$ 466,135**	26%

Research and development expenses increased by $466,135, or 26%, from $1.8 million for the three months ended March 31, 2022 to $2.3 million for the three months ended March 31, 2023. The increase was primarily due to an increase in preclinical expenses and clinical expenses.

Salaries, benefits, and related expenses decreased by $28,484, or 4%, from $772,949 for the three months ended March 31, 2022 to $744,465 for the three months ended March 31, 2023. This decrease was primarily attributable to a $59,000 increase in the amount of reimbursement for certain expenses incurred under the terms of the Wugen License as well as a $11,381 decrease in performance-based bonuses. These decreases were partially offset by an increase of $43,410 in salaries and wages, benefits, and stock-based compensation expenses.

Manufacturing and materials expense increased by $65,867, or 30%, from $219,038 for the three months ended March 31, 2022 to $284,905 for the three months ended March 31, 2023. In the three months ended March 31, 2022, costs were primarily from HCW9302 technology transfer and development process closeout through finalization of reports and the project initiation of a 1000L run for HCW9218. In the three months ended March 31, 2023, costs were primarily costs associated with a 200L cGMP run of HCW9302. Looking ahead for the remainder of 2023, costs will primarily be associated with restoring supply of HCW9101, which is the internally-developed affinity ligand used in our proprietary manufacturing processes in the production of all of our molecules.

Expenses associated with preclinical activities increased by $224,569, or 44%, from $513,117 for the three months ended March 31, 2022 to $737,686 for the three months ended March 31, 2023. Expenses were related primarily to the cost of toxicology studies and experimental materials related to IND-enabling activities required to prepare our IND for Phase 1b/2 clinical trial to evaluate HCW9302 in an autoimmune indication. We expect to complete the toxicology study in the first half of 2023.

Expenses associated with clinical activities increased by $136,991, or 125%, from $109,367 for the three months ended March 31, 2022 to $246,358 for the three months ended March 31, 2023 related to the two ongoing clinical trials to evaluate HCW9218 in chemo-resistant/chemo-refractory solid tumors. The Investigator-sponsored Phase 1 clinical trial at the Masonic Cancer Center, University of Minnesota is designed as a dose escalation study of HCW9218 to identify the maximum tolerated dose for future evaluation. The primary objectives are to determine safety, maximum tolerated dose, and the recommended Phase 2 dose. The Company expects this phase of the study to be complete in the first half of 2023. The Company-sponsored, multi-center Phase 1b/2 clinical trial to evaluate HCW9218 in advanced pancreatic cancer was initiated in October 2022. There are currently four clinical sites participating in this trial, including the NCI Center for Cancer Research, Medical University of South Carolina (an NCI-designated Comprehensive Cancer Center), Washington University in St. Louis (an NCI-designated Comprehensive Cancer Center), and HonorHealth Research Institute. A preliminary human data readout is expected in the first half of 2023. We expect to complete the Phase 1b portion of this study in 2023.

Other expenses, which include overhead allocations, increased by $67,191, or 38%, from $175,207 for the three months ended March 31, 2022 to $242,399 for the three months ended March 31, 2023. The increase in other expenses is due primarily to an increase of $55,773 in the allocation for depreciation. Depreciation increased in the third quarter of 2022, when the Company purchased a property to buildout for a new headquarters and manufacturing facility.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2022 and March 31, 2023:

	Three Months Ended March 31,			
	2022	**2023**	**$ Change**	**% Change**
Salaries, benefits and related expenses	$ 714,286	$ 819,778	$ 105,492	15 %
Professional services	459,164	1,707,588	1,248,424	272 %
Facilities and office expenses	100,679	122,221	21,542	21 %
Depreciation	35,605	69,213	33,608	94 %
Rent and occupancy expense	29,979	42,159	12,180	41 %
Other expenses	540,888	356,331	(184,557)	(34)%
Total general and administrative expenses	**$ 1,880,601**	**$ 3,117,290**	**$ 1,236,689**	66 %

General and administrative expenses increased $1.2 million, or 66%, from $1.9 million for the three months ended March 31, 2022 to $3.1 million for the three months ended March 31, 2023. The increase was primarily due to an increase in professional fees, which includes legal fees associated with the proceedings brought against the Company by Altor/NantCell. Other increases included a $105,492 increase in salaries, benefits and related expenses due to an annual adjustments made in April 2022 and new hires.

Depreciation increased by $33,608, or 94%, from $35,605 for the three months ended March 31, 2022 to $69,213 for the three months ended March 31, 2023. In the third quarter of 2022, the Company purchased a property to buildout for its new headquarters and manufacturing facility. As a result depreciation expense allocated to general and administrative expenses for the three months ended March 31, 2023 reflects depreciation of that acquisition.

Professional services increased $1.2 million, or 272%, from $459,164 for the three months ended March 31, 2022 to $1.7 million for the three months ended March 31, 2023. Professional services include corporate legal services, expenses related to legal actions brought by Altor/NantCell, and other professional services, such as auditing and tax advisory fees. For the three months ended March 31, 2023, the Company incurred $1.1 million for legal fees in connection with the Altor/NantCell matter, $359,754 for legal fees in connection to patents, and $233,007 in fees associated with other professional services such as audit fees and tax advisory services.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2023, our principal source of liquidity was $18.4 million in cash and cash equivalents, including money market investments, and $9.8 million held in U.S. government-backed securities presented in Short-term investments. These funds were provided primarily from the $49.2 million of net proceeds from our IPO and to a lesser extent the Wugen License. On April 21, 2023, the Company entered into a $26.3 million development line of credit agreement. We expect our principal sources of liquidity will continue to be our cash and cash equivalents, the development line of credit, out-licensing agreements, and any additional capital we may obtain through debt or equity offerings.

On August 15, 2022, we purchased a 36,000 square foot building located in Miramar, Florida for approximately $10.1 million, including transaction costs. A portion of the acquisition cost was funded with a $6.5 million five-year loan obtained from the Cogent Bank ("Cogent Loan") and is secured by the building. As of March 31, 2023, the Company owed $6.5 million on the Cogent Loan and was in compliance with all covenants under the Cogent Loan agreement and related documents. The Company obtained a $26.25 million development line of credit on April 21, 2023. We intend to repay the Cogent Loan with part of the proceeds from the development line of credit at the time we draw our first advance under the new loan agreement. We will not incur any prepayment penalties.

We believe that our cash and cash equivalents and short-term investments as of March 31, 2023 will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. We have based our projections of operation expenses requirements on assumptions, including our existing commitments and contingencies, that may prove to be incorrect, and we may use all of our available capital sooner than we expect. Because of the numerous risks and uncertainties associated with the clinical development and commercialization of immunotherapeutics, we are unable to estimate the exact amount of capital requirements to pursue these activities. Our funding requirements will depend on many factors, including, but not limited to:

- timing, progress, costs, and results of our ongoing preclinical studies and clinical trials of our immunotherapeutic products;
- impact of COVID-19 on the timing and progress of our IND-enabling activities, clinical trials and our ability to identify and enroll patients;
- costs, timing, and outcome of regulatory review of our product candidates;
- number of trials required for regulatory approval;
- whether we enter into any cooperative, collaboration or co-development agreements and the terms of such agreements;
- whether we raise additional funding through bank loan facilities, other debt arrangements, out-licensing or joint ventures, cooperative agreements or strategic collaborations;
- effect of competing technology and market developments;
- cost of maintaining, expanding, and enforcing our intellectual property rights;
- impact of arbitration, litigation, regulatory inquiries, or investigations, as well as costs to indemnify our officers and directors against third-party claims related to our patents and other intellectual property:
- cost and timing of buildout of new headquarters, including risks of cost overruns and delays, and ability to obtain additional financing, if needed; and
- costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive regulatory approval.

A change in the outcome of any of these or other factors with respect to the clinical development and commercialization of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures.

Comparison of the Cash Flows for the Three Months Ended March 31, 2022 and March 31, 2023

The following table summarizes our cash flows for the three months ended March 31, 2022 and March 31, 2023:

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2023
Cash used in operating activities	$ (1,592,162)	$ (3,638,213)
Cash provided by (used in) investing activities	7,976,286	(300,385)
Cash provided by financing activities	2,273	1,901
Net increase in cash and cash equivalents	**$ 6,386,397**	**$ (3,936,697)**

Operating Activities

Net cash used in operating activities were $1.6 million for the three months ended March 31, 2022, compared with net cash used by operating activities of $3.6 million for the three months ended March 31, 2023. The difference was primarily due to an increase in net loss from $2.1 million for the three months ended March 31, 2022 to $5.1 million for the three months ended March 31, 2023.

Cash used in operating activities for the three months ended March 31, 2022 consisted primarily of net loss for the period of $2.1 million, $420,000 due to an increase in accounts receivable arising from billed but unpaid amounts that were recognized in revenue for delivery of clinical development materials purchased by Wugen, and $1.1 million due to a decrease in accounts payable and other liabilities. Cash provided by operations consisted primarily of a decrease of $1.4 million in prepaid expenses and other assets. In addition, there were adjustments for non-cash transactions that increased cash provided by operating activities primarily arising from $185,122 for net unrealized loss on investments, $142,785 for depreciation and amortization expense, and $260,348 for compensation expense due to stock-based compensation.

Cash used in operating activities for the three months ended March 31, 2023 consisted primarily of net loss for the period of $5.1 million and $112,500 unrealized loss on investments, net. These amounts were offset by cash provided by operations arising from a $718,675 increase from accounts payable and other liabilities, $164,967 resulting from a decrease in accounts receivable, and $182,294 resulting from a decrease in prepaid expenses and other assets. Further offsets were provided by noncash adjustments arising from addbacks of $298,847 from depreciation and amortization and $259,206 from stock-based compensation.

Investing Activities

Cash provided by investing activities for the three months ended March 31, 2022 consisted of $8.0 million of cash provided when short-term investments reached maturity, offset by $23,554 of cash used to purchase equipment.

Cash used by investment activities for the three months ended March 31, 2023 consisted of $300,385 used for purchases of property and equipment.

Financing Activities

During the three months ended March 31, 2022 and 2023, cash provided by financing activities is due to issuance of common stock upon exercise of vested employee stock options.

Critical Accounting Policies, Significant Judgements and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed interim financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgements about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgements and estimates.

Revenue Recognition

We recognize revenue under the guidance of Topic 606. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of Topic 606, we perform the following five steps: (i) identification of the contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to our customer. See Note 1 to our condensed interim financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for more information.

Other than the above, there have been no material changes to our critical accounting policies and estimates from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies, Significant Judgements and Use of Estimates" in our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 28, 2023.

Recent Accounting Pronouncements

See Note 1 to our unaudited condensed interim financial statements appearing elsewhere in this Quarterly Report for more information about recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of March 31, 2023, we had cash and cash equivalents of $18.4 million and short-term investments in U.S. government-backed securities of $9.8 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. We are exposed to market risk related to the marketability of our Wugen common stock reported within Investments in the accompanying condensed balance sheet. Until such time as these shares become publicly traded, we will have limited access to liquidity for these securities.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended or the Exchange Act, is recorded, communicated to our management to allow timely decisions regarding required disclosure, summarized and reported within the time periods specified in the SEC's rules and forms. Any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgement in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including the Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of March 31, 2023. Based on that evaluation, the CEO and CFO have concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the quarter ended March 31, 2023, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On December 23, 2022, Altor BioScience, LLC and NantCell, Inc. initiated an arbitration against Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, in California alleging breach of contract and fiduciary duty, among other claims. On that same date, Altor/NantCell filed a lawsuit against the Company in the U.S. District Court for the Southern District of Florida (the "Court") alleging misappropriation of trade secrets, inducement of breach of contract and breach of fiduciary duty, among other claims against the Company. On January 31, 2023, the Company filed a motion to compel arbitration, a motion for the stay of the litigation, and a motion to dismiss the complaint ("motion to compel"). On April 18, 2023, the Court heard oral argument on the Company's motion to compel and ordered the parties to provide supplemental briefing by April 28, 2023. Before the Court ruled on the Company's motion to compel, on April 26, 2023, the parties stipulated that Altor/NantCell's action against the Company would be consolidated with the Altor/NantCell arbitration demand against Dr. Wong. On April 27, 2023, 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 the lawsuit described above, 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 financial statements.

Item 1A. Risk Factors.

There have been no material changes to the risk factors previously disclosed by us in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 28, 2023. The risk factors included in the Form 10-K continue to apply to us and describe risks and uncertainties that could cause actual results to differ materially from the results expressed or implied by the forward-looking statements contained in this Quarterly Report on Form 10-Q. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business, financial condition and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Unregistered Sales of Equity Securities

None.

Issuer Repurchases of Equity Securities

None.

Use of Proceeds

There has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus filed by us with the SEC on July 21, 2021.

Item 3. Defaults Upon Senior Securities.

Not Applicable.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.1	Development Line of Credit Agreement, dated as of April 20, 2023 by and between Prime Capital Ventures, LLC and HCW Biologics Inc.	8-K	04/27/2023	001-40591	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Condensed Balance Sheets as of December 31, 2022 and March 31, 2023 (unaudited); (ii) the Condensed Statements of Operations for the three months ended March 31, 2022 (unaudited) and March 31, 2023 (unaudited); (iv) the Condensed Statements of Changes in Stockholders' Equity for the three months ended March 31, 2022 (unaudited) and March 31, 2023 (unaudited); (v) the Condensed Statements of Cash Flows for the three months ended March 31, 2022 (unaudited) and March 31, 2023 (unaudited); and (vi) the notes to the Condensed Financial Statements (unaudited).				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				X

* This certification is deemed not filed for purpose of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

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 Chief Executive Officer (Principal Executive Officer)
Date: May 9, 2023	By:	/s/ Rebecca Byam
		Rebecca Byam Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Hing C. Wong, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HCW Biologics Inc. for the quarter ended March 31, 2023;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Hing C. Wong

Hing C. Wong
Chief Executive Officer

Date: May 9, 2023

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rebecca Byam, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HCW Biologics Inc. for the quarter ended March 31, 2023;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Rebecca Byam
Rebecca Byam
Chief Financial Officer

Date: May 9, 2023

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of HCW Biologics Inc. (the “Company”) on Form 10-Q for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 9, 2023

By: /s/ Hing C. Wong

Hing C. Wong
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of HCW Biologics Inc. (the “Company”) on Form 10-Q for the period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: May 9, 2023

By: /s/ Rebecca Byam

Rebecca Byam
Chief Financial Officer