

**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, 2022

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**

(State or other jurisdiction of  
incorporation or organization)

**82-5024477**

(I.R.S. Employer  
Identification No.)

**2929 N. Commerce Parkway  
Miramar, Florida**

(Address of principal executive offices)

**33025**

(Zip Code)

Registrant's telephone number, including area code: (954) 842-2024

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 12, 2022, the registrant had 35,796,457 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**

	<u>December 31,</u> <u>2021</u>	<u>March 31,</u> <u>2022</u> <u>(unaudited)</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,730,677	\$ 18,117,074
Short-term investments	24,983,520	16,969,298
Accounts receivable, net	133,000	553,007
Prepaid expenses	2,196,557	2,020,545
Other current assets	1,436,616	245,617
Total current assets	40,480,370	37,905,541
Investments	11,522,050	11,351,310
Property and equipment, net	1,119,091	1,012,402
Other assets	393,318	686,414
Total assets	<u>\$ 53,514,829</u>	<u>\$ 50,955,667</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Liabilities		
Current liabilities:		
Accounts payable	\$ 223,664	\$ 743,120
Accrued liabilities and other current liabilities	2,097,925	674,296
Total current liabilities	2,321,589	1,417,416
Other liabilities	—	139,597
Total liabilities	2,321,589	1,557,013
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock:		
Common, \$0.0001 par value; 250,000,000 shares authorized and 35,768,264 shares issued at December 31, 2021; 250,000,000 shares authorized and 35,779,489 shares issued at March 31, 2022	3,577	3,578
Additional paid-in capital	81,827,006	82,089,626
Accumulated deficit	(30,637,343)	(32,694,550)
Total stockholders' equity	51,193,240	49,398,654
<b>Total liabilities and stockholders' equity</b>	<u>\$ 53,514,829</u>	<u>\$ 50,955,667</u>

*See accompanying notes to the unaudited condensed interim financial statements.*

**HCW Biologics Inc.**  
**Condensed Statements of Operations**  
(Unaudited)

	Three Months Ended March 31,	
	2021	2022
<b>Revenues:</b>		
Revenues	\$ —	\$ 3,117,545
Cost of revenues	—	(1,328,076)
Net revenues	—	1,789,469
<b>Operating expenses:</b>		
Research and development	\$ 2,329,812	\$ 1,789,678
General and administrative	1,082,360	1,880,601
Total operating expenses	3,412,172	3,670,279
Loss from operations	(3,412,172)	(1,880,810)
Interest and other income (loss), net	568,176	(176,397)
Net loss	\$ (2,843,996)	\$ (2,057,207)
Less: cumulative preferred dividends earned in the period	(477,358)	—
Net loss available for distribution to common stockholders	\$ (3,321,354)	\$ (2,057,207)
Net loss per share, basic and diluted	\$ (0.69)	\$ (0.06)
Weighted average shares outstanding, basic and diluted	4,839,871	35,778,032

*See accompanying notes to the unaudited condensed interim financial statements.*

**HCW Biologics Inc.**  
**Condensed Statements of Changes in Redeemable Preferred Stock and Stockholders' (Deficit) Equity**  
**For the Three Months Ended March 31, 2021 and 2022**  
**(Unaudited)**

	Redeemable Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance, December 31, 2020</b>	6,316,691	\$ 6,140,792	12,012,617	\$ 13,680,306	5,439,112	\$ 11,294,301	4,793,393	\$ 480	\$ —	\$ (16,718,877)	\$ (16,718,397)
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	88,702	8	13,377	—	13,385
Stock-based compensation	—	—	—	—	—	—	—	—	641	—	641
6% cumulative dividends on redeemable preferred stock	—	95,992	—	213,971	—	167,395	—	—	(14,018)	(463,340)	(477,358)
Accretion of issuance costs	—	—	—	3,929	—	10,200	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(2,843,996)	(2,843,996)
<b>Balance, March 31, 2021</b>	<u>6,316,691</u>	<u>\$ 6,236,784</u>	<u>12,012,617</u>	<u>\$ 13,898,206</u>	<u>5,439,112</u>	<u>\$ 11,471,896</u>	<u>4,882,095</u>	<u>\$ 488</u>	<u>\$ —</u>	<u>\$ (20,026,213)</u>	<u>\$ (20,025,725)</u>

	Redeemable Preferred Stock						Stockholders' Equity				
	Series A		Series B		Series C		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance, December 31, 2021</b>	—	\$ —	—	\$ —	—	\$ —	35,768,264	\$ 3,577	\$ 81,827,006	\$ (30,637,343)	\$ 51,193,240
Issuance of Class A 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)
<b>Balance, March 31, 2022</b>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>35,779,489</u>	<u>\$ 3,578</u>	<u>\$ 82,089,626</u>	<u>\$ (32,694,550)</u>	<u>\$ 49,398,654</u>

*See accompanying notes to the unaudited condensed interim financial statements.*

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

	Three Months Ended March 31,	
	2021	2022
<b>Cash flows from operating activities:</b>		
Net loss	\$ (2,843,996)	\$ (2,057,207)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	158,806	142,785
Stock-based compensation	—	260,348
Gain on extinguishment of debt	(567,311)	—
Unrealized loss on investments, net	—	185,122
Reduction in the carrying amount of right-of-use asset	—	209
Changes in operating assets and liabilities:		
Accounts receivable	1,200,000	(420,007)
Prepaid expenses and other assets	(150,356)	1,380,215
Accounts payable and other liabilities	713,055	(1,071,084)
Operating lease liability	—	(12,543)
Net cash used in operating activities	(1,489,802)	(1,592,162)
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(23,279)	(23,554)
Proceeds for sale or maturities of short-term investments	—	7,999,840
Net cash (used in) provided by investing activities	(23,279)	7,976,286
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock	13,385	2,273
Offering Costs	(100,000)	—
Net cash (used in) provided by financing activities	(86,615)	2,273
Net changes in cash and cash equivalents	(1,599,696)	6,386,397
Cash and cash equivalents at the beginning of the period	8,455,834	11,730,677
<b>Cash and cash equivalents at the end of the period</b>	<b>\$ 6,856,138</b>	<b>\$ 18,117,074</b>
<b>Non-cash operating, investing and financing activities:</b>		
Cumulative dividends earned and accrued in the reporting period	\$ 477,358	\$ —
PPP loan forgiveness	\$ 567,311	\$ —
Offering costs	\$ 200,000	\$ —
Operating lease liabilities arising from obtaining right-of-use assets	\$ —	\$ 306,509

*See accompanying notes to the unaudited condensed interim financial statements.*

**HCW Biologics Inc.**  
**Notes to Condensed Financial Statements**  
**(Unaudited)**

**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 health span 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.

**Reverse Stock Split**

In June 2021, the Company’s board of directors and stockholders approved an amendment to the Company’s certificate of incorporation to effect a 3-for-7 reverse stock split for all issued and outstanding common stock, redeemable preferred stock, and stock options, that was effective on June 25, 2021 (the “Reverse Stock Split”). The number of authorized shares and the par values of the common stock and redeemable preferred stock were not adjusted as a result of the Reverse Stock Split. The accompanying condensed interim financial statements and notes to the condensed interim financial statements give retroactive effect to the Reverse Stock Split for all periods presented.

**Liquidity**

As of March 31, 2022, 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 principally from the Wugen License and manufacturing and supply arrangement with Wugen. In the three months ended March 31, 2022, the Company recognized revenues of \$3.1 million from manufacturing and supply of materials for Wugen.

On July 19, 2021, the Company’s registration statement on Form S-1 for its initial public offering (“IPO”) was declared effective by the Securities and Exchange Commission (the “SEC”). On July 22, 2021, the Company closed its IPO with the sale of 7,000,000 shares of common stock, at a public offering price of \$8.00 per share, resulting in net proceeds of approximately \$49.2 million, after deducting underwriting discounts and commissions and estimated offering expenses paid by the Company. The IPO met the provisions for mandatory conversion of all shares of redeemable preferred stock according to the designations for these securities. As a result of the conversion, the Company issued 23,768,416 shares of common stock to the former holders of redeemable preferred stock. In addition, as a result of conditions for mandatory conversion, the Company was relieved of its obligation to pay \$2.8 million in cumulative dividends that were accrued and unpaid on the conversion date.

As of March 31, 2022, the Company had cash and cash equivalents of \$18.1 million, short-term investments of \$17.0 million held in U.S. government-backed securities, and long-term investments of \$9.8 million held in U.S. government-backed securities. Since inception to March 31, 2022, the Company incurred cumulative net losses of \$30.0 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 through the issuance of additional equity financing and/or third-party collaboration funding. 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, 2022 and for the three months ended March 31, 2021 and 2022 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, 2022 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, 2021 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, 2021 which appear in the Company's Annual Report on Form 10-K (No. 333-256510) filed for the year ended December 31, 2021 with the Securities and Exchange Commission (the "SEC") on March 29, 2022 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 the Wugen License. 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.

##### *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. No contract existed in prior reporting periods and all amounts received for the supply of materials were recorded as deferred revenue. 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, 2022, the Company recognized \$3.1 million in revenue related to sale of development supply materials.

### **Deferred Revenue**

Deferred revenue represents amounts billed, or in certain cases, yet to be billed to the Company's customer for which the related revenues have not been recognized because one or more of the revenue recognition criteria has not been met. The Company had deferred revenue of \$239,000 and nil as of March 31, 2021 and 2022, respectively. All deferred revenue balances are current liabilities and reported within Accrued liabilities and other current liabilities.

### **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 March 31, 2021 and 2022, the Company included \$1.6 million for the investment in Wugen in Investments in the accompanying condensed balance sheet.

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, 2022, the Company held \$17.0 million in U.S. Treasury bills included in Short-term investments and \$9.8 million in U.S. Treasury notes included in 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 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.

## Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (“Topic 842”), which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. The Company adopted Topic 842 as of January 1, 2022. Effective March 1, 2022, the Company entered into noncancelable operating leases for its current location with a two-year term. These are the only leases in scope of Topic 842 or above the Company's capitalization threshold.

## 2. Accrued Liabilities and Other Current Liabilities

As of December 31, 2021, the Company had a balance of \$2.1 million in Accrued liabilities and other current liabilities, consisting of \$1.8 million related to deferred revenue, \$48,750 related to manufacturing materials, \$51,000 related to legal fees, and \$50,000 for other expenses. On January 8, 2021, the Company received full loan forgiveness of \$567,311 for obligations related to the PPP loan. The Company accounted for the PPP loan as debt, and the loan forgiveness was accounted for as a debt extinguishment.

As of March 31, 2022, the Company had a balance of \$674,000 in Accrued liabilities and other current liabilities, consisting of \$229,000 related to salary and benefits, \$167,000 related to short term lease liability, and \$278,000 related to other current liabilities which were primarily accrued legal fees and clinical fees.

## 3. Redeemable Preferred Stock

On July 22, 2021, the Company closed on its IPO, and the requirements for mandatory conversion were met. All outstanding shares of Series A, Series B, and Series C Preferred Stock converted into an equal number of shares of common stock. As a result, the rights, preferences, and terms ascribed to these shares are no longer applicable. Cumulative dividends of \$2.8 million accrued as of the conversion date were forfeited and such forfeiture was recognized through Additional paid-in capital.

At December 31, 2021 and March 31, 2022, the Company has 10,000,000 shares of preferred stock authorized and no shares issued.

## 4. Net Loss Per Share

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

	Three Months Ended March 31,	
	2021	2022
<b>Numerator:</b>		
Net loss	\$ (2,843,996)	\$ (2,057,207)
Less: cumulative preferred dividends earned in the period	(477,358)	—
Net loss available for distribution to common stock holders	<u>\$ (3,321,354)</u>	<u>\$ (2,057,207)</u>
<b>Denominator:</b>		
Weighted-average common shares outstanding	4,839,871	35,778,032
Net loss per share, basic and diluted	<u>\$ (0.69)</u>	<u>\$ (0.06)</u>

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,	
	2021	2022
Redeemable Preferred Stock	23,768,416	—
Common stock options	653,345	1,745,630
Potentially diluted securities	<u>24,421,761</u>	<u>1,745,630</u>

## 5. 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, 2021 and March 31, 2022:

	At December 31, 2021:			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 9,506,499	\$ —	\$ —	\$ 9,506,499
Treasury bills	24,983,520	—	—	24,983,520
Treasury notes	9,922,300	—	—	9,922,300
Total	<u>\$ 44,412,319</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 44,412,319</u>

  

	At March 31, 2022:			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$ 16,294,805	\$ —	\$ —	\$ 16,294,805
Treasury bills	16,969,298	—	—	16,969,298
Treasury notes	9,751,560	—	—	9,751,560
Total	<u>\$ 43,015,663</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 43,015,663</u>

## 6. 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, 2021 and March 31, 2022. 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 asset 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.

## 7. 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, 2022 were as follows:

	Three Months Ended March 31, 2022
Operating lease cost	\$ 13,929

Supplemental cash flow information related to lease was as follows:

	Three Months Ended March 31,
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows	\$ 13,929
Right-of-use assets obtained in exchange for lease obligations:	
Operating lease	\$ 12,543

As of March 31, 2022, the supplemental balance sheet information related to leases were as follows:

	<b>March 31, 2022</b>
Operating lease right-of-use assets	\$ 306,300
Other current liabilities	\$ 166,912
Operating lease liabilities, net of current portion	139,597
Total operating lease liabilities	<u>\$ 306,509</u>

As of March 31, 2022, the remaining lease payments were as follows:

2022 (remaining 9 months)	\$ 125,358
2023	171,322
2024	28,693
Total future minimum lease payments	<u>\$ 325,373</u>

For the three months ended March 31, 2021 and 2022, rent expense recognized by the Company was \$31,516 and \$38,883, respectively, of which \$14,431 and \$19,207, respectively, is included in research and development in the accompanying condensed statements of operations.

### **Contractual Commitments**

The Company operates under the provisions of agreements 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, 2021, future payment obligations under such agreements were \$2.5 million of which approximately \$181,600 was paid in January 2022. At March 31, 2022, future payment obligations under such agreements were \$2.1 million.

### **Legal**

Management has no knowledge of any pending or unasserted claims against the Company.

### **Other**

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a pandemic, which continues to spread throughout the United States and the world. The spread of COVID-19 has caused significant volatility in the U.S. and international markets. There is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the U.S. and international economies and, as such, the Company is unable to determine if it will have a material impact to its operations.

### **8. Subsequent Events**

Subsequent events have been evaluated through the date the financial statements were available to be 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.

## 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 (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, 2021 included in the Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 29, 2022. 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," "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 our Annual Report on Form 10-K, elsewhere in this Quarterly Report on Form 10-Q and in other filings we make with the Securities and Exchange Commission, or 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. ("HCW Biologics", "HCW", the "Company, or "we") is a biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation and age-related diseases. 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 senescent cells and 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 inflammaging. Our novel approach is to treat both of these elements. We believe our approach has the potential to fundamentally change the treatment of age-related diseases.

Senescence is a physiologic process important in promoting wound healing, tissue homeostasis, regeneration, embryogenesis, fibrosis regulation, and tumorigenesis suppression. However, accumulation of senescent cells with a senescence-associated pro-inflammatory factors has been implicated as a major source of chronic sterile inflammation leading to many aging-related pathologies. Subcutaneous administration of our lead drug candidate, HCW9218, activates Natural Killer ("NK") cells, innate lymphoid group-1, and CD8<sup>+</sup> T cells, and neutralizes transforming growth factor beta ("TGF-β"). This bifunctionality gives HCW9218 the ability to reduce senescent cells, that is function as a senolytic, as well as eliminate senescence-associated pro-inflammatory factors, that is function as a senomorphic. As a result, HCW9218 has the ability to lower chronic inflammation and restore tissue homeostasis. HCW9218 is expected to reach the clinical stage of its development in the first half of 2022, with the

initiation of a Phase 1 clinical trial by the Masonic Cancer Center to evaluate HCW9218 in the treatment of solid tumor cancers that progressed after standard-of-care treatment, and the initiation of a Company-sponsored Phase 1b clinical trial to evaluate HCW9218 in patients with advanced pancreatic cancer. We expect to gain human data from these two clinical trials in cancer that will guide the future development of HCW9218 for other age-related pathologies. (See ClinicalTrials.gov: HCW9218 for Advanced Pancreatic Cancer (NCT05304936) and HCW9218 in Select Advanced Solid Tumors (NCT05322408)). We believe that HCW9218 may represent a new class of safe and effective senolytic and senomorphic drugs for the treatment of a broad range of inflammaging indications, including cancer, metabolic dysfunctions, fibrosis-related pathologies, as well as neuro-inflammation and neurodegenerative diseases.

HCW9302 is another lead drug candidate which is designed to activate and expand regulatory T (“T<sub>reg</sub>”) cells to suppress 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 activate T<sub>reg</sub> cells and reduce inflammation-related diseases, supporting the potential of HCW9302 to treat a wide variety of autoimmune and age-related diseases, such as atherosclerosis. IND-enabling activities are currently in progress and are expected to be completed by the end of 2022. If we are successful in completing IND-enabling activities on the expected schedule, we intend to file an Investigational New Drug Application (“IND”) to obtain approval from the Federal Drug Administration (“FDA”) for a Phase 1b/2 clinical trial to evaluate HCW9302 in an autoimmune disorder in the first half of 2023.

## Recent Developments

- At the 105th Annual Meeting of the American Association of Immunologists held in May 2022, HCW Biologics showcased two novel groups of fusion molecules created with the Company’s proprietary and versatile TOBI™ discovery platform. Two posters were presented at the conference and are available on the Company’s website:
  - A “kick and expand” strategy to generate large numbers of Cytokine-Induced-Memory-Like NK cells for adoptive cell therapy for the treatment of cancer using novel fusion proteins HCW9201 and HCW9206.
  - Robust human regulatory T cell expansion with fusion proteins HCW9302 and HCW9213 circumvents need for magnetic-bead or feeder cell approaches for adoptive cell therapy.
- On April 19, 2022, Dr. Hing Wong, the Company's Founder and CEO, presented, “Bifunctional Immunotherapeutic HCW9218 for Cancer and Inflammaging,” at the Third Annual International Conference on Cell and Experimental Biology. Dr. Wong presented preclinical data for the first time that showed results of the Company's investigational work related to the treatment of inflammaging indications in naturally-aged mice. We believe these results demonstrate the potential of HCW9218 to fundamentally change the treatment of a broad range of diseases and conditions associated with aging, even aging itself, to enhance health span that has been diminished with aging.

## Trends and Uncertainties – COVID-19 Pandemic

The spread of COVID-19 and its numerous variants has caused significant volatility in the U.S. and international markets since March 2020. There is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the U.S. and international economies and, as such, we are unable to determine if it will have a material impact on our operations.

The extent to which the COVID-19 or outbreaks of its variants may affect our clinical trials, business, financial condition, and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the potential spread of the vaccine/treatment-resistant disease, the duration of the outbreaks, travel restrictions, and actions to contain the outbreaks or treat their impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures, or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, 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. Our total revenues to date have been generated principally from our Wugen License and manufacturing and supply for Wugen.

We derive revenue from a license agreement granting rights to Wugen to further develop and commercialize products based on two of our proprietary 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 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.

### **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 third-party contract manufacturing organizations ("CMO"), that 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.
- 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 on Form 10-K for the year ended December 31, 2021 filed with the SEC 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.

We expect that our general and administrative expenses will be higher in the foreseeable future. We anticipate increased expenses relating to our operations as a public company, including increased costs for the hiring of additional personnel, and for payment to outside consultants, including lawyers and accountants, to comply with additional regulations, corporate governance, internal control and similar requirements applicable to public companies, as well as increased costs for insurance.

### 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.

### Results of Operations

	Three Months Ended March 31,	
	2021	2022
<b>Revenues:</b>		
Revenues	\$ —	\$ 3,117,545
Cost of revenues	—	(1,328,076)
Net revenues	—	1,789,469
<b>Operating expenses:</b>		
Research and development	\$ 2,329,812	\$ 1,789,678
General and administrative	1,082,360	1,880,601
Total operating expenses	3,412,172	3,670,279
Loss from operations	(3,412,172)	(1,880,810)
Interest and other income (loss), net	568,176	(176,397)
<b>Net loss</b>	<b>\$ (2,843,996)</b>	<b>\$ (2,057,207)</b>

### Comparison of the Three Months ended March 31, 2021 and March 31, 2022

#### Revenues

As of March 31, 2021, the Company did not recognize any revenues. For the three months ended March 31, 2022, the Company recognized \$3.1 million of revenues in the unaudited statements of operation that appear elsewhere in this Quarterly Report. 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.

#### Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2021 and March 31, 2022:

	Three Months Ended March 31,		\$ Change	% Change
	2021	2022		
Salaries, benefits and related expenses	\$ 696,971	\$ 772,949	\$ 75,978	11 %
Manufacturing and materials	762,052	219,038	(543,014)	(71) %
Preclinical expenses	676,342	513,117	(163,225)	(24) %
Clinical trials	49,965	109,367	59,402	119 %
Other expenses	144,482	175,207	30,725	21 %
<b>Total research and development expenses</b>	<b>\$ 2,329,812</b>	<b>\$ 1,789,678</b>	<b>\$ (540,134)</b>	<b>(23) %</b>

Research and development expenses decreased \$540,134, or 23%, from \$2.3 million for the three months ended March 31, 2021 to \$1.8 million for the three months ended March 31, 2022. This decrease was primarily due to a decrease in manufacturing and materials expenses and preclinical expenses. These decreases were offset by increases in salaries, benefits and related expenses; clinical trials expenses; and other expenses.

Salaries, benefits, and related expenses increased by \$75,978, or 11%, from \$696,971 for the three months ended March 31, 2021 to \$772,949 for the three months ended March 31, 2022. This increase was primarily attributable to a \$68,353 increase in salaries and wages due to an increase in headcount. There was an increase of \$17,324 due to increases in health insurance costs, 401(K) employers match, and employers contribution to health savings accounts. Compensation expense arising from vesting of stock options increased by \$9,237. These increases were offset by a reimbursement from Wugen for certain expenses incurred under the terms of the Wugen License that was \$16,000 greater for the three months ended March 31, 2022 versus the comparable period in 2021.

Manufacturing and materials expense decreased by \$543,014, or 71%, from \$762,052 for the three months ended March 31, 2021 to \$219,038 for the three months ended March 31, 2022. In the three months ended March 31, 2021, costs were primarily from a 200-liter cGMP run for HCW9218, establishment of the HCW9206 Master Cell Bank, the initiation of the technology transfer and development runs for HCW9206, and the initiation of manufacturing of HCW9302. 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. Looking ahead for the remainder of 2022, costs will primarily be associated with HCW9302 GMP process closeout through finalization of reports, HCW9302 Fill/Finish activities, HCW9302 drug substance and drug product release testing, and a full 1000L GMP manufacturing run and fill/finish activities for HCW9218.

Expenses associated with preclinical activities decreased by \$163,225, or 24%, from \$676,342 for the three months ended March 31, 2021 to \$513,117 for the three months ended March 31, 2022. In the three months ended March 31, 2021, expenses were related primarily to the cost of toxicology studies and experimental materials for IND-enabling activities required to prepare our IND for clinical trials to evaluate HCW9218 in difficult-to-treat solid tumor cancers. In the three months ended March 31, 2022, expenses were related primarily to the cost of toxicology studies and experimental materials related to IND-enabling activities required to prepare our IND for clinical trials to evaluate HCW9302 in an autoimmune indication, alopecia areata.

Expenses associated with clinical activities increased \$59,402, or 119%, from \$49,965 for the three months ended March 31, 2021 to \$109,367 for the three months ended March 31, 2022. We anticipate expenses related to clinical activities will increase substantially in the future. HCW9218, our lead drug candidate, is expected to enter the clinical stage in the first half of 2022, upon the initiation of an Investigator-sponsored Phase 1 clinical trial at the Masonic Cancer Center, University of Minnesota for a dose escalation study of HCW9218 as a monotherapy in solid tumors, such as breast, ovarian, prostate and colorectal cancers. The trial is designed as a dose escalation study of HCW9218 to identify the maximum tolerated dose for future evaluation. Depending on the toxicities observed in the treated patients, between 12 and 24 patients may be enrolled. We also intend to initiate a Company-sponsored Phase 1b clinical trial to evaluate HCW9218 in advanced pancreatic cancer in the first half of 2022. We plan to enroll up to 24 patients in five NCI-designated centers, with the primary objectives of the study being to determine safety, maximum tolerated dose, and the recommended Phase 2 dose.

Other expenses, which include overhead allocations, increased by \$30,725, or 21%, from \$144,482 for the three months ended March 31, 2021 to \$175,207 for the three months ended March 31, 2022. The increase in other expenses is due primarily to an increase of \$7,000 in occupancy expenses, an increase of \$13,525 in repairs and maintenance, and a \$7,465 increase in employee conferences and training.

#### *General and Administrative Expenses*

The following table summarizes our general and administrative expenses for the three months ended March 31, 2021 and March 31, 2022:

	Three Months Ended March 31,		\$ Change	% Change
	2021	2022		
Salaries, benefits and related expenses	\$ 499,222	\$ 714,286	\$ 215,064	43%
Professional services	393,624	459,164	65,540	17%
Facilities and office expenses	59,725	100,679	40,954	69%
Depreciation	66,642	35,605	(31,037)	(47)%
Rent expense	24,996	29,979	4,983	20%
Other expenses	38,151	540,888	502,737	NM
<b>Total general and administrative expenses</b>	<b>\$ 1,082,360</b>	<b>\$ 1,880,601</b>	<b>\$ 798,241</b>	<b>74%</b>

NM - Not meaningful.

General and administrative expenses increased \$798,241, or 74%, from \$1.1 million for the three months ended March 31, 2021 to \$1.9 million for the three months ended March 31, 2022. The increase was primarily due to an increase in salaries,

benefits and related expenses as a result of stock-based compensation expense associated with an equity award to the CEO upon completion of the IPO and an increase for Board compensation under our non-employee director compensation program, offset by a reduction in performance bonuses.

Professional services increased \$65,540, or 17%, from \$393,624 for the three months ended March 31, 2021 to \$459,164 for the three months ended March 31, 2022, primarily due to a \$101,074 increase for corporate legal services, an \$85,863 increase in expenses for other professional services, such as auditing, and a \$114,240 increase in other consulting services, such as investor relations advisory services. These increases were offset by a decrease of \$240,338 in fees for legal services related to patent filings. Other expenses increased by \$502,737, primarily due to increase in insurance costs required by a public company.

## Liquidity and Capital Resources

### Sources of Liquidity

The Company closed an IPO on July 22, 2021, resulting in net proceeds of approximately \$49.2 million, after deducting underwriting discounts and commissions and offering expenses paid by the Company. As of March 31, 2022, we had cash and cash equivalents of \$18.1 million, short-term investments in U.S. government-backed securities of \$17.0 million, and long-term investments in U.S. government-backed securities of \$9.8 million. We estimate that we will have adequate capital to meet our operating expenses and contractual obligations until the end of 2023.

We have based our projections of operation expenses requirements on assumptions 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 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 collaboration or co-development agreements and the terms of such agreements;
- effect of competing technology and market developments;
- cost of maintaining, expanding, and enforcing our intellectual property rights; 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, 2021 and March 31, 2022

The following table summarizes our cash flows for the three months ended March 31, 2021 and March 31, 2022:

	Three Months Ended March 31,	
	2021	2022
Cash used in operating activities	\$ (1,489,802)	\$ (1,592,162)
Cash (used in) provided by investing activities	(23,279)	7,976,286
Cash (used in) provided by financing activities	(86,615)	2,273
<b>Net decrease in cash and cash equivalents</b>	<b>\$ (1,599,696)</b>	<b>\$ 6,386,397</b>

#### *Operating Activities*

Net cash used in operating activities were \$1.5 million for the three months ended March 31, 2021 and \$1.6 million for the three months ended March 31, 2022, respectively.

Cash used in operating activities for the three months ended March 31, 2021 consisted primarily of net loss for the period of \$2.8 million, a decrease of \$150,356 due to an increase in prepaid expenses and other assets, and an adjustment for a non-cash charge of \$567,311 resulting from the forgiveness of the PPP loan and accrued interest. These were offset by cash provided by operating activities resulting from a decrease in accounts receivable, an increase in accounts payable and other liabilities, and an adjustment for a non-cash charge for depreciation and amortization. Accounts receivable decreased by \$1.2 million, primarily due to the collection of a payment of \$1.2 million from Wugen Inc. Accounts payable and other liabilities increased by \$713,055 primarily due to increases of \$239,000 in deferred revenue, \$194,000 in accrued legal expenses, and \$221,000 in accounts payable. An adjustment for non-cash charges for depreciation and amortization provided cash from operations of \$158,806.

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.

#### *Investing Activities*

Cash used in investing activities for the three months ended March 31, 2021 consisted of purchases of equipment.

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.

#### *Financing Activities*

During the three months ended March 31, 2021, cash used by financing activities is due to the offering costs, offset by cash provided by issuance of common stock upon the exercise of vested employee stock options. During the three months ended March 31, 2022, 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.

During the three months ended March 31, 2022, the Company determined that since we now have an effective MSA and SOWs for all current and historical purchases of development supply of clinical materials with Wugen, a contract exists. We assessed all current and previous transaction to determine the timing and amount of revenue to recognize. 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, 2021, which was filed with the SEC on March 29, 2022.

## **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.**

We are exposed to market risk related to changes in interest rates. On July 22, 2021, we closed our IPO and invested our proceeds in U.S. Treasury securities. As of March 31, 2022, we had cash and cash equivalents of \$18.1 million, short-term investments in U.S. government-backed securities of \$17.0 million, and long-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, 2022. 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, 2022, 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.

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently a party to any material legal proceedings. We may, however, be involved in material legal proceedings in the future. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows.

### 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, 2021 filed with the SEC on March 29, 2022. 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.

		<u>Incorporated by Reference</u>			
<u>Exhibit Number</u>		<u>Descript</u> <u>ion</u>	<u>Form</u>	<u>Date</u>	<u>Filed</u> <u>Herewith</u>
31.1*	<a href="#">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.</a>				X
31.2*	<a href="#">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.</a>				X
32.1*	<a href="#">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.</a>				X
32.2*	<a href="#">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.</a>				X
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Condensed Balance Sheets as of December 31, 2021 and March 31, 2022 (unaudited); (ii) the Condensed Statements of Operations for the three months ended March 31, 2021 (unaudited) and March 31, 2022 (unaudited); (iv) the Condensed Statements of Stockholders' Equity as of March 31, 2021 (unaudited) and March 31, 2022 (unaudited); (v) the Condensed Statements of Cash Flows for the three months ended March 31, 2021 (unaudited) and March 31, 2022 (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 13, 2022

By: /s/ Hing C. Wong  
Hing C. Wong  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 13, 2022

By: /s/ Rebecca Byam  
Rebecca Byam  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

**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, 2022;
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

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Hing C. Wong  
Chief Executive Officer

Date: May 13, 2022

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**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, 2022;
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 13, 2022

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**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, 2022 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 13, 2022

By: \_\_\_\_\_ /s/ Hing C. Wong  
**Hing C. Wong**  
**Chief Executive Officer**

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**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, 2022 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 13, 2022

By: \_\_\_\_\_ /s/ Rebecca Byam  
**Rebecca Byam**  
**Chief Financial Officer**

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