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 September 30, 2021

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 November 12, 2021, the registrant had 35,728,112 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, 2020	September 30, 2021 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,455,834	$ 15,125,073
Short-term investment	—	24,989,700
Accounts receivable, net	2,500,000	70,000
Prepaid expenses	538,306	1,990,890
Other current assets	654,528	1,383,436
Total current assets	12,148,668	43,559,099
Investments	1,599,750	11,577,850
Property and equipment, net	1,649,668	1,269,001
Total assets	$ 15,398,086	$ 56,405,950
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	$ 155,343	$ 637,193
Accrued liabilities and other current liabilities	845,741	1,757,309
Total current liabilities	1,001,084	2,394,502
Commitments and contingencies (Note 7)		
Redeemable preferred stock:		
Series A, $0.0001 par value; 14,738,948 shares authorized and 6,316,691 shares issued at December 31, 2020; nil shares authorized or issued at September 30, 2021	6,140,792	—
Series B, $0.0001 par value; 28,029,449 shares authorized and 12,012,617 shares issued at December 31, 2020; nil shares authorized or issued at September 30, 2021	13,680,306	—
Series C, $0.0001 par value; 18,181,818 shares authorized and 5,439,112 shares issued at December 31, 2020; nil shares authorized or issued at September 30, 2021	11,294,301	—
Total redeemable preferred stock	31,115,399	—
Stockholders' (deficit) equity:		
Common stock:		
Class B convertible, $0.0001 par value; 10,000,000 shares authorized and 4,285,714 shares issued at December 31, 2020; nil shares authorized or issued at September 30, 2021	429	—
Common, $0.0001 par value; 74,950,215 shares authorized and 507,680 shares issued at December 31, 2020; 250,000,000 shares authorized and 35,728,112 shares issued at September 30, 2021	51	3,573
Additional paid-in capital	—	81,471,813
Accumulated deficit	(16,718,877)	(27,463,938)
Total stockholders' (deficit) equity	(16,718,397)	54,011,448
Total liabilities, redeemable preferred stock and stockholders' (deficit) equity	$ 15,398,086	$ 56,405,950

See accompanying notes to the unaudited condensed interim financial statements.

HCW Biologics Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2021	2020	2021
Operating expenses:				
Research and development	$ 2,098,688	$ 2,687,341	$ 5,845,895	$ 6,690,317
General and administrative	609,944	1,404,823	2,039,738	3,565,013
Total operating expenses	2,708,632	4,092,164	7,885,633	10,255,330
Loss from operations	(2,708,632)	(4,092,164)	(7,885,633)	(10,255,330)
Interest and other income, net	(374)	(2,540)	22,627	566,268
Net loss	$ (2,709,006)	$ (4,094,704)	$ (7,863,006)	$ (9,689,062)
Less: cumulative preferred dividends earned in the period, net of forfeitures	(282,861)	—	(842,433)	—
Net loss available for distribution to common stockholders	$ (2,991,867)	$ (4,094,704)	$ (8,705,439)	$ (9,689,062)
Net loss per share, basic and diluted	$ (0.63)	$ (0.14)	$ (1.84)	$ (0.74)
Weighted average shares outstanding, basic and diluted	4,743,823	29,572,267	4,728,816	13,111,087

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 Nine Months Ended September 30, 2020 and 2021
(Unaudited)

	Redeemable Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance, December 31, 2019	6,316,691	$ 5,792,302	12,012,617	$ 12,883,859	—	$ —	4,717,542	$ 472	$ —	$ (9,676,766)	$ (9,676,294)
Stock-based compensation	—	—	—	—	—	—	—	—	76	—	76
6% cumulative dividends on redeemable preferred stock	—	86,646	—	193,140	—	—	—	—	(76)	(279,710)	(279,786)
Accretion of issuance costs	—	—	—	7,857	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(2,375,514)	(2,375,514)
Balance, March 31, 2020	**6,316,691**	**5,878,948**	**12,012,617**	**13,084,856**	**—**	**—**	**4,717,542**	**472**	**—**	**(12,331,990)**	**(12,331,518)**
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	20,742	2	2,304	—	2,306
Stock-based compensation	—	—	—	—	—	—	—	—	9,515	—	9,515
6% cumulative dividends on redeemable preferred stock	—	86,646	—	193,140	—	—	—	—	(11,819)	(267,967)	(279,786)
Accretion of issuance costs	—	—	—	3,929	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(2,778,485)	(2,778,485)
Balance, June 30, 2020	**6,316,691**	**5,965,594**	**12,012,617**	**13,281,925**	**—**	**—**	**4,738,284**	**474**	**—**	**(15,378,442)**	**(15,377,968)**
Issuance of Series C Redeemable Preferred Stock, net of issuance costs	—	—	—	—	3,004,048	6,141,940	—	—	—	—	—
Commitment of Series C Redeemable Preferred Stock	—	—	—	—	2,435,064	5,000,000	—	—	—	—	—
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	6,685	1	813	—	814
Stock-based compensation	—	—	—	—	—	—	—	—	1,752	—	1,752
6% cumulative dividends on redeemable preferred stock	—	87,599	—	195,262	—	—	—	—	(2,565)	(280,296)	(282,861)
Accretion of issuance costs	—	—	—	3,929	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(2,709,006)	(2,709,006)
Balance, September 30, 2020	**6,316,691**	**$ 6,053,193**	**—**	**12,012,617**	**$ 13,481,116**	**5,439,112**	**$ 11,141,940**	**4,744,969**	**$ 475**	**$ —**	**$ (18,367,744)**	**$ (18,367,269)**

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 Nine Months Ended September 30, 2020 and 2021 Continued
(Unaudited)

	Redeemable Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2020	6,316,691	$ 6,140,792	12,012,617	$ 13,680,306	5,439,112	$ 11,294,301	4,793,394	$ 480	$ —	$ (16,718,877)	$ (16,718,397)
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	88,706	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)
Balance, March 31, 2021	**6,316,691**	**6,236,784**	**12,012,617**	**13,898,206**	**5,439,112**	**11,471,896**	**4,882,100**	**488**	**—**	**(20,026,213)**	**(20,025,725)**
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	73,500	8	9,457	—	9,465
Stock-based compensation	—	—	—	—	—	—	—	—	9,578	—	9,578
6% cumulative dividends on redeemable preferred stock	—	97,058	—	216,348	—	169,256	—	—	(19,035)	(463,627)	(482,662)
Accretion of issuance costs	—	—	—	3,929	—	10,198	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(2,750,362)	(2,750,362)
Balance, June 30, 2021	**6,316,691**	**6,333,842**	**12,012,617**	**14,118,483**	**5,439,112**	**11,651,350**	**4,955,600**	**496**	**—**	**(23,240,202)**	**(23,239,706)**
Issuance of common stock upon initial public offering, net of issuance cost	—	—	—	—	—	—	7,000,000	700	49,239,247	—	49,239,947
Conversion of Series A Redeemable Preferred Stock, with forfeited cumulative dividends	(6,316,691)	(6,333,842)	—	—	—	—	6,316,691	632	6,353,474	(20,265)	6,333,842
Conversion of Series B Redeemable Preferred Stock, with forfeited cumulative dividends	—	—	(12,012,617)	(14,118,483)	—	—	12,012,613	1,201	14,170,312	(53,030)	14,118,483
Conversion of Series C Redeemable Preferred Stock, with forfeited cumulative dividends	—	—	—	—	(5,439,112)	(11,651,350)	5,439,112	544	11,706,544	(55,737)	11,651,350
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	4,096		576		576
Stock-based compensation	—	—	—	—	—	—	—	—	1,660		1,660
Net loss	—	—	—	—	—	—	—	—	—	(4,094,704)	(4,094,704)
Balance, September 30, 2021	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**35,728,112**	**$ 3,573**	**$ 81,471,813**	**$ (27,463,938)**	**$ 54,011,448**

See accompanying notes to the unaudited condensed interim financial statements.

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

	Nine Months Ended September 30,	
	2020	**2021**
Cash flows from operating activities:		
Net loss	$ (7,863,006)	$ (9,689,062)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	432,225	448,013
Gain on extinguishment of debt	—	(567,311)
Changes in operating assets and liabilities:		
Accounts receivable	—	2,430,000
Prepaid expenses and other assets	19,595	(2,181,492)
Accounts payable and other liabilities	517,017	1,960,729
Net cash used in operating activities	(6,894,169)	(7,599,123)
Cash flows from investing activities:		
Purchases of property and equipment	(150,291)	(27,411)
Purchases of short-term investments	—	(24,989,700)
Purchases of long-term investments	—	(9,977,900)
Net cash used in investing activities	(150,291)	(34,995,011)
Cash flows from financing activities:		
Proceeds from the sale of Series C Preferred Stock	6,168,319	—
Proceeds from initial public offering	—	56,000,000
Issuance costs of initial public offering	—	(6,760,053)
Proceeds from issuance of common stock	3,119	23,426
Net cash provided by (used in) financing activities	6,171,438	49,263,373
Net changes in cash and cash equivalents	(873,022)	6,669,239
Cash and cash equivalents at the beginning of the period	7,355,834	8,455,834
Cash and cash equivalents at the end of the period	$ 6,482,812	$ 15,125,073
Non-cash operating, investing and financing activities:		
Committed proceeds from redeemable preferred stock	$ 5,000,000	$ —
Cumulative dividends earned, accrued and forfeited in the reporting period	$ 842,433	$ 100,776
Forfeiture of cumulative dividends, upon conversion of Series A Preferred Stock	$ —	$ 753,307
Forfeiture of cumulative dividends, upon conversion of Series B Preferred Stock	$ —	$ 1,550,403
Forfeiture of cumulative dividends, upon conversion of Series C Preferred Stock	$ —	$ 518,371
PPP loan forgiveness	$ —	$ 567,311

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 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

On December 24, 2020, the Company entered into the Exclusive Worldwide License Agreement with Wugen Inc. ("Wugen License"). As a result of this transaction, as of September 30, 2021, the Company holds a minority interest in Wugen carried at $1.6 million, the fair value on the effective date of the Wugen License. These shares were subject to an anti-dilution provision under which the Company was awarded additional shares for no consideration. The underlying shares of common stock is not currently traded on any public market and thus has limited marketability. During the nine-month period ended September 30, 2021, the Company received additional shares in Wugen under the terms of the anti-dilution provision. Also during this period, the Company received payments of $2.5 million due for payment under the terms of the Wugen License for performance obligations completed on the effective date.

As of September 30, 2021, the Company had not generated any revenue from sales of its immunotherapeutic products. 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.

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 September 30, 2021, the Company had cash and cash equivalents of $15.1 million, short-term investments of $25.0 million held in U.S. government-backed securities, and long-term investments of $10.0 million held in U.S. government-backed securities. Since inception to September 30, 2021, the Company incurred cumulative net losses of $24.7 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 September 30, 2021 and for the three months and nine months ended September 30, 2020 and 2021 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 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 and nine months ended September 30, 2021 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, 2020 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 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, 2020 which appear in the Company's registration statement on Form S-1 (File No. 333-256510) for its IPO which was declared effective on July 19, 2021.

Revenue Recognition

The Company recognizes revenue when its customer or collaborator obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services.

To determine revenue recognition for arrangements that are within the scope of Topic 606, it 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 within the contract; and

v. recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of Topic 606 and it is probable of collection, the Company assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the Company's arrangements may consist of a license, or options to license, the Company's intellectual property and research, development, and manufacturing services. The Company may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

The Company determines the transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company then allocates the transaction price to each performance obligation based on the relative standalone selling price and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded as deferred revenue.

The Company did not recognize any revenues for the three or nine months ended September 30, 2020 or 2021.

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 have not been met. The current portion of deferred revenue represents the amount to be recognized within one year from the balance sheet date based on the estimated performance period of the underlying performance obligations. The long-term portion of deferred revenue represents amounts to be recognized after one year. As of September 30, 2021, current deferred revenue includes amounts of $1.1 million allocated to the development supply agreement performance obligation under the Wugen License that is included within Accrued liabilities and other current liabilities. There was no long-term deferred revenue as of September 30, 2021.

Investment

The Company holds a minority interest in Wugen. The underlying shares of common stock is not traded on any public market and thus has limited marketability. The Company does not have significant influence over the operating and financial policies of Wugen. As a result, the Company has accounted for this investment 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 was recognized during the nine months ended September 30, 2021.

The Company invests net proceeds of its IPO in bills and notes issued by the U.S. Treasury. As of September 30, 2021, the Company holds $3.0 million in U.S. Treasury bills which is included in Cash and cash equivalents, $25.0 million in Short-term investments and $10.0 million in U.S. Treasury notes which is included in Long-term investments in the accompanying condensed balance sheet.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders, including both Class A and Class B common stock, by the weighted-average number of common shares outstanding for the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the sum of the weighted average number of common shares plus the potential dilutive effects of potential dilutive securities outstanding during the period. Potential dilutive securities are excluded from diluted earnings or loss per share if the effect of such inclusion is anti-dilutive. The Company's potentially dilutive securities, which include convertible redeemable preferred stock and outstanding stock options under the 2019 Equity Incentive Plan ("2019 Plan") and the 2021 Equity Incentive Plan ("2021 Plan"), have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

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 ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. Topic 842 is effective for the Company in the fiscal years beginning after December 15, 2021, with early adoption permitted. The Company is currently in the process of evaluating the impact of the adoption of Topic 842 on the Company's financial statements and related disclosures.

2. Accrued Liabilities and Other Current Liabilities

In May 2020, HCW Biologics Inc. received an SBA Paycheck Protection Loan ("PPP loan") in the principal amount of $563,590. As of December 31, 2020, the Company had $845,741 of Accrued liabilities and other current liabilities, primarily consisting of the PPP loan of $567,311, including principal and accrued but unpaid interest, and accrued liabilities of $273,907. 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. The amount of loan and interest forgiven is recognized as a gain upon debt extinguishment and is reported within Interest and other income, net in the accompanying condensed statement of operations for the nine months ended September 30, 2021.

As of September 30, 2021, the Company had a balance of $1.8 million in Accrued liabilities and other current liabilities, consisting of $1.1 million related to deferred revenue, $240,000 related to manufacturing materials, $214,408 related to salaries and employee benefits, and $86,666 related to legal fees.

3. Redeemable Preferred Stock

In a series of closings which took place in 2020, the Company completed the private placement of Series C Preferred Stock. The terms of the redeemable preferred stock provide for an adjustment to the conversion price upon the occurrence of certain transactions or events, such as stock splits, split-up, certain dividends, or distributions. Cumulative dividends accrue whether or not declared by the Board of Directors. Giving effect to the Reverse Stock Split, a total of 5,439,112 shares of Series C Preferred Stock were issued at $2.05 per share, for gross proceeds of $11.2 million, net of offering costs. The Company's Series C Preferred Stock is convertible into shares of Class A common stock and earns cumulative dividends at a rate of 6% per annum and compound annually. No dividends have been paid or declared as of the reporting date. Upon conversion, accrued and unpaid cumulative dividends will be forfeited.

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 September 30, 2021, the Company has 10 million 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 September 30,		Nine Months Ended September 30,	
	2020	2021	2020	2021
Numerator:				
Net loss	$ (2,709,006)	$ (4,094,704)	$ (7,863,006)	$ (9,689,062)
Less: cumulative preferred dividends earned in the period, net of forfeitures	(282,861)	—	(842,433)	—
Net loss available for distribution to common stock holders	$ (2,991,867)	$ (4,094,704)	$ (8,705,439)	$ (9,689,062)
Denominator:				
Weighted-average common shares outstanding	4,743,823	29,572,267	4,728,816	13,111,087
Net loss per share, basic and diluted	$ (0.63)	$ (0.14)	$ (1.84)	$ (0.74)

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 September 30,	
	2020	2021
Redeemable Preferred Stock	23,768,416	—
Common stock options	555,634	1,710,817
Potentially diluted securities	24,324,050	1,710,817

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, 2020 and September 30, 2021:

	At December 31, 2020:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 6,752,266	$ —	$ —	$ 6,752,266
Total	$ 6,752,266	$ —	$ —	$ 6,752,266

	At September 30, 2021:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 10,823,904	$ —	$ —	$ 10,823,904
Short-term cash investment	2,999,850	—	—	2,999,850
Short-term investment	24,989,700	—	—	24,989,700
Long-term investment	9,978,100	—	—	9,978,100
Total	$ 48,791,554	$ —	$ —	$ 48,791,554

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, 2020 and September 30, 2021. 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

Leases

The Company leases its operating facilities in Miramar, Florida under non-cancelable operating lease agreements and a short-term sublease agreement for additional office space. Rent expense is recognized for leases with increasing annual rents on a straight-line basis over the term of the lease. The amount of rent expense in excess of cash payments is classified as deferred rent. Lease incentives received are deferred and amortized over the term of the lease.

The future minimum payments for the lease and sublease agreements at September 30, 2021 were as follows:

2021 (remaining 3 months)	$ 54,000
2022	36,000
Total future minimum lease payments	$ 90,000

For the three months ended September 30, 2020 and 2021, rental expense, including common area maintenance costs, recognized by the Company was $45,914 and $52,963, respectively, of which $20,682 and $28,070, respectively, is included in research and development in the accompanying condensed statements of operations.

For the nine months ended September 30, 2020 and 2021, rental expense, including common area maintenance costs, recognized by the Company was $137,987 and $154,533, respectively, of which $62,289 and $79,822, respectively, is included in research and development, in the accompanying condensed statements of operations.

Manufacturing Commitment

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 its clinical trials. At September 30, 2020 and 2021, future payment obligations under statements-of-work agreements were $2.0 million and $1.5 million, respectively.

In the three months ended September 30, 2020, the Company continued with manufacturing activities, fill/finish and testing for a HCW9101 200-liter, cGMP production run and initiation of testing for a 1000-liter, cGMP production run. Additionally, the cGMP process for HCW9218 was initiated, including master cell bank production and characterization, and technology transfer from the Company to its contract manufacturer. In the three months ended September 30, 2021, the Company completed necessary procedures to release clinical materials for HCW9218. Additionally, the Company conducted several manufacturing activities for HCW9302, including initiating the master cell bank characterization, completing technology transfer from the Company to its contract manufacturer, and performing a 200-liter, cGMP production run along with required testing procedures.

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 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 management's discussion and analysis of financial condition and results of operations included in our final prospectus filed with the Securities and Exchange Commission, or the SEC, on July 21, 2021 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, which we refer to as our Prospectus. 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. In preparing the Management's Discussion and Analysis below, we presume the readers have access to and have read the Management's Discussion and Analysis in our Prospectus, pursuant to Instruction 2 to paragraph (b) of Item 303 of Regulation S-K.

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 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," and in our Prospectus and elsewhere 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

We are an innovative, 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 low-grade chronic inflammation, or "inflammaging," is a significant contributing factor to several chronic diseases and conditions, such as cancer, fibrotic disease (NAFLD and liver cancer), cardiovascular disease, diabetes, neurodegenerative disease, and autoimmune disease. We believe our approach has the potential to provide an innovative treatment of these age-related diseases.

Our gateway indication is oncology. Advances in immuno-stimulatory and anti-immunosuppressive therapeutics have revolutionized cancer treatment. Our lead molecule, HCW9218, is designed with both of these functionalities – it rejuvenates the immune system to reduce senescence, and it captures transforming growth factor-ß ("TGF-ß") to neutralize its immunosuppressive activity. HCW9218 is an injectable, fusion protein complex designed to drive bifunctional antitumor activity by activating desired immune responses to attack cancer cells while simultaneously blocking unwanted immunosuppressive activities. In the clinical development of HCW9218, we will attempt to minimize the side effects of chemotherapy through stimulating anti-tumor effector immune cell responses, blocking TGF-ß immunosuppressive activity, eliminating chemotherapy-induced senescent cells in tumors and normal tissues (i.e., senolytic effect), and reducing SASP factor activity (i.e., senomorphic effect). We are leveraging extensive clinical expertise to structure clinical trials with clear, objective, and measurable endpoints. We will manage these clinical trials internally, relying on our in-house expertise in managing clinical trials conducted in collaboration with National Cancer Institute (NCI)-Designated Comprehensive Cancer Centers. Currently, we are engaged in discussions with leading institutions who have shown interest in participating in our clinical trials as clinical sites. The individuals identified as Principal Investigators from these

institutions worked with us to establish clinical development strategies for our product candidates and to refine study protocols for pancreatic, ovarian, breast, prostate, and colorectal cancer trials. We are not certain we will be successful in reaching an agreement with any or all of these institutions, thus we might need to identify alternative clinical sites. This process could impact the start date for initiating our clinical trials. Any delays in our clinical trials could increase our costs and slow down the development and approval process, which could harm our commercial prospects.

We have been cleared by the FDA to proceed to evaluate our lead drug candidate HCW9218 in a first-in-human phase 1b clinical trial in patients with advanced pancreatic cancer. We plan to initiate a Company-sponsored Phase 1b/2 clinical trials for oncology indications in the second half of 2021, working with National Cancer Institute designated comprehensive cancer centers , first in patients with pancreatic cancer, then expanding to patients with breast, ovarian, prostate, and colorectal cancers. The aim of these studies is to evaluate HCW9218 as an adjunct therapy to chemotherapy. In the pancreatic cancer trial, the Phase 1b portion will be a dose escalation study of HCW9218 as monotherapy in refractory patients with advanced pancreatic cancer. The Phase 2 portion of this clinical trial will include a cohort of patients receiving HCW9218 as monotherapy and a cohort of patients receiving HCW9218 as an adjunct to chemotherapy. We plan to have an additional clinical trial to evaluate HCW9218 in solid tumors with an investigator-sponsored IND. Our ability to proceed with this trial depends on the submission and acceptance of the investigator-initiated solid tumor clinical trial as well as finalizing our agreement with the sponsor. We are currently engaged in discussions with an institution that has expressed interest to be a sponsor for an IND using HCW9218 as an adjunct to chemotherapy in patients with solid tumors (breast, ovarian, prostate, and colorectal cancers). However, these discussions are not final, and we may not succeed in reaching an agreement with this institution. Depending on the course of these discussions and whether we need to seek an alternative sponsor for an IND, there could be a delay in initiating a Phase 1b/2 clinical trial to evaluate HCW9218 in patients with solid tumors. Any delays in our clinical trials could increase our costs and slow down the development and approval process, which could harm our commercial prospects.

The Company is also advancing IND-enabling studies for our second lead molecule, HCW9302. We are developing HCW9302 as an IL-2-based immunotherapeutic to stimulate regulatory T ("T_{reg}") cells to suppress the activity of inflammasome-bearing cells and inflammatory factors. Inflammasomes are expressed in innate immune cells. When these cells are stimulated by various signals, the inflammasomes become active and the cells release inflammatory factors. In certain conditions, these signaling pathways persist leading to chronic inflammatory responses and associated tissue destruction. HCW9302 expands T_{reg} cells *in vivo* and *ex vivo* as an injectable or cell-based strategy to reduce inflammation. The FDA-required IND-enabling animal studies in mice are expected to be completed by the end of 2021, and we anticipate nonclinical toxicology studies in nonhuman primates to be completed in the second half of 2022.

We have combined our deep understanding of disease-related immunology with our expertise in advanced protein engineering to internally develop our TOBI™ (**T**issue fact**O**r-**B**ased fus**I**on) discovery platform for the design of immunotherapeutic drugs. This modular and tunable technology has allowed us to generate a novel pipeline of internally-developed product candidates capable of activating and targeting desired immune responses and blocking unwanted immunosuppressive activities. Using our TOBI platform, we have successfully developed molecules that can be administered by subcutaneous injection as well as adoptive cell therapy approaches. We have selected two molecules as our lead product candidates: HCW9218 and HCW9302. We have chosen these product candidates because we believe they have the potential to become transformative immunotherapeutics, which can be administered by subcutaneous injection.

As of September 30, 2021, we have funded our operations primarily with proceeds of $29.4 million from the sale and issuance of redeemable preferred stock, $56.0 million in gross proceeds from an IPO, and to a lesser extent, the proceeds of upfront payments from an out-license agreement. We have incurred significant operating losses to date. Our cumulative net losses for the year ended December 31, 2020 and the nine months ended September 30, 2021 were $15.1 million and $24.7 million, respectively. Our net losses for the three months ended September 30, 2020 and 2021 were $2.7 million and $4.1 million, respectively. Our net losses for the nine months ended September 30, 2020 and 2021 were $7.9 million and $9.7 million, respectively. As of September 30, 2021, we had an accumulated deficit of $24.7 million and cash and cash equivalents of $15.1 million, short-term investments in U.S. government-backed securities of $25.0 million, and long-term investments in U.S. government-backed securities of $10.0 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future, as we continue our clinical development activities, particularly if and as we:

- Advance the development of our lead product candidate, HCW9218, and clinical trials for oncology, and if approved by the FDA, commercialization;
- Advance preclinical development of other indications for HCW9218, including fibrotic indications, especially those resulting in NAFLD and liver cancer;
- Advance the preclinical development of our second lead product candidate, HCW9302, for autoimmune diseases, such as alopecia areata, and metabolic diseases, such as Type 2 Diabetes and coronary artery disease;

- Establish our own domestic manufacturing capability;
- Maintain, expand, and protect our intellectual property portfolio;
- Scale up our clinical and regulatory capabilities; and
- Expand operational and management information systems as well as investor relations, legal, accounting, and audit services required to operate as a public company.

As a result of these anticipated expenditures, we will need substantial additional financing to support our continuing operations and pursuit of our clinical development strategy. Until such time as we can generate significant revenues from product sales, if ever, we expect to finance our operations through a combination of equity offerings, collaborations, strategic alliances, co-development deals, and out-licensing arrangements. We may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition, and we may need to significantly delay, reduce, or eliminate the development and commercialization of one or more of our product candidates.

Our IPO was effective on July 19, 2021, with net proceeds of $49.0 million. We believe that the net proceeds of the offering and our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for 24 months. We expect to continue to incur losses for the foreseeable future and will require additional financial resources to continue to advance our products and intellectual property. If we have based this estimate on assumptions that may prove to be wrong, we could exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources." Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations and fund capital expenditure requirements. Because of the numerous risks and uncertainties associated with our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the preclinical and clinical development of our product candidates.

Recent Developments

- HCW Biologics Inc. (NASDAQ: HCWB) was added to the S&P Total Market Index ("TMI") on September 20, 2021.
- On October 28, 2021, we issued a press release announcing that we were cleared by the FDA to proceed to evaluate our lead drug candidate HCW9218 in a first-in-human Phase 1b clinical trial in patients with advanced pancreatic cancer. We are actively engaged in negotiations with several National Cancer Institute designated comprehensive cancer centers as potential clinical sites. The proposed primary investigators from these institutions participated in the clinical design and protocols for this trial.
- We expanded our board with the addition of two new independent board members in October 2021. Lisa M. Giles has extensive experience in pharmaceutical, diagnostic, device, and other healthcare industries. She held senior leadership positions in strategic planning, operations, and commercial planning. In addition, she brings a wealth of corporate governance experience, having served as a board member for several public companies. Gary M. Winer has led and built successful, multinational businesses in the biopharma and diagnostic healthcare sectors as a Chief Executive Officer or President, including senior leadership positions with AbbVie and Abbott. He brings valuable insights and experience for operations as well as support and advice for strategic transactions.
- Dr. Hing C. Wong, our CEO and Founder, has accepted an invitation to present at the Cambridge Healthtech Institute's 24th Annual PepTalk scheduled for January 17-19, 2022 in San Diego, California. Dr. Wong's presentation, entitled *"A Novel Platform to Create Multi-functional Immunotherapies for Cancer,"* will focus on the TOBI™ discovery platform and HCW9218, one of the novel bifunctional immunotherapeutics created using this platform.
- Dr. Wong has accepted an invitation to present at the BioFlorida Annual Conference scheduled for December 8-10, 2021 in Orlando, Florida. He will be one of the featured speakers in the keynote session, "*New Strategies in the Fight Against Cancer*."
- We continue to expand our intellectual property portfolio through filing provisional U.S. applications based upon new research, filing non-U.S. national stage phase patent applications, and filing U.S. trademark applications. As of September 30, 2021, we own 60 pending patent applications worldwide, including 11 pending U.S. utility patent applications, 2 pending provisional U.S. patent applications, 7 pending PCT applications, 36 pending non-U.S. national phase patent applications, and 4 pending Hong Kong patent applications. We also own 5 U.S. trademark applications for our corporate name and logo, and the TOBI platform.

Trends and Uncertainties – COVID-19 Pandemic

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, we are unable to determine if it will have a material impact on our operations.

The ultimate extent of the impact of the COVID-19 pandemic will depend on future developments which are highly uncertain, including new information that may emerge concerning the severity and expected duration of the COVID-19 pandemic, and public health actions taken to contain or prevent its spread, among others. Accordingly, we cannot fully predict the full extent to which our business and results of operations will be affected. In particular, we have seen many clinical trial sites delay patient enrollment in clinical trials as a result of the COVID-19 pandemic. Other required IND-enabling activities, such as toxicology studies, were slowed due to the volume of COVID-19 related trials that have been initiated during the pandemic. The COVID-19 pandemic or local outbreaks associated with the COVID-19 pandemic could result in difficulty manufacturing our product candidates, securing clinical trial site locations, and securing critical vendors and consultants supporting our clinical trials. In addition, outbreaks or the perception of an outbreak near a clinical trial site location could impact our ability to enroll patients or to complete all scheduled physician visits for currently enrolled patients. These situations, or others associated with COVID-19 pandemic, could cause delays in our clinical trial plans and could increase expected costs, all of which could have a material adverse effect on our business and its financial condition. At the current time, we are unable to quantify the potential effects of the COVID-19 pandemic on our future operations.

Components of our Results of Operation

Revenues

To date, we have not generated any revenue from product sales and do not expect to generate revenue from product sales for the foreseeable future. Until that occurs, our sole source of revenue will be derived from out-licenses, collaborative agreements, and co-development deals.

We have retained the manufacturing rights under the terms of the Wugen License. On June 18, 2021, we entered into a master services agreement with Wugen related to a development supply agreement to provide cGMP and non-cGMP grade licensed molecules based on industry-standard terms. We have not finalized any statements of work under the master services agreement, which will specify the performance obligations required to be completed by the Company for supplies ordered by Wugen. We also intend to enter into a supply agreement with Wugen for commercial supply when commercialization commences. In future periods, under the terms of the Wugen License, we may be eligible to receive additional cash payments that will be recognized as revenue, including development and commercialization milestones and single-digit royalties based on annual net sales of licensed products.

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. We expect our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our lead product candidates, advance into later stages of development, begin to conduct larger clinical trials, expand our product pipeline, continue to maintain, expand, protect, and enforce our intellectual property portfolio, and establish our own manufacturing capabilities. In particular, we expect our research and development expenses will increase substantially as we progress to Phase 2 and Phase 2/3 clinical trials for our lead product candidates, primarily due to the increased size and duration of later-stage clinical trials.

The duration, costs, and timing of the clinical development of our product candidates are highly uncertain and will depend on a variety of factors, including, but not limited to:

- Number and scope of preclinical and IND-enabling studies;
- Successful and timely patient enrollment in, and completion of, clinical trials;
- Per subject trial costs;
- Number of trials required for regulatory approval;
- Number of sites included in the trials;
- Number of subjects needed for each trial;
- Cost and timing of manufacturing of cGMP materials for clinical trials;
- Receipt of regulatory approvals from applicable regulatory authorities;
- Establishing commercial manufacturing capabilities; and
- Costs to maintain, defend, and enforce our intellectual property rights.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the 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, 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 September 30,		Nine Months Ended September 30,	
	2020	2021	2020	2021
Operating expenses:				
Research and development	$ 2,098,688	$ 2,687,341	$ 5,845,895	$ 6,690,317
General and administrative	609,944	1,404,823	2,039,738	3,565,013
Total operating expenses	2,708,632	4,092,164	7,885,633	10,255,330
Loss from operations	(2,708,632)	(4,092,164)	(7,885,633)	(10,255,330)
Interest and other income, net	(374)	(2,540)	22,627	566,268
Net loss	**$ (2,709,006)**	**$ (4,094,704)**	**$ (7,863,006)**	**$ (9,689,062)**

Comparison of the Three Months ended September 30, 2020 and September 30, 2021

Revenue

On June 18, 2021, the Company entered into a master services agreement with Wugen related to supply of licensed molecules for use in research and clinical development. The Company has not finalized any statements of work, which will specify the performance obligations required to be completed by the Company for supplies ordered by Wugen. The standalone selling price for these materials has been determined using industry-standard "cost plus" terms for supply agreements.

In the three months ended September 30, 2021, we continued to receive orders from Wugen for research and clinical grade materials. For the three months ended September 30, 2021, we recognized $435,000 of additional deferred revenue, increasing the balance of deferred revenue to $1.1 million included within accrued liabilities and other current liabilities on the unaudited condensed balance sheet as of September 30, 2021 that appears elsewhere in this Quarterly Report. Deferred revenue represents the payments received in advance of the satisfaction of performance obligations for delivery and acceptance of research and clinical grade materials.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2020 and September 30, 2021:

	Three Months Ended September 30,			
	2020	2021	$ Change	% Change
Salaries, benefits and related expenses	$ 721,890	$ 675,155	$ (46,735)	(6)%
Manufacturing and materials	824,859	1,034,080	209,221	25%
Preclinical expenses	322,987	769,179	446,192	138%
Clinical trials	87,988	69,556	(18,432)	(21)%
Other expenses	140,964	139,371	(1,593)	(1)%
Total research and development expenses	**$ 2,098,688**	**$ 2,687,341**	**$ 588,653**	**28%**

Research and development expenses increased $588,653, or 28%, from $2.1 million for the three months ended September 30, 2020 to $2.7 million for the three months ended September 30, 2021. The increase was due primarily to an increase in expenses related to manufacturing and IND-enabling activities, offset by a decrease in salaries, benefits and related expenses, clinical activities, and other expenses.

Salaries, benefits, and related expenses decreased by $46,735, or 6%, from $721,890 for the three months ended September 30, 2020 to $675,155 for the three months ended September 30, 2021. The decrease was due primarily to the $70,000 reimbursement we received for certain expenses incurred under the terms of the Wugen License, offset by a $33,308 increase in salaries and wages.

Manufacturing and materials expense increased $209,221, or 25%, from $824,859 for the three months ended September 30, 2020 to $1.0 million for the three months ended September 30, 2021. In the three months ended September 30, 2020, the Company continued with manufacturing activities, fill/finish and testing for a HCW9101 200-liter, cGMP production run and initiation of testing for a 1000-liter, cGMP production run. Additionally, the cGMP process for HCW9218 was initiated, including master cell bank production and characterization, and technology transfer to our contract manufacturer required for internally-developed manufacturing processes. In the three months ended September 30, 2021, the Company completed necessary procedures to release clinical materials for HCW9218. Additionally, the Company conducted several manufacturing activities for HCW9302, including initiating the master cell bank characterization, effecting a technology transfer to our contract manufacturer, performing a 200-liter, cGMP production run as well as other testing procedures.

Expenses associated with preclinical activities increased by $446,192, or 138%, from $322,987 for the three months ended September 30, 2020 to $769,179 for the three months ended September 30, 2021. The increase is due primarily to an increase in expenses for the toxicology studies for HCW9218 required for our IND application to evaluate HCW9218 in a pancreatic cancer trial. For our other lead molecule, HCW9302, we are currently designing a multi-dose nonhuman primate toxicology study, and we are targeting the initiation of this study in late 2021. This study will last several months. We may continue to deal with COVID-related delays which may impact the expected completion date for the toxicology final report for HCW9302, a requirement for filing our IND for the Phase 1b/2 clinical trial to evaluate HCW9302 in the autoimmune disease, alopecia areata. We are currently expecting the IND to be filed in the second half of 2022.

Expenses associated with clinical activities decreased by $18,432, or 21%, from $87,933 for the three months ended September 30, 2020 to $69,556 for the three months ended September 30, 2021. The decrease is due primarily to a decrease in expenses for outsourcing.

Other expenses, which includes overhead allocations, decreased by $1,593, or 1%, from $140,964 for the three months ended September 30, 2020 to $139,371 for the three months ended September 30, 2021. The decrease in other expenses is due to an increase of $16,698 in primarily from an increase in the allocation for rent expense as well as the expenses for repairs and maintenance, and a decrease of $18,684 primarily from a decrease in the allocation of depreciation.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2020 and September 30, 2021:

	Three Months Ended September 30,			
	2020	2021	$ Change	% Change
Salaries, benefits and related expenses	$ 384,705	$ 523,818	$ 139,113	36 %
Professional services	50,784	331,706	280,922	553 %
Facilities and office expenses	59,663	83,623	23,960	40 %
Depreciation	56,753	44,820	(11,933)	(21)%
Rent expense	25,233	24,893	(340)	(1)%
Other expenses	32,806	395,963	363,157	— *
Total general and administrative expenses	**$ 609,944**	**$ 1,404,823**	**$ 794,879**	**130 %**

* Not meaningful.

General and administrative expenses increased $794,879, or 130%, from $609,944 for the three months ended September 30, 2020 to $1.4 million for the three months ended September 30, 2021. The increase was primarily due to an increase in salaries brought about by the payment of a performance-based bonus and the initiation of Board compensation; increase in professional services expenses arising from legal services required for patent filings; and an increase in other expenses primarily due to an increase in insurance premiums.

Comparison of Nine Months Ended September 30, 2020 and September 30, 2021

Revenue

As of September 30, 2021, we recognized $1.1 million of deferred revenue, included within accrued liabilities and other current liabilities on the unaudited condensed balance sheet as of September 30, 2021. This was an increase of $435,000 over the amount recognized as of June 30, 2021. Deferred revenue represents the payments received in advance of the satisfaction of performance obligations for delivery and acceptance of research and clinical grade materials.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2020 and September 30, 2021:

	Nine Months Ended September 30,			
	2020	2021	$ Change	% Change
Salaries, benefits and related expenses	$ 2,163,573	$ 2,147,907	$ (15,666)	(1)%
Manufacturing and materials	2,274,657	2,109,534	(165,123)	(7)%
Preclinical expenses	854,502	1,764,117	909,615	106%
Clinical trials	152,226	227,108	74,882	49%
Other expenses	400,937	441,651	40,714	10%
Total research and development expenses	**$ 5,845,895**	**$ 6,690,317**	**$ 844,422**	**14%**

Research and development expenses increased by $844,422, or 14%, from $5.9 million for the nine months ended September 30, 2020 to $6.7 million for the nine months ended September 30, 2021. The increase was due primarily to the increase in preclinical activities, offset by a decrease in manufacturing and materials expenses.

Salaries, benefits and related expenses decreased by $15,666, or 1%, for the nine months ended September 30, 2020 compared with the nine months ended September 30, 2021. The change was primarily due to an increase of $125,225 in salaries and bonuses and an increase of $27,411 for Company-sponsored employee benefits, offset by a $170,000 reimbursement of certain expenses as required under the terms of the Wugen License.

Manufacturing and materials expense decreased by $165,123, or 7%, from $2.3 million for the nine months ended September 30, 2020 to $2.1 million for the nine months ended September 30, 2021. In nine months ended September 30, 2020, we began to initiate manufacturing activities for five internally-developed molecules. We accomplished several milestones for HCW9101 and HCW9201, including master cell bank production and characterization reports; preparation for drug testing, and cGMP manufacturing runs in multiple quantities. In addition, the fill/finish and testing was completed for HCW9201. We initiated the cGMP process for HCW9218 , including master cell bank production and characterization and conducted several manufacturing activities related to HCW9302, including initiating the master cell bank characterization, effecting a technology transfer to our contract manufacturer required for internally-developed manufacturing processes. In the nine months ended September 30, 2021, we completed manufacturing activities related to establishing master cell banks for several molecules, effecting a technology transfer to our contract manufacturer, and successfully completing multiple cGMP production runs for several of our molecules. In addition, the Company completed necessary procedures to release clinical materials for HCW9218. The Company also conducted several manufacturing activities related to HCW9302, including initiating the master cell bank characterization, effecting a technology transfer to our contract manufacturer, performing a 200-liter, cGMP production run as well as other testing procedures.

Expenses associated with preclinical activities increased $909,615, or 106%, from $854,502 for the nine months ended September 30, 2020 to $1.8 million for the nine months ended September 30, 2021. The majority of the increase in costs was attributable to the toxicology study required to complete our application for an IND for clinical trials to evaluate HCW9218 in advanced pancreatic cancer.

Expenses associated with clinical activities increased $74,882, or 49%, from $152,226 for the nine months ended September 30, 2020 to $227,108 for the nine months ended September 30, 2021. The majority of this increase was attributable to the costs of a collaboration with Washington University. Professional fees for outside services also contributed to this increase.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2020 and September 30, 2021:

	Nine Months Ended September 30,			
	2020	2021	$ Change	% Change
Salaries, benefits and related expenses	$ 1,181,440	$ 1,634,048	$ 452,608	38%
Professional services	334,622	1,000,206	665,584	199%
Facilities and office expenses	180,516	211,038	30,522	17%
Depreciation	172,809	172,545	(264)	0%
Rent expense	75,698	74,711	(987)	(1)%
Other expenses	94,653	472,465	377,812	399%
Total general and administrative expenses	**$ 2,039,738**	**$ 3,565,013**	**$ 1,525,275**	**75%**

General and administrative expenses increased $1.5 million or 75%, from $2.0 million for the nine months ended September 30, 2020 to $3.5 million for the nine months ended September 30, 2021. The increase is primarily due to increases in salaries, benefits, and related expenses, professional fees, and other expenses. The increase in salaries, benefits, and related expenses is primarily attributable to performance-based bonuses earned in connection with entering the Wugen License and completion of our IPO. Professional services increased primarily due to legal services required for patent filings. Other expenses increase is primarily due to an increase in insurance premiums.

We expect to incur increasing general and administrative expenses as a result of operating as a public company, including expenses for SEC reporting, investor relations, additional insurance requirements, and other administrative expenses. We expect to increase our administrative function to support the growth in our business and public company reporting requirements.

Interest and Other Income, Net

For the nine months ended September 30, 2020 and 2021, interest and other income, net increased by $543,641 primarily due to the forgiveness of the PPP loan and accrued interest.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have funded our operations primarily from the issuance of redeemable preferred stock, and as of July 19, 2021, an IPO. From our inception in 2018 to July 19, 2021, the effective date of our IPO, we raised net proceeds of approximately $83.8 million, including $49.0 million of net proceeds from the IPO. As of September 30, 2021, we had cash and cash equivalents of $15.1 million, short-term investments in U.S. government-backed securities of $25.0 million, and long-term investments in U.S. government-backed securities of $10.0 million. After giving effect to our IPO, we estimate that we will have adequate capital to meet our operating expenses, capital expenditure requirements, and contractual obligations for a period of at least 22 months following the date our most recent financial statements were issued.

We have based our projections of operation expenses and capital expenditure 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 Nine Months Ended September 30, 2020 and September 30, 2021

The following table summarizes our cash flows for the nine months ended September 30, 2020 and 2021:

	Nine Months Ended September 30,	
	2020	2021
Cash used in operating activities	$ (6,894,169)	$ (7,599,123)
Cash used in investing activities	(150,291)	(34,995,011)
Cash provided by financing activities	6,171,438	49,263,373
Net (decrease) increase in cash and cash equivalents	**$ (873,022)**	**$ 6,669,239**

Operating Activities

Net cash used in operating activities was $6.9 million and $7.6 million for the nine months ended September 30, 2020 and September 30, 2021, respectively.

Cash used in operating activities for the nine months ended September 30, 2020 consisted primarily of a net loss of $7.9 million, offset by cash provided by an increase accounts payable and other liabilities of $517,017 and a noncash adjustment of $432,225 for depreciation and amortization.

Cash used in operating activities for the nine months ended September 30, 2021 consisted primarily of a net loss of $9.7 million, $2.2 million from an increase in prepaid expenses and other assets, and $567,311 from extinguishment of debt. The $2.2 million increase in prepaid expenses primarily relates to an increase in insurance premiums. These were offset by cash provided from a $2.5 million decrease in accounts receivable, a $2.0 million increase in accounts payable, and a noncash adjustment of $448,013 for depreciation and amortization. The decrease in accounts receivable reflects collection of the $2.5 million cash payment due from Wugen under the terms of the Wugen License. The increase in accounts payable and other liabilities primarily reflects an increase in deferred revenue and purchase of manufacturing materials.

Investing Activities

During the nine months ended September 30, 2020 cash used in investing activities reflects the purchase of scientific lab equipment and general office equipment. During the nine months ended September 30, 2021 cash used in investing activities reflects the purchase of U.S. government-backed securities with the proceeds of our IPO and the purchase of scientific lab equipment and general office equipment. As of September 30, 2021, we held $35.0 million in short-term U.S. government-backed securities.

Financing Activities

During the nine months ended September 30, 2020 cash provided by financing activities primarily of $6.2 million resulted from the completion of the private placement of Series C Preferred Stock. During the nine months ended September 30, 2021 cash provided by financing activities primarily resulted from our IPO, offset by offering costs. On July 19, 2021, the Company's registration statement on Form S-1 for its 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 $49.0 million, after deducting underwriting discounts and commissions and estimated offering expenses paid by the Company.

Emerging Growth Company Status

The JOBS Act permits us, as an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies and thereby allows us to delay the adoption of those standards until those standards would apply to private companies.

We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our common stock less attractive to investors.

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 financial statements, which have been prepared in accordance with the accounting principles generally accepted in the United States of America. 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

For the year ended December 31, 2020, we adopted provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers ("Topic 606"). Under Topic 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. 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.

- Identification of the Contracts with the Customers

We evaluate every contract to determine whether it in its entirety or in part represents a contract with a customer, or a collaboration agreement and, based on this determination, apply appropriate accounting guidance.

We account for a contract with a customer that is within the scope of Topic 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods or services to be transferred can be identified, (iv) the arrangement has commercial substance, and (v) collection of substantially all of the consideration to which we will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

- Identification of the Performance Obligations

The promised goods or services in our collaboration and option arrangements consist of research and development services. The arrangements also have options for additional items (i.e., license rights). Options are considered to be marketing offers and are to be accounted for as separate contracts when the customer elects such options, unless we determine the option provides a material right which would not be provided without entering into the contract. The determination as to whether such options are material rights requires significant management judgment, and management considers factors such as other similar arrangements, market data, and the terms of the contractual arrangement to make such conclusion.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when: (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of our customer to develop the intellectual property on their own, and whether the required expertise is readily available.

- Determination of the Transaction Price

We estimate the transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of the potential payments and the likelihood that the payments will be received. We utilize either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

All contingent future payments, which include research, development, regulatory, and sales-based royalty payments, have not been considered in the initial analysis, as they are contingent upon option(s) being exercised or are subject to significant risk of achievement.

- Allocation of Transaction Price

We allocate the transaction price based on the estimated standalone selling price. We must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction, and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration related to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for satisfying each performance obligation.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC Topic 820, Fair Value Measurements and Disclosures, establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between fair value measurements based on market data (observable inputs), and those based on our own assumptions (unobservable inputs). This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require a reporting entity to develop its own assumptions.

Fair Value

Under the Wugen License, we received shares of common stock of Wugen on the effective date of the Wugen License. We estimated that the fair value of the stock was $1.6 million. As the common stock of Wugen is not currently publicly traded, the fair value was determined based on inputs other than a public market price. We relied primarily on the most recent third-party financing completed by Wugen. In addition, we considered the results of a third-party valuation assessment. Since our ownership interest in Wugen is less than 20% and we do not have significant influence over the operations of Wugen, we account for these securities as a cost method investment. We will carry this investment at cost less impairment, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same investee. In the event that a public market becomes available for the common stock of Wugen in the future and the shares are freely tradeable, we will recognize changes in fair value according to the market price in other income in the statements of operations.

Research and Development Costs

Research and development costs are expensed as incurred and include salaries, benefits, and other operating costs such as outside services, supplies, and allocated overhead expenses. We may perform research and development for our own internally-developed drug candidates and technology development or for certain third parties under collaborative arrangements. For our internally-developed drug candidates and our internal technology development programs, we invest own funds without reimbursement from a third party. Where we perform research and development activities under a clinical joint development collaboration, we record the partner’s share of collaboration expenses as a reduction to research and development expense when reimbursement amounts are due under the agreement.

We record an accrued expense for the estimated costs of our contract manufacturing activities performed by third parties. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven

payment flows to vendors. Payments under the contracts include upfront payments and milestone payments, which depend on factors such as the achievement of the completion of certain stages of the manufacturing process. For purposes of recognizing expense, we assess whether the production process is sufficiently defined to be considered the delivery of a good, as evidenced by predictive or contractually required yields in the production process, or the delivery of a service, where processes and yields are developing and less certain. If we consider the process to be the delivery of a good, we recognize the expense when the drug product is delivered, or otherwise bears risk of loss. If we consider the process to be the delivery of a service, the expense is recognized based on its best estimates of the contract manufacturer's progress towards completion of the stages in the contracts. We recognize and amortize upfront payments and accrue liabilities based on the specific terms of each arrangement. Arrangements may provide upfront payments for certain stages of the arrangement and milestone payments for the completion of certain stages, and, accordingly, may result in advance payments for services that have not been completed or goods not delivered and liabilities for stages where the contract manufacturer is entitled to a milestone payment.

Advance payments for goods or services that will be used or rendered for future research and development activities are capitalized as prepaid expenses and recognized as expense as the related goods are delivered or the related services are performed. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Such increases or decreases in cost are generally considered to be changes in estimates and will be reflected in research and development expenses in the period identified.

Stock-based Compensation

We maintain a stock-based compensation plan as a long-term incentive for employees, non-employees, and directors. The plan allows for grants of incentive stock options, non-qualified stock options, and other forms of equity awards. We have granted options with service-based and performance-based vesting conditions.

We measure our stock-based awards granted to employees and directors based on the estimated fair value of the option on the date of grant (grant date fair value) and recognize compensation expense over the vesting period. Compensation expense is recorded as either research and development or general and administrative expenses in the statements of operations based on the function to which the related services are provided. Forfeitures are accounted for as they occur. Prior to the IPO, we estimated grant date fair value using the Black-Scholes option-pricing model. Upon completion of our IPO, our board of directors now determines the fair value of each share of underlying common stock based on its closing price as reported on the date of grant according to the quoted market price on the primary stock exchange on which our common stock is traded.

For stock option grants with service-based and performance-based vesting, stock-based compensation expense represents the portion of the grant date fair value of employee stock option grants recognized over the requisite service period of the awards on a straight-line basis, net of estimated forfeitures. For options that vest upon the achievement of performance milestones, the Company estimates the vesting period based on the evaluation of the probability of achievement of each respective milestone and the related estimated date of achievement.

Prior to the IPO, in determining the fair value of the stock-based awards, we use the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and its determination generally requires significant judgment. These assumptions include, but are not limited to:

- *Expected term*—The expected term of stock options with service-based vesting is determined using the "simplified" method, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data.
- *Expected volatility*—Since there is no trading history for our common stock, the expected volatility was estimated based on the historical equity volatility for comparable publicly traded biotechnology companies. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.
- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury Bond in effect at the time of grant for periods corresponding with the expected term of the exit event.
- *Dividend yield*—The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its common stock.

Determination of the Fair Value of Our Common Stock

Prior to our IPO, there was no public market for our common stock, and the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering a third-party valuation of common stock and our board of directors' assessment of additional objective and subjective third-party financing events and other factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Prior to the IPO, for third-party valuations performed in connection with the valuation of our common stock, we used the Black-Scholes option-pricing model. Third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting Practice Aid entitled, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Prior to our IPO, in addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, which may be as a date later than the most recent third-party valuation date, including:

- the prices at which we sold shares of redeemable preferred stock and the superior rights and preferences of the redeemable preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical and planned clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our redeemable preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering ("IPO"), or a sale of our company considering prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

Prior to IPO, for financial reporting purposes, it is our policy to perform a contemporaneous valuation when a material number of stock awards or options are granted. As a private company, we relied primarily on the evidence of third-party financings to support valuation of common stock. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change, and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

Upon completion of our IPO, our board of directors now determines the fair value of each share of underlying common stock based on its closing price as reported on the date of grant according to the quoted market price on the primary stock exchange on which our common stock is traded.

Income Taxes

We recognize deferred income taxes for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. In evaluating our valuation allowance, we consider all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance. Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance.

Under Sections 382 and 383 of the Code, substantial changes in our ownership may limit the amount of NOL and research and development credit carryforwards that could be used annually in the future to offset taxable income. The tax benefits related to future utilization of federal and state NOL carryforwards, credit carryforwards, and other deferred tax assets may be limited or lost if cumulative changes in ownership exceeds 50% within any three-year period. We have not completed a Section 382/383 analysis under the Code regarding the limitation of NOL and credit carryforwards. If a change in ownership were to have occurred, the annual limitation may result in the expiration of NOL carryforwards and credits before utilization.

We record unrecognized tax benefits as liabilities or reduce the underlying tax attribute, as applicable, and adjust them when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the

unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available.

Recent Accounting Pronouncements

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

Available information

Our corporate website address is www.hcwbiologics.com. We use the investor relations page of our website for purposes of compliance with Regulation FD and as a routine channel for distribution of important information, including news releases, analyst presentations, financial information and corporate governance practices. Our filings with the SEC are posted on our website and available free of charge as soon as reasonably practical after they are electronically filed with, or furnished to, the SEC. The SEC's website, www.sec.gov, contains reports, proxy statements and other information regarding issuers that file electronically with the SEC. The content on any website referred to in this Quarterly Report on Form 10-Q is not incorporated by reference in this Form 10-Q unless expressly noted. Further, the Company’s references to website URLs are intended to be inactive textual references only.

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 on our initial IPO and invested our proceeds in U.S. Treasury securities. As of September 30, 2021, we had cash and cash equivalents of $15.1 million, short-term investments in U.S. government-backed securities of $25.0 million, and long-term investments in U.S. government-backed securities of $10.0 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.

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 judgment 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 September 30, 2021. 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 during the quarter ended September 30, 2021, that 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 the Prospectus filed by us with the SEC on July 21, 2021. The risk factors included in the Prospectus 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.

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

On July 19, 2021, our registration statement on Form S-1 (File No. 333-258025) was declared effective by the SEC for our IPO. At the closing of the offering on July 22, 2021, we sold 7,000,000 shares of common stock, at an IPO price of $8.00 per share and received gross proceeds of $56.0 million, which resulted in net proceeds to us of approximately $49.0 million, after deducting underwriting discounts and commissions of approximately $3.9 million and offering-related transaction costs of approximately $2.8 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. EF Hutton, division of Benchmark Investments, LLC acted as sole book-running manager and Revere Securities LLC acted as co-manager for the offering.

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	
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 September 30, 2021, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Condensed Balance Sheets as of December 31, 2020 and September 30, 2021 (unaudited); (ii) the Condensed Statements of Operations for the three and nine months ended September 30, 2020 (unaudited) and September 30, 2021 (unaudited); (iv) the Condensed Statements of Stockholders' Equity as of September 30, 2020 (unaudited) and September 30, 2021 (unaudited); (v) the Condensed Statements of Cash Flows for the nine months ended September 30, 2020 (unaudited) and September 30, 2021 (unaudited); and (vi) the notes to the Condensed Financial Statements (unaudited).				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

* 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: November 12, 2021

By: /s/ Hing C. Wong

Hing C. Wong
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2021

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 September 30, 2021;

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: November 12, 2021

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 September 30, 2021;

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: November 12, 2021

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 September 30, 2021 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: November 12, 2021

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 September 30, 2021 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: November 12, 2021

By: /s/ Rebecca Byam

Rebecca Byam
Chief Financial Officer