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, 2022
OR

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

For the transition period from _____ to
Commission File Number: 001-40591

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

Delaware	**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 7, 2022, the registrant had 35,871,470 shares of common stock, $0.0001 par value per share, outstanding.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

HCW Biologics Inc.
Condensed Balance Sheets

	December 31, 2021	September 30, 2022 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,730,677	$ 26,224,260
Short-term investments	24,983,520	—
Accounts receivable, net	133,000	355,555
Prepaid expenses	2,196,557	1,921,993
Other current assets	1,436,616	205,921
Total current assets	40,480,370	28,707,729
Investments	11,522,050	11,268,500
Property and equipment, net	1,119,091	10,957,946
Other assets	393,318	419,027
Total assets	$ 53,514,829	$ 51,353,202
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities		
Current liabilities:		
Accounts payable	$ 223,664	$ 1,410,357
Accrued liabilities and other current liabilities	2,097,925	882,775
Total current liabilities	2,321,589	2,293,132
Debt	—	6,448,166
Other liabilities	—	56,676
Total liabilities	2,321,589	8,797,974
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Common stock:		
Common, $0.0001 par value; 250,000,000 shares authorized and 35,768,264 shares issued at December 31, 2021; 250,000,000 shares authorized and 35,836,135 shares issued at September 30, 2022	3,577	3,584
Additional paid-in capital	81,827,006	82,670,949
Accumulated deficit	(30,637,343)	(40,119,305)
Total stockholders' equity	51,193,240	42,555,228
Total liabilities and stockholders' equity	$ 53,514,829	$ 51,353,202

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,	
	2021	2022	2021	2022
Revenues:				
Revenues	$ —	$ 1,809,025	$ —	$ 5,380,570
Cost of revenues	—	(1,447,220)	—	(3,062,496)
Net revenues	—	361,805	—	2,318,074
Operating expenses:				
Research and development	2,687,341	2,648,794	6,690,317	6,408,353
General and administrative	1,404,823	1,732,666	3,565,013	5,321,262
Total operating expenses	4,092,164	4,381,460	10,255,330	11,729,615
Loss from operations	(4,092,164)	(4,019,655)	(10,255,330)	(9,411,541)
Interest and other income (loss), net	(2,540)	105,461	566,268	(70,421)
Net loss	$ (4,094,704)	$ (3,914,194)	$ (9,689,062)	$ (9,481,962)
Net loss per share, basic and diluted	$ (0.14)	$ (0.11)	$ (0.74)	$ (0.26)
Weighted average shares outstanding, basic and diluted	29,572,267	35,835,135	13,111,087	35,809,216

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, 2021 and September 30, 2022
(Unaudited)

	Redeemable Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2020	6,316,691	$ 6,140,792	12,012,617	$ 13,680,306	5,439,112	$ 11,294,301	4,793,393	$ 480	$ —	$ (16,718,877)	$ (16,718,397)
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	88,702	8	13,377	—	13,385
Stock-based compensation	—	—	—	—	—	—	—	—	641	—	641
6% cumulative dividends on redeemable preferred stock	—	95,992	—	213,971	—	167,395	—	—	(14,018)	(463,340)	(477,358)
Accretion of issuance costs	—	—	0 —	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**	**4,882,095**	**$ 488**	**$ —**	**$ (20,026,213)**	**$ (20,025,725)**
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	73,487	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)	(463,623)	(482,658)
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**	**4,955,582**	**496**	**—**	**(23,240,198)**	**(23,239,702)**
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)	6,333,841
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	(55,741)	11,651,347
Issuance of Common Stock upon exercise of stock options	—	—	—	—	—	—	4,114	—	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 Changes in Redeemable Preferred Stock and Stockholders' (Deficit) Equity
For the Nine Months Ended September 30, 2021 and September 30, 2022
(Unaudited)

	Redeemable Preferred Stock						Stockholders' Equity				
	Series A		Series B		Series C		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance, December 31, 2021	—	$ —	—	$ —	—	$ —	35,768,264	$ 3,577	$ 81,827,006	$ (30,637,343)	$ 51,193,240
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	11,225	1	2,272	—	2,273
Stock-based compensation	—	—	—	—	—	—	—	—	260,348	—	260,348
Net loss	—	—	—	—	—	—	—	—	—	(2,057,207)	(2,057,207)
Balance, March 31, 2022	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**35,779,489**	**$ 3,578**	**$ 82,089,626**	**$ (32,694,550)**	**$ 49,398,654**
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	44,434	4	5,996	—	6,000
Stock-based compensation	—	—	—	—	—	—	—	—	271,335	—	271,335
Net loss	—	—	—	—	—	—	—	—	—	(3,510,561)	(3,510,561)
Balance, June 30, 2022	**—**	**—**	**—**	**—**	**—**	**—**	**35,823,923**	**3,582**	**82,366,957**	**(36,205,111)**	**46,165,428**
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	12,212	2	1,672	—	1,674
Stock-based compensation	—	—	—	—	—	—	—	—	302,320	—	302,320
Net loss	—	—	—	—	—	—	—	—	—	(3,914,194)	(3,914,194)
Balance, September 30, 2022	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**35,836,135**	**$ 3,584**	**$ 82,670,949**	**$ (40,119,305)**	**$ 42,555,228**

See accompanying notes to the unaudited condensed interim financial statements.

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

	Nine Months Ended September 30,	
	2021	**2022**
Cash flows from operating activities:		
Net loss	$ (9,689,062)	$ (9,481,962)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	436,135	456,696
Stock-based compensation	11,878	834,003
Gain on extinguishment of debt	(567,311)	—
Unrealized loss on investments, net	—	253,550
Reduction in the carrying amount of right-of-use asset	—	1,463
Changes in operating assets and liabilities:		
Accounts receivable	2,430,000	(222,555)
Prepaid expenses and other assets	(2,181,492)	1,854,155
Accounts payable and other liabilities	1,960,729	(202,979)
Operating lease liability	—	(89,110)
Net cash used in operating activities	(7,599,123)	(6,596,739)
Cash flows from investing activities:		
Purchases of property and equipment	(27,411)	(10,206,441)
Proceeds for sale or maturities of short-term investments	—	24,983,520
Purchases of short-term investments	(24,989,700)	—
Purchases of long-term investments	(9,977,900)	—
Net cash (used in) provided by investing activities	(34,995,011)	14,777,079
Cash flows from financing activities:		
Proceeds from initial public offering	56,000,000	—
Issuance costs of initial public offering	(6,760,053)	—
Proceeds from issuance of common stock	23,426	9,947
Proceeds from issuance of debt, net	—	6,448,166
Offering costs	—	(144,870)
Net cash provided by financing activities	49,263,373	6,313,243
Net changes in cash and cash equivalents	6,669,239	14,493,583
Cash and cash equivalents at the beginning of the period	8,455,834	11,730,677
Cash and cash equivalents at the end of the period	$ 15,125,073	26,224,260
Noncash operating, investing and financing activities:		
Cumulative dividends earned and accrued in the reporting period	$ 100,776	$ —
Forfeiture of cumulative dividends, upon conversion of all preferred stock	$ 2,822,081	$ —
PPP loan forgiveness	$ 567,311	$ —
Operating lease liabilities arising from obtaining right-of-use assets	$ —	$ 231,196

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 clinical-stage 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.

Liquidity

As of September 30, 2022, the Company had not generated any revenue from commercial product sales of its internally-developed immunotherapeutic products for the treatment of cancer and other age-related diseases. In the course of its development activities, the Company has sustained operating losses and expects to continue to incur operating losses for the foreseeable future. Since inception, substantially all the Company's activities have consisted of research, development, establishing large-scale cGMP production for clinical trials, and raising capital. The Company's total revenues to date have been generated principally from its exclusive worldwide license with Wugen, Inc. ("Wugen"), pursuant to which Wugen licensed limited rights to develop, manufacture, and commercialize cell therapy treatments for cancer based on two of our internally-developed multi-cytokine fusion protein molecules, and its manufacturing and supply arrangement with Wugen. In the three months and nine months ended September 30, 2022, the Company recognized revenues of $1.8 million and $5.4 million, respectively, generated from the supply of clinical and research grade material to Wugen.

On August 15, 2022, the Company entered into a loan and security agreement for a $6.5 million, five-year loan to provide financing for the purchase of a building which will become the Company's new headquarters. The remainder of the purchase price was paid in cash. See Note 3 Debt.

On August 26, 2022, the Company's $100.0 million shelf registration statement on Form S-3, including a prospectus for the issuance and sale of up to $15.5 million of shares of the Company's common stock through an at-the-market equity program, was declared effective by the Securities and Exchange Commission ("SEC").

As of September 30, 2022, the Company had cash and cash equivalents of $26.2 million and long-term investments of $9.7 million held in U.S. government-backed securities. Since inception to September 30, 2022, the Company incurred cumulative net losses of $37.3 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 which may include 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, 2022 and for the three months and nine months ended September 30, 2021 and 2022 have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Act of 1933, as amended (the "Securities Act"). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed interim financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company's financial position and the results of its operations and cash flows. The results for the three and nine months ended September 30, 2021 and 2022 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The condensed balance sheet at December 31, 2021 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed interim financial statements and the notes accompanying them should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2021 which appear in the Company's Annual Report on Form 10-K filed for the year ended December 31, 2021 with the SEC on March 29, 2022 and in other filings with the SEC.

Revenue Recognition

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

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

License Grants:

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

Milestone and Contingent Payments:

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

Materials Supply:

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

On June 18, 2021, the Company entered into a master services agreement ("MSA") with Wugen for the supply of materials for clinical development of licensed products. The terms set forth in the MSA were not sufficient to meet all the requirements for the Company to determine that a contract existed for a transaction. In order for a contract to exist, additional terms for each transaction require the Company to enter into a statement-of-work ("SOW") for each purchase. Each of these transactions represents a single performance obligation that is satisfied over time. The Company recognizes revenue using an input method based on the costs incurred relative to the total expected cost, which determines the extent of the Company's progress toward completion. As part of the accounting for these arrangements, the Company must develop estimates and assumptions that require judgement to determine the progress towards completion. The Company reviews its estimate of the progress toward completion based on the best information available to recognize the cumulative progress toward completion as of the end of each reporting period, and makes revisions to such estimates, if facts and circumstances change during each reporting period.

On March 14, 2022, the Company entered into SOWs with Wugen for each of the then-current and historical purchases of clinical and research grade materials under the MSA. As a result, the Company determined that all requirements were met to qualify as contracts under Topic 606 for the related transactions covered by these SOWs. For the three months and nine months ended September 30, 2022, the Company recognized revenue related to sale of development supply materials to Wugen of $1.8 million and $5.4 million, respectively.

Deferred Revenue

Deferred revenue represents amounts billed, or in certain cases yet to be billed, to the Company's customer for which the related revenues have not been recognized because one or more of the revenue recognition criteria has not been met. The Company had deferred revenue of $1.8 million and nil as of December 31, 2021 and September 30, 2022, respectively. All deferred revenue balances are current liabilities and reported within Accrued liabilities and other current liabilities in the accompanying condensed balance sheets.

Investments

The Company holds a minority interest in Wugen which is accounted for using the measurement alternative whereby the investment is recorded at cost less impairment, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same investee. No impairment has been recognized. As of December 31, 2021 and September 30, 2022, the Company included $1.6 million for the investment in Wugen included in Investments in the accompanying condensed balance sheets.

The Company invested net proceeds of its IPO in bills and notes issued by the U.S. Treasury which are classified as trading securities. As of December 31, 2021, the company held $25.0 million in U.S. Treasury bills included in Short-term investments and $9.9 million in U.S Treasury notes included in Investments in the accompanying condensed balance sheet. As of September 30, 2022, the Company held $9.7 million in U.S. Treasury notes included in Investments in the accompanying condensed balance sheet.

Operating Leases

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

Net Loss Per Share

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

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases ("Topic 842"), which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. The Company adopted Topic 842 as of January 1, 2022.

2. Accrued Liabilities and Other Current Liabilities

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

As of September 30, 2022, the Company had a balance of $882,775 in Accrued liabilities and other current liabilities, consisting primarily of $70,000 related to salary and benefits, $174,520 related to short-term lease liability, $230,400 related to clinical trials expenses, $166,000 legal fees and $240,000 related primarily to other accrued liabilities.

3. Debt

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

As of September 30, 2022, the Company had $6.5 million in gross principal outstanding in a loan under the 2022 Loan Agreement. The outstanding loan will mature on August 15, 2027, or the Maturity Date, and bears interest at a fixed per annum rate equal to 5.75%. An interest-only period is one year followed by 48 months of equal payments of principal and interest beginning on September 15, 2023 based on a 25-year amortization rate. Upon the Maturity Date, a final payment of unamortized principal will be due to Cogent. The Company has the option to prepay the outstanding balance of the loan prior to the Maturity Date without penalty. As of September 30, 2022, the loan is presented net of debt issuance costs in Debt on the accompanying condensed balance sheet.

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,	
	2021	2022	2021	2022
Numerator:				
Net loss	$ (4,094,704)	$ (3,914,194)	$ (9,689,062)	$ (9,481,962)
Denominator:				
Weighted-average common shares outstanding	29,572,267	35,835,135	13,111,087	35,809,216
Net loss per share, basic and diluted	$ (0.14)	$ (0.11)	$ (0.74)	$ (0.26)

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,	
	2021	2022
Common stock options	1,710,817	1,907,991
Potentially diluted securities	1,710,817	1,907,991

At December 31, 2021, and September 30, 2022, the Company has 10,000,000 shares of preferred stock authorized and no shares issued.

5. Fair Value of Financial Instruments

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

Money market funds included in cash and cash equivalents and U.S. government-backed securities are measured at fair value based on quoted prices in active markets, which are considered Level 1 inputs. No transfers between levels occurred during the periods presented. The following table presents the Company's assets which were measured at fair value at December 31, 2021 and September 30, 2022:

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

	At September 30, 2022:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 24,787,557	$ —	$ —	$ 24,787,557
Treasury notes	9,668,750	—	—	9,668,750
Total	$ 34,456,307	$ —	$ —	$ 34,456,307

6. Income Taxes

The Company computes its quarterly income tax expense/(benefit) by using a forecasted annual effective tax rate and adjusts for any discrete items arising during the quarter. The Company did not have a provision for income taxes (current or deferred tax expense) as of December 31, 2021 and September 30, 2022. The Company will continue to maintain a 100% valuation allowance on total deferred tax assets. The Company believes it is more likely than not that the related deferred tax asset will not be realized. As a result, the Company's effective tax rate will remain at 0.00% because no items either estimated or discrete items would impact the tax provision.

7. Commitments and Contingencies

Operating Leases

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

The components of the lease expense for the three months and nine months ended September 30, 2022 were as follows:

	For the Three Months Ended September 30, 2022	For the Nine Months Ended September 30, 2022
Operating lease cost	$ 42,413	$ 84,825

Supplemental cash flow information related to lease for the nine months ended September 30, 2022 was as follows:

	For the Nine Months Ended September 30, 2022
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows	$ 111,429
Right-of-use assets obtained in exchange for lease obligations:	
Operating lease	$ 89,110

As of September 30, 2022, the supplemental balance sheet information related to leases was as follows:

	As of September 30, 2022
Operating lease right-of-use assets	$ 229,733
Other current liabilities	$ 174,520
Operating lease liabilities, net of current portion	56,676
Total operating lease liabilities	$ 231,196

As of September 30, 2022, the remaining lease payments were as follows:

2022 (remaining 3 months)	$ 41,786
2023	171,322
2024	28,693
Total future minimum lease payments	$ 241,801

For the three months ended September 30, 2021 and 2022, rent expense recognized by the Company was $36,300 and $43,700 respectively, of which $19,200 and $22,200, respectively, is included in research and development in the accompanying condensed statements of operations. Certain comparative figures have been reclassified to conform to the current year presentation under Topic 842 for rent expense.

For the nine months ended September 30, 2021 and 2022, rent expense recognized by the Company was $104,100 and $130,300, respectively, of which $52,600 and $57,800, respectively, is included in research and development in the accompanying condensed statements of operations. Certain comparative figures have been reclassified to conform to the current year presentation under Topic 842 for rent expense.

Contractual Commitments

The Company operates under the provisions of agreements with a third-party global contract development and manufacturer of biologics for the manufacture of the Company's proprietary molecules for use in clinical trials. At December 31, 2021, future payment obligations under such agreements were $2.5 million. At September 30, 2022, future payment obligations under such agreements were $2.0 million.

Legal

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend the indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. To date, the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require it to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by law. The Company also has directors' and officers' insurance.

Other

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

8. Subsequent Events

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

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (i) our unaudited condensed interim financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q (this "Quarterly Report on Form 10-Q") and (ii) our audited financial statements and related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the fiscal year ended December 31, 2021 included in the Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 29, 2022. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to the "Company," "HCW Biologics," "we," "us" and "our" refer to HCW Biologics Inc.

Forward-Looking Statements

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

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

Overview

HCW Biologics Inc. ("HCW Biologics," "HCW," the "Company," or "we") is a clinical-stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation and age-related diseases. We believe age-related, chronic, low-grade inflammation, or "inflammaging," is a significant contributing factor to several diseases and conditions, such as cancer, cardiovascular disease, diabetes, neurodegenerative diseases, and autoimmune diseases. The induction and retention of low-grade inflammation in an aging human body is mainly the result of the accumulation of non-proliferative but metabolically active senescent cells, which can also be caused by persistent activation of protein complexes, known as inflammasomes, in innate immune cells. These two elements share common mechanisms in promoting secretion of pro-inflammatory proteins and in many cases interact to drive senescence, and thus, inflammaging. Our novel approach is to eliminate senescent cells and the pro-inflammatory factors they secrete systemically through multiple pathways. We believe our approach has the potential to fundamentally change the treatment of age-related diseases.

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

HCW9218 reached the clinical stage of its development in the first half of 2022, with the initiation of a Phase 1 clinical trial by the Masonic Cancer Center to evaluate HCW9218 in the treatment of solid tumor cancers that progressed after standard-of-care treatment. The first patient was dosed in a multi-center Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in patients with chemo-refractory/chemo-resistant advanced pancreatic cancer in October 2022. In both of these studies in solid tumor cancers, we will be gathering additional data to obtain insights for future phases of clinical trials, such as the level of immune system reaction and serum TGF-β neutralization to and by HCW9218 as well as any incidence of mucosal bleeding caused by the HCW9218 TGF-β trap. In addition, the Masonic Cancer Center will present preliminary human data from the solid tumor trial in a poster presentation at the Society for Immunotherapy of Cancer ("SITC") conference to be held from November 8 through November 12, 2022 in Boston, Massachusetts. We are targeting a readout of preliminary human data from the pancreatic study in the first half of 2023. We expect that the human data from these two clinical trials in cancer will guide future development of HCW9218 for other age-related pathologies. We believe that HCW9218 may represent a new class of safe and effective senolytic and senomorphic drugs for the treatment of a broad range of inflammaging indications, including cancer, metabolic dysfunctions, fibrosis-related pathologies, as well as neuro-inflammation and neurodegenerative diseases

HCW9302 is another lead drug candidate which is designed to activate and expand regulatory T ("T_{reg}") cells to reduce senescence by suppressing the activity of inflammasome-bearing cells and the inflammatory factors which they secrete. This molecule is a single-chain, IL-2-based fusion protein. Preclinical studies in mouse models have demonstrated the ability of HCW9302 to expand and activate T_{reg} cells and reduce inflammation-related diseases, supporting the potential of HCW9302 to treat a wide variety of autoimmune and proinflammatory diseases, such as atherosclerosis. IND-enabling activities are currently in progress, but due to COVID-related delays, the completion date for toxicology studies required by the Federal Drug Administration ("FDA") for an Investigational New Drug Application ("IND") is expected to extend to the first half of 2023. If we are successful in completing IND-enabling activities and have no further delays in the expected schedule, we continue to plan to file an IND to obtain approval from the FDA for a Phase 1b/2 clinical trial to evaluate HCW9302 in an autoimmune disorder in the first half of 2023.

Recent Developments

- On August 15, 2022, the Company purchased a building located in Miramar, Florida for approximately $10.0 million, as our new headquarters. The Company received a $6.5 million five-year loan to finance the purchase of the new property. The loan bears a fixed interest of 5.75% per annum with interest only payment due in the first year.
- The multi-center, Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in patients with chemo-refractory/chemo-resistant advanced pancreatic cancer has initiated. HonorHealth Research Institute dosed its first patient on October 17, 2022, and a second patient on October 31, 2022. We are in the process of activating other clinical sites at NCI-designated Comprehensive Cancer Centers.
- As of September 30, 2022, there were no reports of dose-limited toxicity in the Phase 1 clinical trial to evaluate HCW9218 in patients with chemo-refractory/chemo-resistant solid tumors with disease progression after prior treatment with standard of care therapies, being conducted at the Masonic Cancer Center. Patients have been enrolled and dosed for two levels of dose escalation in this trial.
- On August 26, 2022, the Company's $100.0 million shelf registration statement on Form S-3, including a prospectus for the issuance and sale of up to $15.5 million of shares of the Company's common stock through an at-the-market program, was declared effective by the SEC.
- The 37th Annual Meeting of the Society for Immunotherapy of Cancer accepted an abstract submitted by the Masonic Cancer Center, University of Minnesota, entitled: A phase 1 study of HCW9218, a bifunctional TGF-β Antagonist/IL-15 protein complex, in advanced solid tumors. Preliminary clinical results from the Phase 1 clinical study to evaluate HCW9218 in chemo-refractory/chemo-resistant solid tumors will be presented in a poster at the SITC 2022 conference by Dr. Melissa Geller, Principal Investigator.

Trends and Uncertainties

COVID-19

The spread of COVID-19, including the resurgence of cases related to the spread of new variants, has caused significant volatility in the U.S. and international markets since March 2020. 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 how long it will impact our operations and if it will have a material impact over time.

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

Inflationary Cost Environment, Supply Chain Disruption and the Macroeconomic Environment

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

For discussion of risks related to potential impacts of supply chain, inflation, geopolitical and macroeconomic challenges on our operations, business results and financial condition, see “Part II, Item 1A. Risk Factors.”

Components of our Results of Operation

Revenues

We have no products approved for commercial sale and have not generated any revenue from commercial product sales of internally-developed immunotherapeutic products for the treatment of cancer and other age-related diseases. The principal source of our revenues to date have been generated from our Wugen License and MSA with Wugen. See Note 1 to our condensed interim financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for these definitions and more information.

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

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

Operating Expenses

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

Research and Development

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

- Employee-related expenses, including salaries, benefits, and stock-based compensation expense.

- Expenses related to manufacturing and materials, consisting primarily of expenses incurred primarily in connection with third-party contract manufacturing organizations ("CMO"), which produce cGMP materials for clinical trials on our behalf.
- Expenses associated with preclinical activities, including research and development and other IND-enabling activities.
- Expenses incurred in connection with clinical trials.
- Other expenses, such as facilities-related expenses, direct depreciation costs for capitalized scientific equipment, and allocation for overhead.

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

We expect research and development expenses to increase substantially for the foreseeable future as we continue the development of our product candidates. We cannot reasonably determine the nature, timing, and costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. Product candidates in later stages of development generally have higher development costs than those in earlier stages. See "Risk Factors -- Risks Related to the Development and Clinical Testing of Our Product Candidates," elsewhere in this Quarterly Report on Form 10-Q for a discussion of some of the risks and uncertainties associated with the development and commercialization of our product candidates. Any changes in the outcome of any of these risks and uncertainties with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

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

During the period ended September 30, 2022, allegations were made by a former employer of Dr. Hing C. Wong, our Founder and Chief Executive Officer, against Dr. Wong and the Company related to certain of our core intellectual property assets. Although no claims have been filed, we began incurring legal expenses on our own behalf as well as on behalf of Dr. Wong, as required under the Company's indemnification agreement with our officers and directors.

We expect that our general and administrative expenses will continue to be higher in the foreseeable future due to expenses relating to our operations as a public company, including increased costs for the recruitment and retention of personnel and payment to outside consultants, advisors and accountants, as well as increased costs to comply with government regulations, corporate governance, internal control, insurance and similar requirements applicable to public companies. In addition, we also expect we may have increased legal expenses in connection with any matters or claims arising from the allegations of Dr. Wong's former employer.

Interest and Other Income (Loss), Net

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

On August 15, 2022, the Company entered into a short-term, market-rate lease with the former owner of the building purchased by the Company on the same date. The lease provides the tenant with the right to occupy offices that comprise approximately 15,000 square feet for a period of one year, ending August 14, 2023. The lease may be terminated at any time by the tenant with 60 days written notice. During the three months ended September 30, 2022, the Company reported $30,894 in miscellaneous income, which is included within Interest and other income (loss), net in the condensed statements of operation for the three and nine months ended September 30, 2022 included elsewhere in this Quarterly Report on Form 10-Q.

Results of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2022	2021	2022
Revenues:				
Revenues	$ —	$ 1,809,025	$ —	$ 5,380,570
Cost of revenues	—	(1,447,220)	—	(3,062,496)
Net revenues	—	361,805	—	2,318,074
Operating expenses:				
Research and development	2,687,341	2,648,794	6,690,317	6,408,353
General and administrative	1,404,823	1,732,666	3,565,013	5,321,262
Total operating expenses	4,092,164	4,381,460	10,255,330	11,729,615
Loss from operations	(4,092,164)	(4,019,655)	(10,255,330)	(9,411,541)
Interest and other income (loss), net	(2,540)	105,461	566,268	(70,421)
Net loss	**$ (4,094,704)**	**$ (3,914,194)**	**$ (9,689,062)**	**$ (9,481,962)**

Comparison of the Three Months ended September 30, 2021 and September 30, 2022

Revenues

On June 18, 2021, the Company entered into a MSA with Wugen for the supply of materials for clinical development of licensed products. The terms set forth in the MSA were not sufficient to meet all the requirements for the Company to determine that a contract exists. In order for a contract to exist, additional terms are needed that must be set forth in a SOW. Until March 14, 2022, the Company has not entered into any SOWs for transactions to supply Wugen with clinical and research grade materials, and all amounts received for such transactions were recorded as deferred revenue. On March 14, 2022, the Company entered into SOWs with Wugen for each of the then-current and historical purchases of clinical and research grade materials under the MSA. As a result, the Company determined that all requirements were met for these transactions to qualify as contracts under Topic 606. As of September 30, 2021, the Company did not recognize any revenue for supply of clinical and research grade materials, since we did not have a contract in place. For the three months ended September 30, 2022, the Company recognized $1.8 million of revenues in the condensed statement of operations that appears elsewhere in this Quarterly Report on Form 10-Q.

For any transactions to supply materials for clinical development for which a SOW has not been finalized, revenue is not recognized because one or more of the criteria for revenue recognition has not been met, in which case, the Company records deferred revenue. There were $1.1 million and nil of short-term deferred revenues as of September 30, 2021 and September 30, 2022, respectively.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2021 and September 30, 2022:

	Three Months Ended September 30,			
	2021	2022	$ Change	% Change
Salaries, benefits and related expenses	$ 675,155	$ 693,774	$ 18,619	3%
Manufacturing and materials	1,034,080	751,945	(282,135)	(27)%
Preclinical expenses	769,179	729,172	(40,007)	(5)%
Clinical trials	69,556	292,276	222,720	320%
Other expenses	139,371	181,627	42,256	30%
Total research and development expenses	**$ 2,687,341**	**$ 2,648,794**	**$ (38,547)**	(1)%

Research and development expenses decreased by $38,547, or 1%, from $2.7 million for the three months ended September 30, 2021 to $2.6 million for the three months ended September 30, 2022. This decrease was primarily due to a decline in manufacturing expenses of $282,135 and an increase in clinical trial expenses of $222,720.

Salaries, benefits, and related expenses increased by $18,619, or 3%, from $675,155 for the three months ended September 30, 2021 to $693,744 for the three months ended September 30, 2022. This increase was primarily attributable to a $78,314 increase in salaries and wages and a $13,262 increase in compensation expenses related to stock-based compensation, offset by a reimbursement from Wugen for certain expenses incurred under the terms of the Wugen License that was $74,667 greater for the three months ended September 30, 2022 versus the comparable period in 2021.

Manufacturing and materials expense decreased by $282,135, or 27%, from $1.0 million for the three months ended September 30, 2021 to $751,945 for the three months ended September 30, 2022. In the three months ended September 30, 2021, manufacturing activities focused on our lead molecules, HCW9218 and HCW9302. For HCW9218, we finalized a 200L GMP run as well as initiated the fill/finish process and final testing for product release for clinical trials. For HCW9302, we initiated master cell bank production and completed a scale-up run of GMP materials. In the three months ended September 30, 2022, costs were primarily from the initiation of a 1000L GMP run for HCW9218. Looking ahead for the remainder of 2022, costs are expected to be primarily associated with several procedures required to finalize production of HCW9302, including GMP process closeout through finalization of reports, fill/finish activities, as well as drug substance and drug product release testing. In addition, we expect to complete the 1000L GMP manufacturing run and fill/finish activities for HCW9218 that was initiated in the second quarter of 2022.

Expenses associated with preclinical activities decreased by $40,007, or 5%, from $769,179 for the three months ended September 30, 2021 to $729,172 for the three months ended September 30, 2022. In the three months ended September 30, 2021, expenses were related primarily to the cost of toxicology studies and experimental materials for IND-enabling activities required to prepare our IND for clinical trials to evaluate HCW9218 in difficult-to-treat solid tumor cancers. In the three months ended September 30, 2022, expenses were related primarily to the cost of toxicology studies and experimental materials related to IND-enabling activities required to prepare our IND for clinical trials to evaluate HCW9302 in an autoimmune indication, alopecia areata.

Expenses associated with clinical activities increased by $222,720, or 320%, from $69,556 for the three months ended September 30, 2021 to $292,276 for the three months ended September 30, 2022. We anticipate expenses related to clinical activities will increase substantially in the future, as there will be multiple clinical trials in progress for the foreseeable future. HCW9218, our lead drug candidate, entered clinical stage in the first half of 2022, upon the initiation of an Investigator-sponsored Phase 1 clinical trial at the Masonic Cancer Center, University of Minnesota for a dose escalation study of HCW9218 as a monotherapy in chemo-refractory/chemo-resistant solid tumors, such as breast, ovarian, prostate and colorectal cancers. The trial is designed to identify the maximum tolerated dose for future evaluation. Depending on the toxicities observed in the treated patients, between 12 and 24 patients may be enrolled. For a Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in patients with chemo-refractory/chemo-resistant advanced pancreatic cancer, three clinical sites were opened as of September 30, 2022. The first patient was dosed by HonorHealth on October 17, 2022. We plan to enroll up to 24 patients from several clinical sites at NCI-designated Comprehensive Cancer Centers. The primary objectives of this study are to determine safety, maximum tolerable dose, and the recommended Phase 2 dose. Besides safety and dosing data, during the course of these clinical studies, we are gathering additional data to obtain further insights for future phases of clinical trials, such as immune system reaction and serum TGF-β neutralization to and by HCW9218 and incidence of mucosal bleeding caused by the HCW9218 TGF-β trap.

Other expenses, which include overhead allocations increased by $42,256, or 30%, from $139,371 for the three months ended September 30, 2021 to $181,627 for the three months ended September 30, 2022. The increase in other expenses was primarily attributable to an increase of $14,294 in facility-related expenses for warranties, $7,451 in travel and travel-related activities to attend scientific conferences, and an increase of $15,709 in depreciation expense.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2021 and September 30, 2022:

	Three Months Ended September 30,			
	2021	2022	$ Change	% Change
Salaries, benefits and related expenses	$ 523,818	$ 779,713	$ 255,895	49%
Professional services	331,706	352,166	20,460	6%
Facilities and office expenses	83,623	85,661	2,038	2%
Depreciation	44,820	31,939	(12,881)	(29)%
Rent expense	24,893	31,217	6,324	25%
Other expenses	395,963	451,970	56,007	14%
Total general and administrative expenses	**$ 1,404,823**	**$ 1,732,666**	**$ 327,843**	23%

General and administrative expenses increased by $327,843, or 23%, from $1.4 million for the three months ended September 30, 2021 to $1.7 million for the three months ended September 30, 2022. This increase was primarily due to an increase of $255,895 in salaries, benefits and related expenses, resulting primarily from an increase of $287,398 in compensation expense for stock-based compensation associated with an equity award to the CEO upon completion of the IPO, expensing $144,870 of offering costs incurred in connection with our shelf registration statement on Form S-3, and an increase of $20,000 for the Company's Board of Directors ("Board") compensation under our non-employee director compensation program put in place post-IPO. These increases were partially offset by a decrease of $75,000 in performance bonuses and a decrease of $10,326 for employee benefits in the three months ended September 30, 2022 versus the comparable period in 2021.

Professional services expense increased by $20,460, or 6%, from $331,706 for the three months ended September 30, 2021 to $352,166 for the three months ended September 30, 2022. The increase is primarily attributable to an increase of $75,236 for legal services related to patents, offset by a decrease of $46,800 in fees paid to advisors for investor relations and communications and a decrease of $13,177 in fees paid to other professional services.

Depreciation expense decreased by $12,881 primarily due to a decrease of $26,494 in amortization for leasehold improvements and an increase of $15,709 in depreciation expense. The Company accelerated amortization of leasehold improvements when the underlying lease expired in February 2022. Depreciation expenses increased as a result of the purchase of a new building for the Company's headquarters in August 2022.

Other expenses increased by $56,007, or 14%, from $395,963 for the three months ended September 30, 2021 to $451,970 for the three months ended September 30, 2022. The increase is primarily due to expensing offering costs of $144,870 incurred in connection with our shelf registration statement on Form S-3 and an increase of $16,200 primarily resulting from an increase in Delaware franchise tax, offset by a net decrease of $117,800 in insurance costs.

Comparison of the Nine Months ended September 30, 2021 and September 30, 2022

Revenues

There was no revenue for the nine months ended September 30, 2021. For the nine months ended September 30, 2022, the Company recognized $5.4 million of revenues in the unaudited statements of operations included elsewhere in this Quarterly Report on Form 10-Q. All revenues were generated under the MSA with Wugen. Revenue was recognized for all transactions made under the MSA for which the Company entered SOWs, since we determined that all requirements were met for the related transactions to qualify as a contract under Topic 606.

For those transactions for which revenues were not recognized because one or more of the criteria for revenue recognition had not been met under Topic 606, the Company recorded deferred revenue. There were $1.1 million and nil of short-term deferred revenues as of September 30, 2021 and September 30, 2022, respectively.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2021 and September 30, 2022:

	Nine Months Ended September 30,			
	2021	2022	$ Change	% Change
Salaries, benefits and related expenses	$ 2,147,907	$ 2,268,755	$ 120,848	6%
Manufacturing and materials	2,109,534	1,273,902	(835,632)	(40)%
Preclinical expenses	1,764,117	1,841,809	77,692	4%
Clinical trials	227,108	486,992	259,884	114%
Other expenses	441,651	536,895	95,244	22%
Total research and development expenses	**$ 6,690,317**	**$ 6,408,353**	**$ (281,964)**	(4)%

Research and development expenses decreased by $281,964, or 4%, from $6.7 million for the nine months ended September 30, 2021 to $6.4 million for the nine months ended September 30, 2022. The decrease of $835,632 in manufacturing and materials expenses were partially offset by increases in all other expenses.

Salaries, benefits, and related expenses increased by $120,848, or 6%, from $2.1 million for the nine months ended September 30, 2021 to $2.3 million for the nine months ended September 30, 2022. This increase was primarily attributable to a $275,209 increase in salaries and wages, performance bonuses, and benefits and an increase of $34,819 in compensation expense related to stock-based compensation. These increases were partially offset by a reimbursement from Wugen for certain expenses incurred under the terms of the Wugen License that was $185,333 greater for the nine months ended September 30, 2022 versus the comparable period in 2021.

Manufacturing and materials expense decreased by $835,632, or 40%, from $2.1 million for the nine months ended September 30, 2021 to $1.3 million for the nine months ended September 30, 2022. Manufacturing and materials expenses in the nine months ended September 30, 2021 resulted from activities related to establishing master cell banks for several molecules, effecting a technology transfer to our contract manufacturer required for internally-developed manufacturing processes, and successfully completing multiple cGMP production runs for our molecules. For HCW9218, we successfully completed cGMP manufacturing runs in multiple quantities and initiated the fill/finish process and testing for product release. For HCW9302, we had initiated master cell bank production and completed a scale-up run of cGMP-grade material. In the nine months ended September 30, 2022, costs were primarily from a 1000L GMP run for HCW9218 as well as HCW9302 technology transfer and development process closeout through finalization of reports and the project initiation.

Expenses associated with preclinical activities increased by $77,692, 4%, from $1.8 million for the nine months ended September 30, 2021 to $1.8 million for the nine months ended September 30, 2022. In the nine months ended September 30, 2021, expenses were related primarily to the cost of toxicology studies and experimental materials for IND-enabling activities required to prepare our IND for clinical trials to evaluate HCW9218 in difficult-to-treat solid tumor cancers. In the nine months ended September 30, 2022, expenses were related primarily to the cost of toxicology studies and experimental materials related to IND-enabling activities required to prepare our IND for clinical trials to evaluate HCW9302 in an autoimmune indication, alopecia areata.

Expenses associated with clinical activities increased by $259,884, or 114%, from $227,108 for the nine months ended September 30, 2021 to $486,992 for the nine months ended September 30, 2022. We anticipate expenses related to clinical activities will increase substantially in the future. HCW9218, our lead drug candidate, entered clinical stage in the first half of 2022, upon the initiation of an Investigator-sponsored Phase 1 clinical trial at the Masonic Cancer Center, University of Minnesota for a dose escalation study of HCW9218 as a monotherapy in chemo-refractory/chemo-resistant solid tumors, such as breast, ovarian, prostate and colorectal cancers. As of September 30, 2022, there were three clinical sites opened for the Company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in chemo-refractory/chemo-resistant advanced pancreatic cancer. The first patient was dosed on at HonorHealth Research Institute on October 17, 2022. For the pancreatic cancer study, we plan to enroll up to 24 patients from several clinical sites.

Other expenses, which include overhead allocations, increased by $95,244, or 22%, from $441,651 for the nine months ended September 30, 2021 to $536,895 for the nine months ended September 30, 2022. The increase in other expenses is primarily attributable to an increase of $22,640 in facility-related expenses for warranties, an increase of $42,467 in travel and travel-related activities to attend scientific conferences and an increase of $19,512 in depreciation expense.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2021 and September 30, 2022:

	Nine Months Ended September 30,			
	2021	2022	$ Change	% Change
Salaries, benefits and related expenses	$ 1,634,048	$ 2,237,841	$ 603,793	37%
Professional services	1,000,206	1,098,530	98,324	10%
Facilities and office expenses	211,038	299,595	88,557	42%
Depreciation	172,545	84,484	(88,061)	(51)%
Rent expense	74,711	96,493	21,782	29%
Other expenses	472,465	1,504,319	1,031,854	218%
Total general and administrative expenses	**$ 3,565,013**	**$ 5,321,262**	**$ 1,756,249**	49%

General and administrative expenses increased by $1.7 million, or 49%, from $3.6 million for the nine months ended September 30, 2021 to $5.3 million for the nine months ended September 30, 2022. The increase was primarily due to an increase of $787,307 related to stock-based compensation expense associated with an equity award to the CEO upon completion of the IPO and an increase of $755,092 related to an increase in insurance coverage appropriate for a public company.

Salaries, benefit and related expenses increased by $603,793, or 37%, from $1.6 million for the nine months ended September 30, 2021 to $2.2 million for the three months ended September 30, 2022. The increase was primarily due to an increase of $99,657 in salaries, benefits and related expenses, an increase of $787,307 related to stock-based compensation expense associated with an equity award to the CEO upon completion of the IPO, and an increase of $103,214 for Board compensation under our non-employee director compensation program put in place post-IPO offset by a $370,750 reduction in performance bonuses.

Professional services increased by $98,324, or 10%, from $1.0 million for the nine months ended September 30, 2021 to $1.1 million for the nine months ended September 30, 2022, primarily due to a $174,339 increase for corporate legal services, a $103,905 increase in expenses for other professional services, such as auditing and tax advisers, and a $47,813 increase in other consulting services, such as architectural services related to the Company's new headquarters building. These increases were partially offset by a decrease of $226,277 in fees for legal services related to patent filings.

Other expenses increased by $1.0 million, or 218%, from $472,465 for the nine months ended September 30, 2021 to $1.5 million for the nine months ended September 30, 2022. The increase is primarily due to an increase of $755,092 in insurance costs associated with being a public company, expensing $144,870 of offering costs related to our shelf registration statement on Form S-3 and an increase of $109,047 in Delaware franchise taxes.

Liquidity and Capital Resource

Sources of Liquidity

As of September 30, 2022, we had cash and cash equivalents held in a money market account of $26.2 million and long-term investments in U.S. government-backed securities of $9.7 million.

On August 15, 2022, we purchased a 36,000 square foot building located in Miramar, Florida for approximately $10.1 million, including transaction costs. A portion of the acquisition cost was funded with a $6.5 million five-year term facility, secured by the building. The remainder of the purchase price was funded with cash. Amounts borrowed under the term facility have a fixed interest rate of 5.75%, with interest only payments required for the first year and 25-year amortization thereafter. With our remaining IPO proceeds, we estimate we have adequate capital to fund operations and the buildout of our new facility to the end of 2023.

We have based our projections of operation expenses requirements on assumptions that may prove to be incorrect, and we may use all of our available capital sooner than we expect. Because of the numerous risks and uncertainties associated with the clinical development and commercialization of immunotherapeutics, we are unable to estimate the exact amount of capital requirements to pursue these activities. Our funding requirements will depend on many factors, including, but not limited to:

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

A change in the outcome of any of these or other factors with respect to the clinical development and commercialization of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures.

Comparison of the Cash Flows for the Nine Months Ended September 30, 2021 and September 30, 2022

The following table summarizes our cash flows for the nine months ended September 30, 2021 and September 30, 2022:

	Nine Months Ended September 30,	
	2021	2022
Cash used in operating activities	$ (7,599,123)	$ (6,596,739)
Cash (used in) provided by investing activities	(34,995,011)	14,777,079
Cash provided by financing activities	49,263,373	6,313,243
Net increase in cash and cash equivalents	**$ 6,669,239**	**$ 14,493,583**

Operating Activities

Net cash used in operating activities was $7.6 million for the nine months ended September 30, 2021 and $6.6 million for the nine months ended September 30, 2022, respectively.

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 $436,135 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.

Cash used in operating activities for the nine months ended September 30, 2022 consisted primarily of a net loss of $9.5 million, $222,555 cash decrease arising from an increase accounts receivable, and $202,979 cash decrease arising from a decrease in accounts payable and other currently liabilities. These uses were partially offset by a $1.9 million cash increase arising from a decrease in prepaid expenses and other assets and noncash adjustments of $834,003 for stock-based compensation expense and $456,696 for depreciation and amortization expense.

Investing Activities

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.

During the nine months ended September 30, 2022, cash provided by investing activities consisted of $25.0 million of cash provided when short-term investments reached maturity, offset by $10.2 million of cash used to purchase property, plant and equipment.

Financing Activities

During the nine months ended September 30, 2021 cash provided by financing activities primarily resulted from our IPO, offset by offering costs. Net proceeds were approximately $49.2 million, after deducting underwriting discounts and commissions and estimated offering expenses paid by us.

During the nine months ended September 30, 2022, cash provided by financing activities resulted from obtaining purchase financing to acquire our new headquarters building.

Critical Accounting Policies, Significant Judgements and Use of Estimates

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

Revenue Recognition

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

See Note 1 to our condensed interim financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for more information.

Other than the above, there have been no material changes to our critical accounting policies and estimates from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies, Significant Judgements and Use of Estimates" in our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 29, 2022.

Recent Accounting Pronouncements

See Note 1 to our unaudited condensed interim financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for more information about recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of September 30, 2022, we had cash and cash equivalents held in a money market account of $26.2 million and long-term investments in U.S. government-backed securities of $9.7 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. We are exposed to market risk related to the marketability of our Wugen common stock reported within Investments in the accompanying condensed balance sheet. Until such time as these shares become publicly traded, we will have limited access to liquidity for these securities.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Under the supervision and with the participation of our management, including the Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2022. Based on that evaluation, the CEO and CFO have concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the three months ended September 30, 2022, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

See Note 7 to our condensed interim financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for more information.

Item 1A. Risk Factors.

Our operations and financial results are subject to various risks and uncertainties, including those described below that could adversely affect our business, financial condition, results of operations, cash flows and the trading price of our common stock. It is not possible to predict or identify all such risks; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, you should carefully consider the following risks, together with all of the other information in this Quarterly Report on Form 10-Q, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," our financial statements and the related notes thereto. You should not consider the following risks to be a complete statement of all the potential risks or uncertainties we could face.

Summary of Key Risk Factors

- We have incurred significant losses since our inception and we expect to incur losses for the foreseeable future. We may never achieve or maintain profitability.
- We may require additional funding in order to complete development of our product candidates and commercialize our products, if approved. Additional funding may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs, our efforts to access manufacturing capacity and our commercialization efforts.
- Public health crises such as pandemics or similar public health crises could materially and adversely affect our preclinical and clinical trials, business, financial condition, and results of operations.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.
- Preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.
- The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis if at all, our business will be substantially harmed.
- Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our product candidates are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.
- Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.
- We expect to rely on patents and other intellectual property rights to protect our technology, including product candidates and our immunotherapy platform technology, the prosecution, enforcement, defense, and maintenance of which may be challenging, time-consuming and costly. Failure to defend, protect or enforce these rights adequately, and costs and expenses associated with the same, could impact our financial condition and results of operations or otherwise harm our ability to compete and impair our business.
- We rely on third-parties to manufacture our product candidates. Any failure by a third-party manufacturer to produce acceptable drug substance for us or to obtain authorization from the FDA or comparable regulatory authorities may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory approvals or commercialize approved products.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and we expect to incur losses for the foreseeable future. We may never achieve or maintain profitability.

Since our inception, we have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials, and have incurred significant operating losses. For the nine months ended September 30, 2021 and 2022, we reported a net loss of $9.7 million and $9.3 million, respectively. As of September 30, 2022, we had $26.2 million in a money market account and $9.7 million in long-term investments held in U.S. Treasury notes. From inception to September 30, 2022, we incurred cumulative net losses of $37.3 million. To date, we have financed our operations primarily through our initial public offering, or the IPO, the sale of our redeemable preferred stock, and to a lesser extent, upfront payments received under our Wugen License for certain rights to two of our internally-developed molecules and proceeds from a PPP loan obtained through the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") which was forgiven.

Our losses have resulted principally from expenses incurred in the research and development of our product candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses for the foreseeable future. The only revenue we have generated to date relates to our Wugen License. We have not generated any revenues from product sales. We anticipate that our expenses will increase substantially as we initiate preclinical and clinical studies, scale up our manufacturing process and capabilities to support our clinical studies and grow to scale.

We have no products for which we have obtained marketing approval and have not generated any revenue from product sales. Even if we obtain marketing approval for, and are successful in commercializing, one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, accessing manufacturing capacity, establishing marketing capabilities, and ultimately selling any products for which we may obtain regulatory approval. We may never succeed in these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Since our inception in 2018, we have devoted a significant portion of our resources to identifying and developing our product candidates emerging from our internally-developed immunotherapy platform technology, our other research and development efforts, building our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully complete clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We may require additional funding in order to complete development of our product candidates and commercialize our products, if approved. However, this additional financing may not be available on acceptable terms, or at all. If we are unable raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

Based on our current business plans, including anticipated revenues from out-license agreements, we believe that our existing cash and cash equivalents and short-term investments, will enable us to fund our operating expenses through the end of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect, requiring us to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product

candidates. Our future capital requirements will depend on many factors, and our ability to raise additional funds will depend on financial, economic, and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from the COVID-19 pandemic, macro-economic developments, or other factors could also adversely impact our ability to access capital as and when needed. Additional funds may not be available when we need them, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we could be required to:

- delay, limit, reduce, or terminate preclinical studies, clinical trials, or other research and development activities, or eliminate one or more of our development programs altogether; or
- delay, limit, reduce, or terminate our efforts to access manufacturing capacity, establish sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

Public health crises such as pandemics or similar public health crises outbreaks could materially and adversely affect our preclinical and clinical trials, business, financial condition, and results of operations.

The effects of health epidemics, including the COVID-19 pandemic, and related public health guidance measures and orders, have had, and may continue to have, an adverse impact on our clinical trials, business, financial condition and results of operations. In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. As a result of the COVID-19 pandemic, we have experienced delays in the development of our lead product candidates as a result of the ongoing COVID-19 pandemic as new variants spread and prolong its impacts, including delays with certain third-party vendors conducting preclinical IND-enabling studies. For example, some of our suppliers have experienced and may continue to experience disruption to their respective supply chain due to the effects of the COVID-19 pandemic, which could delay, prevent or impair our development or commercialization efforts.

Additionally, the worldwide demand and rapid development of COVID-19 diagnostics, vaccines and therapeutics has limited and may continue to limit the availability of services and materials necessary for our product candidates' manufacture and testing. Staffing shortages due to COVID-19 at our clinical sites have delayed our clinical trial and may continue to adversely impact our operations clinical activities. While we are using our best efforts to mitigate these disruptions, we expect that our clinical development program timelines, including the timing of the IND submissions, may continue to be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition, and results of operations.

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

If we or any collaborators we work with in the future are unable to successfully develop and commercialize our product candidates, or experience significant delays in doing so, our business, financial condition, and results of operations will be materially adversely affected.

Our ability to generate product and royalty revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. Each of our product candidates and any future product candidates we develop will require significant clinical development; management of clinical, preclinical, and manufacturing activities; regulatory approval in multiple jurisdictions; establishing manufacturing supply, including commercial manufacturing supply; and require us to build a commercial organization and make substantial investment and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

If we do not successfully execute or address these matters in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially adversely affect our business, financial condition, and results of operations.

A key element of our strategy is to enter into out-licensing arrangements for certain rights to HCW internally-developed molecules that we do not intend to develop into lead product candidates on our own or together with co-development partners. We may not be able to identify licensees, which could lower any return on our investments and increase our need for external funding.

Since we have already generated over 30 immunotherapeutic molecules, and plan to develop additional molecules, through our immunotherapy platform technology, our strategy includes funding operations in part through revenues derived from out-licensing molecules that are outside our oncological and anti-aging focus to third parties. Despite our efforts, we may be unable to enter into such licensing agreements. Supporting diligence activities conducted by potential licensors and negotiating the financial and other terms of a license agreement are long and complex processes with uncertain results, and we may fail to derive any revenues from these activities. Further, our potential licensors may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, potentially resulting in our receiving no future milestone or royalty payments under any such licenses. For example, we have an exclusive worldwide license arrangement with Wugen pursuant to the development of certain cellular therapy products under which we may earn additional milestone or royalty payments, but there can be no assurance that Wugen will be successful in commercializing any products related to this license or that any such payments will ever be earned. If we fail to successfully out-license to third parties internally-developed molecules that are outside our focus areas, our revenues and return on our research and development activities would be negatively affected and we could be required to seek additional funding of our operations through the issuance of additional shares of common stock, or other equity or debt securities convertible into common stock, which could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

We expect to continue to expand our capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of September 30, 2022, we had 43 full-time employees. We expect to experience continued growth in the number of our employees and the scope of our operations, particularly in the areas of drug development and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems; expand our facilities; and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a public company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating additional employees; managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving our operational, financial and management controls, reporting systems, and procedures.

We currently rely on certain independent organizations, advisors, and consultants to provide certain services, including strategic, financial, business development services, as well as certain aspects of regulatory approval, clinical management, manufacturing, and preparation for a potential commercial launch. There can be no assurance that the services of independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants or contract manufacturing organizations is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, volatility associated with the COVID-19 pandemic has caused significant instability and disruptions in the capital and credit markets and, in recent months, our operations and the global economy have been impacted by increasing interest rates and inflation. Likewise, the capital and credit markets may be adversely affected by the recent conflict between Russia and Ukraine, and the possibility of a wider European or global conflict, global sanctions imposed in response thereto, or an energy crisis. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific, and technical personnel, many of whom have been instrumental for us and have substantial experience with our product candidates and related technology. The loss of key managers and senior scientists could delay our research and development activities. Despite our efforts to retain valuable employees, members of our management, scientific, and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. In addition, the competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly-skilled scientific, technical, and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.

Risks Related to the Development and Clinical Testing of Our Product Candidates

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our investigational drug products are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing.

Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials, and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications, patient population, and regulatory agency. Prior to obtaining approval to commercialize our product candidates and any future product candidates in the United States or abroad, we, our collaborators or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols, and the rate of dropout among clinical trial participants. If the results of our clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials could limit the prospects for regulatory approval of that product candidate or other product candidates in any indications.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in clinical trials. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates, and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

Preliminary, topline or interim data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our company in general.

From time to time, we may also disclose data from planned interim analyses of our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available and could result in volatility in the price of our common stock. Adverse differences between interim data and final data could significantly harm our business, operating results, prospects, or financial condition.

Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our product candidates are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to produce the same results or to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Our future clinical trial results may not be successful.

To date, we have not completed any clinical trials required for the approval of our product candidates. We may experience delays in our clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time, or be completed on schedule, if at all. These clinical trials can be delayed, suspended, or terminated for a variety of reasons. In addition, even if the regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or similar application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Ethics Committees or IRBs at the medical institutions where the clinical trials are conducted. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted, by the Data Review Committee or Data Safety Monitoring Board for such trial or by the FDA, or other regulatory authorities. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

In addition, clinical trials must be conducted with supplies of our product candidates produced under current good manufacturing practices, or cGMP, requirements and other regulations. Furthermore, we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions to conduct our clinical trials in compliance with good clinical practice ("GCP") requirements. To the extent our collaborators fail to enroll participants for our clinical trials, fail to conduct the study in accordance with GCP, or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, and additional regulatory requirements, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening, and medical care.

Our lead product candidate, HCW9218, has been cleared by the FDA to proceed with two initial Phase 1/1(b) clinical trials in cancer indications. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of HCW9218 could be harmed, and our ability to generate revenues from HCW9218 may be delayed. In addition, any delays in our clinical trials would require us to store material which could expose us to inventory risk, increased costs, slow down in development and approval process, as well as jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We depend on enrollment of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling in our clinical trials, our research and development efforts and business, financial condition, and results of operations could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays for a variety of reasons, including delays in completion of internal procedures required to open a clinical sites, patient enrollment taking longer than anticipated, patient withdrawal, or adverse events. For example, there were delays in commencing clinical trials of HCW9218 as a result of the ongoing pandemic and staffing shortages at clinical sites. These types of developments could cause us to delay the trial or halt further development.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Moreover, enrolling patients in clinical trials for cancer therapies is challenging, as cancer patients will first receive the applicable standard of care. This may limit the number of eligible patients able to enroll in our clinical trials who have the potential to benefit from our drug candidates and could extend development timelines or increase costs for these programs. Patients who fail to respond positively to the standard of care treatment will be eligible for clinical trials of unapproved drug candidates. However, these patients may have either compromised immune function from prior administration of chemotherapy or an enhanced immune response from the prior administration of checkpoint inhibitors. Either of these prior treatment regimens may render our therapies less effective in clinical trials. Additionally, patients who have failed approved therapies will typically have more advanced cancer and a poorer long-term prognosis.

Patient enrollment depends on many factors, which may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the current and future use of product candidates by us and our partners in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, our partners, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our product candidates; injury to our reputation; withdrawal of clinical trial participants; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any product candidate; and a decline in our share price.

Although we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may be unable to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims, and our business operations could be impaired.

Risks Related to Our Regulatory Environment

The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis if at all, our business will be substantially harmed.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to our product candidates are subject to extensive regulation. In the United States, marketing approval of biologics requires the submission of a BLA to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product candidate. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing, and controls. Outside the United States, many comparable foreign regulatory authorities employ similar approval processes.

We have not previously submitted a BLA to the FDA or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval. Obtaining approval of a BLA can be a lengthy, expensive, and uncertain process, and as a company we have no experience with the preparation of a BLA submission or any other application for marketing approval. In addition, the FDA has the authority to require a REMS as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. We also would not be permitted to market our product candidates in countries outside of the United States until we receive marketing approval from applicable regulatory authorities in those countries.

Our product candidates could fail to receive regulatory approval for many reasons, and the lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. The FDA and other regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. As a result, we may be required to conduct additional preclinical studies, alter our proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which we hope to conduct clinical trials and develop and market our products, if approved. Further, even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include issuing warning letters or untitled letters, imposing fines on us, imposing restrictions on the product or its manufacture, and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our product labeling, or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition, and results of operations.

In addition, if we have any product candidate approved, our product labeling, advertising, and promotion will be subject to regulatory requirements and continuing regulatory review. In the United States, the FDA and the Federal Trade Commission ("FTC"), strictly regulate the promotional claims that may be made about pharmaceutical products to ensure that any claims about such products are consistent with regulatory approvals, not misleading or false in any particular, and adequately substantiated by clinical data. The promotion of a drug product in a manner that is false, misleading, unsubstantiated, or for unapproved (or off-label) uses may result in enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or the FTC. In particular, a product may not be promoted for uses that are not consistent with the uses approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions and may result in false claims litigation under federal and state statutes, which can lead to consent decrees, civil monetary

penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid, and other federal and state healthcare programs. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Our employees, independent contractors, principal investigators, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, theft of trade secrets as well as patient privacy and other privacy laws and regulations. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, labeling, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations, and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us or our collaborators, from research institutions and our collaborators, and directly from individuals.

We and our partners and vendors are subject to various federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address data privacy and security). If we fail to comply with these laws and regulations we may be subject to litigation, regulatory investigations, enforcement notices, enforcement actions, fines, and criminal or civil penalties, as well as negative publicity and a potential loss of business.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, most healthcare providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"). Under HIPAA, we could potentially face substantial criminal or civil penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information, or otherwise violate applicable HIPAA requirements related to the protection of such information. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute a violation of the Federal Trade Commission Act.

In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws (for example, the California Consumer Privacy Act) requiring notification of affected individuals and state regulators in the event of a breach of personal information.

Our clinical trial programs and research collaborations outside the United States may implicate international data protection laws, including, in Europe, the General Data Protection Regulation ("GDPR"). If our privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions requiring us to change the way we use personal data and/or fines. In addition to statutory enforcement, a personal data breach can lead to negative publicity and a potential loss of business. Further, following the United Kingdom's withdrawal from the E.U. effective as of December 31, 2020, we have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, which may have differing requirements. If we fail to comply with United Kingdom data protection laws we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions, as well as negative publicity and a potential loss of business.

We are also subject to evolving EEA laws on data export, as we may transfer personal data from the EEA to other jurisdictions. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. For example, on July 16, 2020, the Court of Justice of the European Union ("CJEU"), invalidated the EU-US Privacy Shield Framework ("Privacy Shield"), under which personal data could be transferred from the EEA to United States entities who had self-certified under the Privacy Shield scheme. Moreover, it is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature.

As government authorities issue further guidance on personal data export mechanisms and/or start taking enforcement action, we could suffer additional costs, complaints, and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. These laws and regulations may apply, not only to us, but also to vendors that store or otherwise process data on our behalf, such as information technology vendors. If such a vendor misuses data we have provided to it, or fails to safeguard such data, we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions, as well as negative publicity and a potential loss of business.

Risks Related to Commercialization of Our Product Candidates

We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop, and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large pharmaceutical and biotechnology companies, academic institutions, government agencies, and other public and private research organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and marketing of products that compete with our product candidates. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

With the proliferation of new oncology drugs and therapies, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical, which could adversely impact our business, financial condition, or results of operations.

Failure to successfully identify, develop and commercialize additional product candidates could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of our product candidates in our current pipeline, we expect to continue to innovate and potentially expand our portfolio. Because we have limited financial and managerial resources, research programs to identify product candidates may require substantial additional technical, financial and human resources, whether or not any new potential product candidates are ultimately identified. Our success may depend in part upon our ability to identify, select, and develop promising product candidates and therapeutics. We may expend resources and ultimately fail to discover and generate additional product candidates suitable for further development. All product candidates are prone to risks of failure typical of biotechnology product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics indicating that it is unlikely to receive approval by the FDA, the European Medicines Agency ("EMA"), and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize new product candidates we have identified and explored, our business, prospects, financial condition, and results of operations could be adversely affected.

Even if approved, our products may not gain market acceptance, in which case we may not be able to generate product revenues, which will materially adversely affect our business, financial condition, and results of operations.

Even if the FDA or any other regulatory authority approves the marketing of any product candidates that we develop on our own or with a collaborator, physicians, healthcare providers, patients, or the medical community may not accept or use them. Additionally, the product candidates that we are developing are based on our internally-developed immunotherapy platform technology, which is a new technology. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any of our product candidates will depend on a variety of factors, and if our product candidates fail to gain market acceptance, our ability to generate revenues to provide a satisfactory, or any, return on our investments may be materially and adversely impacted. Even if some products candidates achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

We currently have no marketing, sales, or distribution infrastructure and we intend to either establish a sales and marketing infrastructure or outsource this function to a third party. Either of these commercialization strategies carries substantial risks to us.

We currently have no marketing, sales, and distribution capabilities because all of our product candidates are still in clinical or preclinical development. If any of our product candidates are approved, we intend to either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in a legally compliant manner, or to outsource this function to a third party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy.

If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses, which would have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Dependence on Third Parties

We rely on third-parties to manufacture our product candidates. Any failure by a third-party manufacturer to produce acceptable drug substance for us or to obtain authorization from the FDA or comparable regulatory authorities may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory approvals or commercialize approved products.

We do not currently own or operate any cGMP manufacturing facilities nor do we have any in-house cGMP manufacturing capabilities. We rely on third-party contract manufacturers to produce sufficient quantities of materials required for the manufacture of our product candidates for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards, and intend to do so for the commercial manufacture of our products, if approved. If we are unable to arrange for such third-party manufacturing sources, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. Such failure or substantial delay could materially harm our business.

We rely on third parties for biological materials that are used in our discovery and development programs. These materials can be difficult to produce and occasionally have variability from the product specifications. Any disruption in the supply of these biological materials consistent with our product specifications could materially adversely affect our business. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. We may also have lower yields in manufacturing batches, which can increase our costs and slow our development timelines. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our biological raw materials or product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications), and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us.

If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed. In addition, the fact that we are dependent on our collaborators, our suppliers, and other third parties for the manufacture, filling, storage, and distribution of our product candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition, and results of operations. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

Pharmaceutical manufacturers are also subject to extensive post-marketing oversight by the FDA and comparable regulatory authorities in the jurisdictions where the product is marketed, which include periodic unannounced and announced inspections by the FDA to assess compliance with cGMP requirements. If an FDA inspection of a manufacturer's facilities reveals conditions that the FDA determines not to comply with applicable regulatory requirements, the FDA may issue observations through a Notice of Inspectional Observations, commonly referred to as a "Form FDA 483". If observations in the Form FDA 483 are not addressed in a timely manner and to the FDA's satisfaction, the FDA may issue a Warning Letter or pursue other forms of enforcement action. Any failure by one of our contract manufacturers to comply with cGMP or to provide adequate and timely corrective actions in response to deficiencies identified in a regulatory inspection could result in enforcement action that could lead to a shortage of products and harm our business, including withdrawal of approvals previously granted, seizure, injunction or other civil or criminal penalties. The failure of a manufacturer to address any concerns raised by the FDA or foreign regulators could also lead to plant shutdown or the delay or withholding of product approval by the FDA in additional indications, or by foreign regulators in any indication. Certain countries may impose additional requirements on the manufacturing of drug products or drug substances, and on manufacturers, as part of the regulatory approval process for products in such countries. The failure by our third-party manufacturers to satisfy such requirements could impact our ability to obtain or maintain approval of our products in such countries.

We expect to rely on third parties, including independent clinical investigators, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We plan to rely upon third parties, including independent clinical investigators, to conduct our preclinical studies and clinical trials and to monitor and manage data for our preclinical and clinical programs. We will rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, our reliance on these third parties will not relieve us of our regulatory responsibilities, and we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, including GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators, and trial sites. If we fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed

unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party laboratories, or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed. Switching or adding additional laboratories or investigators involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

We may not realize the benefits of any existing or future co-development or out-licensing arrangement, and if we fail to enter into new strategic relationships our business, financial condition, commercialization prospects, and results of operations may be materially adversely affected.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. Therefore, for some of our product candidates, we may decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all. If our strategic collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. In instances where we do enter into collaborations, we could be subject to a number of risks which may materially harm our business, commercialization prospects, and financial condition. For example, we may not be able to control the amount and timing of resources that is required of us to complete our development obligations or that the collaboration partner devotes to the product development or marketing programs, the collaboration partner may experience financial difficulties or we may be required to relinquish important rights such as marketing, distribution, and intellectual property rights.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue, or specific net income that justifies such transaction.

To date, we have relied on one third-party manufacturer for the cGMP production of our drug product candidates. The loss of this third-party manufacturer could negatively impact our ability to develop our product candidates and adversely affect our business.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and currently rely on a single third-party vendor to manufacture supplies and process our product candidates. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

Although in the future we intend to develop our own manufacturing facility, we also intend to use third parties as part of our manufacturing process and may, in any event, never be successful in developing our own manufacturing facility.

Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

The lead time needed to establish relationships with new manufacturers can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new manufacturer. The time and effort to qualify a new manufacturer could result in additional costs, diversion of resources, or reduced manufacturing yields, any of which would negatively impact our operating results.

Moreover, to meet anticipated demand, our third-party manufacturer may need to increase manufacturing capacity, which could involve significant challenges. This may require us and our vendor to invest substantial additional funds and hire and retain the technical personnel who have the necessary experience. Neither we nor our third-party manufacturer may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all.

Supply sources could be interrupted from time to time and, if interrupted, there is no guarantee that supplies could be resumed within a reasonable time frame and at an acceptable cost or at all.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs, and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event a new supplier must be used. The time and effort to qualify a new supplier could result in additional costs, diversion of resources, or reduced manufacturing yields, any of which would negatively impact our operating results. Although we will not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing, and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Risks Related to Intellectual Property and Information Technology

We expect to rely on patents and other intellectual property rights to protect our technology, including product candidates and our immunotherapy platform technology, the prosecution, enforcement, defense, and maintenance of which may be challenging and costly. Failure to protect or enforce these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for technology related to our product candidates, including, but not limited to, our immunotherapy platform technology, product candidates, methods used to manufacture those product candidates, formulations thereof, and the methods for treating patients using those product candidates. Given that the development of our technology and product candidates is at an early stage, our intellectual

property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel platform technology and product candidates that are important to our business. The patent prosecution process is expensive and time-consuming, and we may not be able to prepare, file, and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, during the patent prosecution process, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections.

The issuance, scope, validity, enforceability, and commercial value of our current or future patent rights are highly uncertain. It is possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Our pending and future patent applications may not result in patents being issued which protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and product candidates. The patent examination process may require us to narrow the scope of the claims of our pending and future patent applications, which may limit the scope of patent protection that may be obtained. Further, even if we obtain patents with sufficient scope to protect our technology or product candidates in their present forms, future technical changes to our technology or product candidates may render the patent coverage inadequate.

We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate or narrow the scope of a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation actions in court or before patent offices, or similar proceedings challenging the validity, ownership, enforceability, or scope of such patents, which may result in the patent claims being narrowed, invalidated, or held unenforceable or circumvented. Because patent applications in the United States and other jurisdictions are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file any patent applications related to such inventions. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued from such applications, and then only to the extent the issued claims cover the technology. Furthermore, even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. Additionally, our competitors or other third parties may be able to evade our patent rights by developing new biologics, biosimilars, or alternative technologies or products in a non-infringing manner.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned patent applications may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our owned patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

The United States Patent and Trademark Office ("USPTO") and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent application process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO, foreign patent offices, and patent courts or other authorities in granting patents and ruling on claim scope and validity are not always applied uniformly or predictably. Patent positions of life sciences companies can be uncertain and involve complex factual, scientific, and legal questions. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our product candidates.

We may become involved in lawsuits to protect or enforce our issued patents relating to one or more of our product candidates or our internally-developed platform, which could ultimately render our patents invalid or unenforceable and adversely affect our competitive position. Intellectual property litigation or other legal proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Competitors may infringe our patents or other intellectual property that relate to our immunotherapy platform technology and product candidates, their respective methods of use, manufacture, and formulations thereof. Third parties may in the future claim that our operations infringe their intellectual property rights. To defend against such claims, protect our competitive position and counter infringement or unauthorized use, we may from time to time need to resort to litigation to enforce or defend any patents or other intellectual property rights owned or licensed by us by filing infringement claims. We have received notices (and we may be subject to litigation in the future) that claims we have misappropriated or misused other parties' trade secrets or information. To the extent we gain greater market visibility, we face a higher risk of being the subject of intellectual property infringement claims, which is not uncommon with respect to the biopharmaceutical industry.

As enforcement of intellectual property rights is difficult, unpredictable, time-consuming, and expensive, we may fail in enforcing our rights, in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our product candidates or methods, or our immunotherapy platform technology, and then compete directly with us, without payment to us.

Even if resolved in our favor, such litigation and other legal proceedings may cause us to incur significant expenses and would be likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities, and may impact our reputation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Intellectual property rights of third parties could adversely affect our ability to develop or commercialize our product candidates, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our product candidates or any products, if approved without infringing, or otherwise violating the intellectual property and other proprietary rights of third parties. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our methods or product candidates or elements thereof, our manufacture or uses relevant to our development plans, our product candidates or other attributes of our product candidates, or our immunotherapy platform technology. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, which can be expensive and time-consuming, or have to enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. If we are sued for patent infringement, we would need to demonstrate that our product candidates or platform technology either do not infringe the patent claims of a relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. We may not have sufficient resources to bring these actions to a successful conclusion. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable, and time-consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates.

In addition, indemnity provisions in various agreements and our corporate documents potentially expose us to substantial liability for intellectual property infringement and other claims. In the ordinary course of business, we enter into agreements that may include indemnification provisions under which we agree to indemnify them for losses suffered or incurred as a result of claims of intellectual property infringement or other liabilities relating to or arising from our clinical trials, breach of warranties or other contractual obligations. In some cases, the indemnification will continue after the termination of the applicable agreement. In addition, in accordance with our bylaws and pursuant to indemnification agreements entered into with directors, officers and certain employees, we have indemnification obligations for claims brought against these persons arising out of certain events or

occurrences while they are serving at our request in such capacities. For example, our founder and chief executive officer is subject to a claim from a former employer. We agreed to advance certain defense costs and other expenses, subject to an undertaking to repay us such amounts if, and to the extent that, it is ultimately determined that he is not entitled to indemnification. The matter is ongoing. If this matter is resolved in favor of the third party and if we are required to indemnify our founder and chief executive officer for a loss, we may be required to make an indemnity payment. While we maintain directors' and officers' liability insurance, such insurance may not be applicable, be adequate, or cover all liabilities that we may incur. Large indemnity payments, individually or in the aggregate, could have a material impact on our financial position.

Our involvement in litigation, and in any interferences, post-grant proceedings, opposition proceedings, or other intellectual property proceedings inside and outside of the United States may divert management from focusing on business operations, and even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We may need to obtain licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We own and are pursuing rights to the intellectual property, including patent applications relating to our immunotherapy platform technology and our product candidates. In the future, we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our platform technology and product candidates. The fusion components of our product candidates may have also been the subject of research by companies that could have filed patent applications on their specific construct and therapeutic methods. There can be no assurance any such patents will not be asserted against us or that we will not need to seek licenses from such third parties. We may not be able to secure such licenses on acceptable terms, if at all, and any such litigation would be costly and time-consuming.

Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use, or sell our product candidates or any products, if approved, the growth of our business will likely depend in part on our ability to acquire, in-license, maintain, or use these proprietary rights. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program and our business and financial condition could suffer.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own. In addition, interferences, post-grant proceedings, opposition proceedings, derivation proceedings, or other intellectual property proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications.

The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or

ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may rely on trade secret and proprietary know-how, which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value, to maintain our competitive position with respect to our research programs and product candidates. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees or by other third parties of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus adversely eroding our competitive position in our market. Further, monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our internally-developed technology will be effective. Enforcing a claim that a third party illegally obtained and is using trade secrets and/or confidential know-how is also expensive, time-consuming, and unpredictable.

The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, some courts inside and outside the United States are less willing or are unwilling to protect trade secrets or other proprietary information.

Trade secrets can over time be disseminated within the biopharmaceutical industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our employees, consultants, contractors, collaborators, advisors, and other third parties to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our product candidates and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

In addition, our competitors may independently develop substantially equivalent trade secrets, proprietary information, or know-how and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how. Under certain circumstances and to make it more likely that we have our freedom to operate, we may also decide to publish some know-how to make it difficult for others to obtain patent rights covering such know-how, at the risk of potentially exposing our trade secrets to our competitors.

We may be subject to third-party claims asserting that our employees, consultants, contractors, collaborators, or advisors have misappropriated or wrongfully used or disseminated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure, and non-competition agreements in connection with such previous employment. Similarly, we work with consultants, contractors, collaborators, advisors, or other third parties who have worked with, and do currently work with, other companies, including our competitors or potential competitors, and have executed proprietary rights, non-disclosure, and non-competition agreements in connection with such other companies. Although we try to ensure that our employees, consultants, contractors, collaborators, advisors, or other third parties do not use or disclose the proprietary information or know-how of others in

their work for us, we may be subject to claims that we or these employees or individuals that we work with have used or disclosed confidential information or intellectual property of others, including trade secrets or other proprietary information, or that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement with a current or former employer or competitor.

Litigation may be necessary to defend against these claims and, even if we are successful, could result in substantial costs and could be a distraction to management, our employees, and our routine business. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to develop or commercialize our technology or product candidates. Such a license may not be available on commercially reasonable terms or at all. Moreover, any such litigation or the threat thereof may adversely affect our reputation and our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations, and financial condition.

Our information technology systems, or those used by other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business.

We collect and maintain information in digital form that is necessary to conduct our business, and we are dependent on our information technology systems and those of third parties to operate our business. In the ordinary course of our business, we collect, store, and transmit large amounts of confidential information, including intellectual property, proprietary business information, and personal information, and data to comply with cGMP, clinical and data integrity requirements. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Despite the implementation of security measures, our information technology systems and data and those of our contractors and consultants are vulnerable to compromise or damage from computer hacking, malicious software, fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail, or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers, and others. Although to our knowledge we have not experienced any material cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to regulatory actions taken by governmental authorities, litigation under laws that protect the privacy of personal information, or other forms of legal proceedings, which could result in significant liabilities or penalties. Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price, stockholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile or may decline regardless of our operating performance, resulting in substantial losses for investors.

The market price of our common stock may be highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors described in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q.

In addition, the stock market in general, and the Nasdaq Stock Market, or Nasdaq, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Additionally, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile as a result of the COVID-19 pandemic. Also, broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of September 30, 2022, our executive officers, directors and their respective affiliates beneficially owned approximately 50% of our outstanding voting stock (excluding any stock options exercisable within 60 days of such date held by such persons). Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Future sales of our common stock in the public market could cause our common stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisitions, strategic partnerships (including licensing or acquiring complementary products), employee arrangements, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

We are an emerging growth company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual reports on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We will remain an emerging growth company until the earlier of:

- the last day of the fiscal year in which we have more than $1.235 billion in annual revenue;
- the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- December 31, 2026.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded to emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these audited financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. When we lose our status as an "emerging growth company" and a "smaller reporting company," and become an "accelerated filer" or a "large accelerated filer," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we have implemented and will continue to implement additional financial and management controls, reporting systems and procedures and we have hired and intend to continue to hire additional accounting and finance staff.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a staggered Board divided into three classes serving staggered three-year terms, such that not all members of the Board will be elected at one time;
- authorize our Board to issue new series of redeemable preferred stock without stockholder approval and create, subject to applicable law, a series of redeemable preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our Board;
- establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our Board to establish the number of directors;
- provide that our Board is expressly authorized to make, alter or repeal our amended bylaws;
- provide that stockholders can remove directors only for cause and only upon the approval of not less than 66 2/3 of all outstanding shares of our voting stock;
- require the approval of not less than 66 2/3 of all outstanding shares of our voting stock to amend our bylaws and specific provisions of our certificate of incorporation; and
- limit the jurisdictions in which certain stockholder litigation may be brought.

As a Delaware corporation, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two-thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of our company.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation, provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or any director, officer, or other employee arising pursuant to the Delaware General Corporation Law, (4) any action to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. These provisions may limit an investor's ability to bring a claim in a judicial forum that it finds favorable for disputes with our company, including by increasing the cost of such lawsuits, which may discourage such claims. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

Through September 30, 2022, we have used approximately $13.3 million of the $49.2 million net proceeds from our IPO. There has been no material change in the use of proceeds described in the final prospectus filed by us with the SEC on July 21, 2021.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333-256510), which was declared effective by the SEC on July 19, 2021. EF Hutton, division of Benchmark Investments, LLC acted as representative and sole underwriter of the offering.

Item 3. Defaults Upon Senior Securities.

Not Applicable.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.1	Loan Agreement by and between HCW Biologics Inc. and Cogent Bank, dated August 15, 2022.				X
10.2	Mortgage and Security Agreement by and between HCW Biologics Inc. and Cogent Bank, dated August 15, 2022.				X
10.3	Capital on Demand™ Sales Agreement, dated August 19, 2022, by and between HCW Biologics Inc. and Jones Trading Institutional Services LLC	S-3	8/19/2022	###-##-####	
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, 2022, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Condensed Balance Sheets as of December 31, 2021 and September 30, 2022 (unaudited); (ii) the Condensed Statements of Operations for the three months and nine months ended September 30, 2021 (unaudited) and September 30, 2022 (unaudited); (iv) the Condensed Statements of Stockholders' Equity for the three and nine months ended September 30, 2021 (unaudited) and September 30, 2022 (unaudited); (v) the Condensed Statements of Cash Flows for the nine months ended September 30, 2021 (unaudited) and September 30, 2022 (unaudited); and (vi) the notes to the Condensed Financial Statements (unaudited).				X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				X

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

HCW Biologics Inc.

Date: November 7, 2022

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

Date: November 7, 2022

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

EXHIBIT 10.1

LOAN AGREEMENT

THIS LOAN AGREEMENT ("Agreement") dated the 15th day of August, 2022 (the "Closing Date"), by and between HCW BIOLOGICS INC., a Delaware corporation, whose mailing address is 2929 North Commerce Parkway, Miramar, Florida 33025 (the "Borrower") and COGENT BANK, a State Chartered Bank, whose address is 420 South Orange Avenue, Suite 150, Orlando, Florida 32801 (the "Lender").

RECITALS

A. The Borrower has requested the Lender to lend the sum of SIX MILLION FIVE HUNDRED THOUSAND AND NO/100 DOLLARS ($6,500,000.00) subject to the availability of eligible collateral and subject to the compliance by Borrower of all the terms and conditions hereof; and

B. The Lender is willing to make such loan on the terms and conditions and on the security as set forth herein and the parties are desirous of entering into this Agreement.

NOW, THEREFORE, in consideration of the mutual promises, conditions, repre sentations and warranties hereinafter set forth and for other good and valuable consideration, the parties hereto have mutually agreed as follows:

ARTICLE I

DEFINITIONS

For the purposes of this Agreement the following definitions shall apply:

1.1. "Closing Date" shall be defined as August 15, 2022.

1.2. "Collateral" shall be defined as the Mortgage and all other security granted by the Borrower to the Lender as more particularly set forth in Article III of this Agreement.

1.3. "Event of Default" shall be defined as the occurrences or events set forth in Article VII hereof.

1.4. "Lender Service Fee" shall be defined as one-half of one percent of the Loan Amount or THIRTY-TWO THOUSAND FIVE HUNDRED AND 00/100 DOLLARS ($32,500.00)

1.5. "Loan" shall be defined as the credit accommodation extended by the Lender to the Borrower in the amount of SIX MILLION FIVE HUNDRED THOUSAND AND NO/100 DOLLARS ($6,500,000.00) to be disbursed in accordance with this Agreement.

1.6. "Loan Amount" shall be defined as SIX MILLION FIVE HUNDRED THOUSAND AND NO/100 DOLLARS ($6,500,000.00).

1.7. "Loan Documents" shall be defined as the Note, the Mortgage, this Agreement and all instruments and documents executed in connection with the Loan.

1.8. "Mortgage" shall be defined as that certain Mortgage and Security Agreement dated as of the Closing Date, encumbering the Property owned by the Owners and securing the Note to be recorded in the Public Records of Broward County, Florida, as such may be modified from time to time.

1.9. "Note" shall be defined as that certain Promissory Note dated as of the Closing Date made by the Borrower **in** favor of the Lender in the amount of the Loan Amount and any renewals, amendments and modifications thereof.

1.10. "Project" or "Property" shall be defined as that certain property more particularly described on Exhibit "A" attached hereto and made a part hereof and the improvements located thereon.

1.11. "Title Insurance Commitment" shall be defined as that title insurance commitment written on a title insurance company licensed by the State of Florida and satisfactory to Lender's counsel which shall insure the Lender in the Loan Amount and contain such endorsements as is required by the Lender.

1.12. "Title Insurance Policy" shall be defined as the title insurance policy issued pursuant to the Title Insurance Commitment and any endorsements thereto.

ARTICLE II

AMOUNT AND TERMS OF LOAN

Section 2.1 The Loan.

The Lender hereby grants the Loan to the Borrower subject to the terms, conditions and collateral requirements hereinafter set forth in this Agreement.

Section 2.2. Promissory Note.

Under the terms of this Agreement, the Borrower shall execute and deliver to the Lender the Note.

ARTICLE III

SECURITY AND GUARANTY

As security for the full and timely payment of the principal and interest under the Note and for any and all other indebtedness or liability of the Borrower to the Lender, whether now existing or hereafter arising, the Borrower grants and/or agrees to the following (all of which is herein referred to collectively as the "Collateral"):

Section 3.1. Mortgage.

The Borrower grant to the Lender the Mortgage which shall be and continue to be a first lien encumbering the Property. In addition, the Borrower shall cause to be delivered to the Lender a Mortgagee Title Insurance Commitment and Policy naming the Lender as insured in an amount equal to the Loan Amount. Such policy shall be written by a title insurance company licensed by the State of Florida and satisfactory to Lender's counsel without any exception in the commitment or final policy for matters of survey, unrecorded mechanic's liens or easements and/or parties in possession, unless approved of by Lender. All exceptions shall be subject to the approval of counsel to the Lender. The Borrower shall provide, at the request of Lender's counsel, any corrective instruments, releases, satisfactions, affidavits, etc., necessary to cause the policy to be issued. The cost of the Commitment and Policy shall be paid for by the Borrower.

Section 3.2. Additional Security.

If at any time or times in the reasonable opinion of the Lender, the prospect of payments or performance hereunder is impaired or the Lender deems itself or the Collateral insecure, the Borrower shall furnish to the Lender, within ten (10) days of the Lender's demand therefor, such further security, guaranties, or endorsements as may be satisfactory to the Lender and shall execute and deliver, or cause to be executed and delivered, all such instruments and documents as, in the opinion of the Lender, are necessary or desirable in connection herewith.

Section 3.3. Filing and Recording.

The Borrower shall, at its cost and expense, cause all instruments and documents given as security pursuant to this Agreement to be duly recorded and/or filed in all places necessary, in the opinion of the Lender, to perfect and protect the security interest of the Lender in the property covered thereby. The Borrower hereby authorizes the Lender to file any financing statement in respect of any security interest created pursuant to this Agreement which may at any time be required or which, in the opinion of the Lender, may at any time be desirable, although the same may have been executed only by the Lender, or, at the option of the Lender, to sign such financing statement on behalf of the Borrower and file the same, and the Borrower hereby irrevocably designates the Lender, its agents, representatives and designees as agents and attorneys-in-fact for the Borrower for this purpose. In the event that any re-recording or refiling thereof (or the filing of any statements of continuation or assignment of any financing statement) is required to protect and preserve security interest, the Borrower shall, at its cost and expense, cause the same to be re-recorded and/or refiled at the time and in the manner requested by the Lender.

ARTICLE IV

BORROWER'S REPRESENTATIONS AND WARRANTIES

To induce the Lender to enter into this Agreement, the Borrower makes the following representations and warranties which shall be deemed to be continuous representations and warranties so long as any credit hereunder remains available or any indebtedness of the Borrower to the Lender remains unpaid:

Section 4.1. Organization and Standing.

The Borrower is a corporation duly organized and existing under the laws of the State of Delaware and duly qualified to do business in each jurisdiction in which the conduct of their business requires such qualification, including the State of Florida. To the best of the Borrower's knowledge and belief, the Borrower is in compliance with all applicable laws and regulations governing the conduct of their business and governing consummation of the transac tions.

Section 4.2. Power and Authority.

The execution, delivery and performance hereof by the Borrower is within its corporate powers and have been duly authorized by all necessary director and shareholder action, are not in contravention of law or the terms of their Articles of Incorporation or Bylaws or any amendment thereto, or any indenture, agreement or undertaking to which it is a party or by it is bound.

Section 4.3. Valid and Binding Obligations.

This Agreement, the Note and Loan Documents constitute the legal, valid and binding respective obligations of the Borrower subject to applicable bankruptcy and insolvency laws and laws affecting creditors' rights and the enforcement thereof generally.

Section 4.4. Title to Collateral.

The Borrower has good and marketable title to all of the Collateral given as security to the Lender free and clear of all mortgages, pledges, liens, security interests or other encum brances except as may appear on the Commitment for Title Insurance approved by Lender's counsel. The Borrower will warrant and defend the Collateral against the claims and demands of all persons.

Section 4.5. Financial Statements and Other Information.

Subject to any limitation stated therein or in connection therewith by the Borrower in writing, all balance sheets, earnings statements and other financial data which have been or shall hereafter be furnished to the Lender to induce it to enter into this Agreement or otherwise in connection herewith do or will fairly represent the financial condition of the Borrower as of the dates and the results of its operations for the period for which the same are furnished to the Lender and have been or will be prepared in accordance with generally accepted accounting principles consistently maintained, and all other information, reports and other papers and data furnished to the Lender are and or will be, at the time the same are so furnished, accurate and correct in all material respects and complete insofar as completeness may be necessary to give the Lender a true and accurate knowledge of the subject matter. There are no material liabilities of any kind of the Borrower as of the date of the most recent financial statements which are not reflected therein. There have been no materially adverse changes in the financial condition or operation of the Borrower since the date of such financial statements.

Section 4.6. Litigation.

There is not now pending against the Borrower, nor to the knowledge of the officers of the Borrower is there threatened, any litigation, investigations or any proceeding the outcome of which, in the opinion of such officers, would in any case, or in the aggregate, materially adversely affect the assets or financial condition of the Borrower or seriously affect its continued operations.

Section 4.7. Consent or Filing.

No consent, approval or authorization of, or registration, declaration or filing with any court, any governmental body or authority or other person or entity is required in connection with the valid execution, delivery or performance of this Agreement or any document required by this Agreement or in connection with any of the transactions contemplated thereby, except the filing of any financing statements contemplated hereunder.

Section 4.8. Patriot Act.

Neither Borrower, any affiliate of the Borrower, nor any person owning an interest in either of the foregoing is a "Specially Designated National" or a "Blocked Person" as those terms are defined in the Office of Foreign Asset Control Regulations (31 CFR Section 500 et seq.) and/or any other list of terrorists or terrorist organizations maintained pursuant to any of the rules and regulations of Office of Foreign Asset Control, Department of the Treasury or pursuant to any other applicable Executive Orders (such lists are collectively referred to as the "OFAC Lists").

ARTICLE V

CONDITIONS PRECEDENT

The effectiveness of this Agreement and the obligations of the Lender to consummate any of the transactions contemplated hereby shall be subject to the satisfaction of the following conditions precedent, at or prior to the Closing Date:

Section 5.1. Documents and Instruments.

The Lender shall have received all the instruments, documents and property contemplated to be delivered by the Borrower hereunder, and the same shall be in full force and effect.

Section 5.2. Correctness of Warranties.

All representations and warranties contained herein or otherwise made to the Lender in connection herewith shall be true and correct.

Section 5.3. Certificate of Resolution.

The Board of Directors of the Borrower shall have passed a specific resolution authorizing the execution and delivery of all documents and the taking of all actions called for by this Agreement, and the Borrower shall have furnished to the Lender copies of such resolutions, certified by the Chief Executive Officer of the Borrower.

Section 5.4. Expenses of Lender.

The Borrower promises to reimburse the Lender promptly for all reasonable out-of-pocket expenses of every nature which the Lender may incur in connection with the Loan Documents, the making of any loans provided for herein or the collection of the Borrower's indebtedness, including, but not limited to, reasonable attorneys' fees of Lender's counsel relating to the preparation of the Loan Documents, all appraisal fees, all recording fees, documentary stamps and title insurance premiums. Such expenses shall be paid at closing or in a reasonable time thereafter upon receipt of written invoices. The Borrower shall also pay reasonable post-closing expenses incurred by the Lender on behalf of the Borrower, including, but not limited to, recertification of title expenses and preparation of documents to terminate the loan and release the security therefor. Furthermore, the Borrower shall be liable for post-closing collection expenses, including, but not limited to, expenses related to the repossession, storage or sale of the Collateral and to the collection of obligations of the Borrower hereunder, including reasonable attorneys' fees, including appellate proceedings, post-judgment proceedings and bankruptcy proceedings. In the event the Borrower fails to pay such expenses within a reasonable time, the Lender may either (a) disburse to itself under the terms of the Note any sums payable to Lender and such disbursement shall be considered with like effect as if same had been made to Borrower, or (b) pay such expenses on the Borrower's behalf and charge the Borrower's account.

ARTICLE VI

BORROWER'S AFFIRMATIVE COVENANTS

The Borrower covenants and agrees that until the Note, together with interest and all other indebtedness to the Lender under the terms of this Agreement, are paid in full, unless specifically waived by the Lender in writing:

Section 6.1. Corporate Existence and Qualification.

The Borrower will do, or cause to be done, all things necessary to preserve, renew and keep in full force and effect their corporate existence, rights, licenses and permits and comply with all laws applicable to it, operate its businesses in a proper and efficient manner and substantially as presently operated or proposed to be operated; and at all times maintain, preserve and protect all franchises and trade names and preserve all property used or useful in the conduct of its business, and keep the same in good repair, working order and condition, and from time to time make, or cause to be made, all needful and proper repairs, renewals, replacements, betterments and improvements thereto, so that the business carried on in connection therewith may be properly and advantageously conducted at all times.

Section 6.2. Financial Statements/Tax Returns.

The Borrower will keep its books of accounts in accordance with generally accepted accounting practices and will furnish to the Lender:

6.2(1) Borrower Annual Financial Statements. On or before one hundred twenty (120) days following the end of each calendar year, a balance sheet as of the close of such year, a profit and loss statement and statement of reconciliation of surplus for such year for the Borrower a balance sheet as of the close of such year for the Borrower, each prepared in form acceptable to Lender and certified as true, correct and complete by the Chief Executive Officer of the Borrower;

6.2(2) Borrower Tax Return. Within forty-five (45) days after the filing thereof, the annual federal income tax return for the prior year of the Borrower certified as true, correct and complete by the Chief Executive Officer of the Borrower;

The Borrower also, with reasonable promptness, will furnish to the Lender such other data as the Lender may reasonably request.

Section 6.3. Financial Certificate.

The statements called for by Section 6.2 shall be accompanied by a certificate of the Chief Executive Officer of the Borrower stating that there exists no Event of Default as defined in the Loan Documents and no event which, with the giving of notice or passage of time, or both, would constitute such an Event of Default, or, if this is not the case, that one or more specified events of default or above-specified events have occurred.

Section 6.4. Taxes and Claims.

The Borrower shall properly pay and discharge: (a) all taxes, assessments and govern mental charges upon or against the Borrower or its assets prior to the date on which penalties attach thereto, unless and to the extent that such taxes are being diligently contested in good faith and by appropriate proceedings and appropriate reserves therefor have been established; and (b) all lawful claims, whether for labor, materials, supplies, services or anything else which might or could, if unpaid, become a lien or charge upon the properties or assets of the Borrower, unless and to the extent only that the same are being diligently contested in good faith and by appropriate proceedings and appropriate reserves therefor have been established.

Section 6.5. Inspection by Lender.

The Borrower shall allow any representative of the Lender to visit and inspect any of the properties of the Borrower, to examine the books of account and other records and files of the Borrower, to make copies thereof and to discuss the affairs, business, finances and accounts of the Borrower with their respective officers and employees, all at such reasonable time upon reasonable notice to Borrower of the date and time of such inspection and as often as the Lender may request.

Section 6.6. Pay Indebtedness to Lender and Perform Other Covenants.

The Borrower shall: (a) make full and timely payments of the principal of and interest, and premium, if any, on the Note and all other indebtedness of the Borrower to the Lender, whether now existing or hereafter arising; (b) duly comply with all the terms and covenants contained in each of the instruments and documents given to the Lender pursuant to this Agreement or of the times and places and in the manner set forth herein; and (c) at all times maintain the liens and security interests provided for under or pursuant to this Agreement as valid and perfected liens and security interests on the property intended to be covered thereby.

Section 6.7. Litigation.

The Borrower will promptly notify the Lender upon the commencement of any action, suit, claim, counterclaim or proceeding against or investigation of the Borrower (except when the alleged liability is fully covered by insurance): (a) the result of which could materially adversely affect the business of the Borrower; or (b) which questions the validity of this Agreement or any other document executed in connection herewith or any action taken or to be taken pursuant to any of the foregoing.

Section 6.8. Defaults.

The Borrower will promptly notify the Lender in writing of: (a) any material assessment by any taxing authority for unpaid taxes as soon as the Borrower has knowledge thereof; (b) any default by the Borrower in the performance of or any modification of any of the terms or conditions contained in any agreement, mortgage, indenture or instrument to which the Borrower is a part or which is binding upon the Borrower and of any default by the Borrower in the payment of any of its indebtedness; provided, however, the Borrower shall not be required to so notify the Lender of any such default of the Borrower in the performance of or any such modifications of the terms or conditions of any document or agreement pertaining to a transac tion in the ordinary course of business which does not pertain to its indebtedness for borrowed money and which does not materially adversely affect its business or assets.

Section 6.9. Further Assurances.

The Borrower shall, at its sole cost and expense, upon the request of the Lender, duly execute and deliver or cause to be duly executed and delivered to the Lender such further instruments and do and cause to be done such further acts that may be reasonably necessary or proper in the opinion of the Lender to carry out more effectively the intent and purpose of this Agreement.

Section 6.10. Banking Relationship.

For so long as the Borrower is indebted to the Lender pursuant to the terms of the Note, Borrower shall maintain an operating account with Lender from which Lender will draft automatic payments for the principal and interest payments due under the Loan. In addition, Borrower shall maintain a segregated account (the "Escrow Account") with Lender with a balance of not less than an amount equal to three (3) months of its property insurance, taxes, and principal and interest payments due under the Note. The Escrow Account shall be assigned to Lender as additional collateral for the Loan. Withdrawals from the Escrow Account may only be made with the approval of an officer of Lender.

Section 6.11. Leases.

Within thirty (30) days of execution, Borrower shall submit copies of all signed leases (and any amendments thereto). In addition, Borrower shall provide prompt written notice to Lender if there is any change in the status of the current tenant within the Project (e.g., lease extension).

ARTICLE VII

EVENTS OF DEFAULT

Section 7.1. Immediate Acceleration.

If one or more of the following-described events of default shall occur:

7.1(1) The Borrower (a) shall file a petition for adjudication as a bankrupt; (b) shall file a petition or answer seeking reorganization or an arrangement under any bankruptcy or similar statute of the United States of America or any subdivision thereof or of any foreign jurisdiction; (c) shall consent to the filing of a petition in any such bankruptcy or reorganization proceeding; (d) shall consent to the appointment of a receiver or trustee or officer performing similar functions with respect to any substantial part of its property; (e) shall make a general assignment for the benefit of its creditors; or (f) shall execute a consent to any other type of insolvency proceeding (under the Bankruptcy Act or otherwise) or any informal proceeding for the dissolution or liquidation of, or settlement of, claims against or winding up of affairs of, the Borrower; or

7.1(2) The appointment of a receiver or trustee or officer performing similar functions for the Borrower or for any of its assets, or the filing against the Borrower of a petition for adjudication as a bankrupt or insolvent or for reorganization under any bankruptcy or similar laws of the United States of America or of any state thereof or of any foreign jurisdiction, or the institution against the Borrower of any other type of insolvency proceeding (under the Bankruptcy Act or otherwise) or of any formal or informal proceeding for the dissolution or liquidation of, settlement of claims against or winding up of affairs of, the Borrower, and the failure to have such appointment vacated or such petition or proceeding dismissed within sixty (60) days after such appointment, filing or institution; then the credit hereby granted and all

obligations to make loans hereunder shall immediately terminate without notice, and all principal and interest owing hereunder shall forthwith become due and payable without presentment, demand, protest or further notice of any kind, all of which are hereby expressly waived.

Section 7.2. Discretionary Acceleration.

Subject to any applicable cure periods set forth in the Loan Documents the following shall constitute an Event of Default:

7.2(1) Scheduled Payment. Subject to any applicable grace and/or cure periods, Borrower's failure to make any payment required by the Note on or before the date it is due, without further notice or demand.

7.2(2) Monetary Default. Borrower's failure to make any other payment required by this Agreement, or the other Loan Documents, or both, within fifteen (15) days after written demand therefor.

7.2(3) Non-Monetary Default. The occurrence of any non-monetary default under this Agreement or the other Loan Documents, if such default is not cured by the Borrower within thirty (30) days after receipt of written notice thereof; provided (i) if Borrower reasonably cannot perform within such thirty (30) day period, and in Lender's judgment, Lender's security reasonably will not be impaired and Borrower is proceeding in good faith to cure, perform and observe such covenant, condition, agreement or obligation, Borrower may have such additional time to perform as Borrower reasonably may require; and (ii) if Lender's security reasonably will be materially impaired if Borrower does not perform in less than thirty (30) days, Borrower will have only such period following written demand in which to perform as Lender reasonably may specify.

7.2(4) Default Under Agreement with Lender. The existence of any uncured Event of Default under any loan agreement by and between Lender and Borrower.

7.2(5) Pay Sums Due. Failure of the Borrower to pay any sums due in connection with the construction of any improvements. This requirement shall not obligate the Borrower to make payments that the Borrower does not think are reasonably due and payable so long as the non-payment of any such amounts does not jeopardize the lien of the Mortgage or the financial stability of the Project.

7.2(6) Judgment Against Borrower. The rendition by any court of a final judgment against the Borrower in an amount in excess of TWO HUNDRED FIFTY THOUSAND DOLLARS ($250,000.00) which shall not be satisfactorily stayed, discharged, vacated, transferred to security or set aside within ninety (90) days of the making thereof; or the attachment of the property of the Borrower in an amount of TWO HUNDRED FIFTY THOUSAND DOLLARS ($250,000.00) or more which has not been released or provided for to the satisfaction of the Lender within sixty (60) days after the making thereof.

7.2(7) Litigation. Any litigation or any proceedings which are pending against the Borrower, the outcome of which would seriously affect the continued operation of the

Borrower, and the Borrower failing to (i) have the same dismissed within sixty (60) days or (ii) take corrective measures reasonably satisfactory to the Lender within sixty (60) days.

7.2(8) Organizational Change. Should Hing C. Wong cease to own at least a 20% voting interest in the Borrower or cease to be Chief Executive Officer of the Borrower.

7.2(9) Dissolution. The dissolution of the Borrower.

7.2(10) Failure to Subordinate Indebtedness. The failure to fully subordinate any indebtedness incurred by Borrower to all indebtedness owed to Lender.

7.2(11) Insecurity. Lender deems itself or the prospect for payment and/or performance of the Loan Documents insecure; provided, however, that Lender shall not be unreasonable, arbitrary or capricious in making such determination.

Section 7.3. Waiver of Default.

The Lender at any time may waive any default or any Event of Default which shall have occurred and any of its consequences, in which case the parties hereto shall be restored to their former positions and rights and obligations hereunder, respectively; but no such waiver shall extend to any subsequent or other default or impair any right consequent thereon, and no such waiver shall be effective unless it is in a written document executed by a duly authorized officer.

ARTICLE VIII

LENDER'S REMEDIES FOR DEFAULT

Upon the occurrence of an Event of Default and acceleration of the indebtedness of the Borrower to the Lender, the Lender shall have the following remedies:

Section 8.1. Action for Enforcement.

In case any one or more Events of Default shall occur and be continuing, the Lender may proceed to protect and enforce its rights or remedies either by suit in equity or by action at law, or both, whether for the specific performance of any covenants, agreement or other provision contained herein or in any Loan Document, or to enforce the payment of the Note or any other legal or equitable right or remedy.

Section 8.2. Foreclosure of Mortgage.

Lender shall have all the rights given it pursuant to the Loan Documents and the Florida Statutes and other applicable laws to foreclose its mortgage.

Section 8.3. Foreclosure of Security Interest.

The Lender shall have all the rights given to it under Chapter 679 of the Florida Statutes and other applicable law. The Lender may take possession of the Collateral after the occurrence

of an Event of Default and dispose for the Collateral either by public or private proceedings and by one or more contracts.

Section 8.4. Rights and Remedies Cumulative.

No right or remedy herein conferred upon the Lender is intended to be exclusive of any other right or remedy contained herein, in the Note, Loan Documents or in any instrument or document delivered in connection with or pursuant to this Agreement, and every such right or remedy shall be cumulative and shall be in addition to every other such right or remedy contained herein and therein or now or hereafter existing at law or in equity or by statute or otherwise.

Section 8.5. Rights and Remedies Not Waived.

No course of dealing between the Borrower and the Lender or any failure or delay on the part of the Lender in exercising any rights or remedies hereunder shall operate as a waiver of any rights or remedies of the Lender and no single or partial exercise of any rights or remedies hereunder shall operate as a waiver or preclude the exercise of any other rights or remedies hereunder.

Section 8.6. Possession.

Lender shall have the absolute right, at its option and election, and in its sole discretion to take immediate possession of the Property as well as all other security for the Loan as is necessary and to do anything in its sole judgment to fulfill the obligations of the Borrower hereunder.

Section 8.7. Other Rights.

Lender shall have the absolute right, at its option and election, and in its sole discretion to exercise any and all rights, privileges or remedies available to Lender under any Loan Document, or as otherwise may be permitted by applicable law.

ARTICLE IX

MISCELLANEOUS

Section 9.1. Lien; Setoff By Lender.

The Borrower hereby grants to the Lender a continuing lien for all indebtedness and other liabilities of the Borrower to the Lender upon any and all moneys, securities, and other property of the Borrower and the proceeds thereof, now or hereafter held or received by or in transit to, the Lender from or to the Borrower, whether for safekeeping, custody, pledge, transmission, collection or otherwise, and also upon any and all deposits (general or special) and credits of the Borrower with, and any and all claims of the Borrower against the Lender at any time existing. Upon the occurrence of any Event of Default, the Lender is hereby authorized at any time and from time to time, without notice to the Borrower, to setoff, appropriate, and apply any

or all items hereinabove referred to against all indebtedness and other liabilities of the Borrower to the Lender, whether under this Agreement, the Loan Documents or otherwise, and whether now existing or hereafter arising.

Section 9.2. Waivers.

The Borrower waives presentment, demand, protest, notice of default, nonpayment, partial payments and all other notices and formalities relating to this Agreement other than notices specifically required hereunder. The Borrower consents to and waives notice of the granting of indulgences or extensions of time of payment, the taking or releasing of security, the addition or release of persons primarily or secondarily liable on or with respect to liabilities of the Borrower to the Lender, all in such manner and at such time or times as the Lender may deem advisable. No act or omission of the Lender shall in any way impair or affect any of the indebtedness or liabilities of the Borrower to the Lender or rights of the Lender in any security. No delay by the Lender to exercise any right, power or remedy hereunder or under any security agreement, and no indulgence given to the Borrower in case of any default, shall impair any such right, power or remedy or be construed as having created a course of dealing or performance contrary to the specific provisions of this Agreement or as a waiver of any default by the Borrower or any acquiescence therein or as a violation of any of the terms or provisions of this Agreement. The Lender shall have the right at all times to enforce the provisions of this Agreement and all other documents executed in connection herewith in strict accordance with their terms, notwithstanding any course of dealing or performance by the Lender in refraining from so doing at any time and notwithstanding any custom in the banking trade. No course of dealing between the Borrower and the Lender shall operate as a waiver of any of the Lender's rights.

Section 9.3. Governing Law; Benefit.

This Agreement and all rights hereunder shall be governed by the laws of the State of Florida. This Agreement shall bind and inure to the benefit of, and the terms "Borrower" and "Lender", respectively, as used in this Agreement shall include, the respective parties and their respective successors and assigns.

Section 9.4. Notices.

Any written notice, demand or request that is required to be made in any of the Loan Documents shall be served in person, or by registered or certified mail, return receipt requested, or by express mail or similar courier service, addressed to the party to be served at the address set forth in the first paragraph hereof. The addresses stated herein may be changed as to the applicable party by providing the other party with notice of such address change in the manner provided in this paragraph. In the event that written notice, demand or request is made as provided in this paragraph, then in the event that such notice is returned to the sender by the United States Postal Service because of insufficient address or because the party has moved or otherwise, other than for insufficient postage, such writing shall be deemed to have been received by the party to whom it was addressed on the date that such writing was initially placed in the United States Postal Service by the sender.

Section 9.5. Controlling Agreement.

In the event any provision of this Agreement is inconsistent with any provision of any other document, whether heretofore executed, required or executed pursuant to this Agreement or otherwise, the provisions of this Agreement shall be controlling.

Section 9.6. Titles.

Titles to the sections of this Agreement are solely for the convenience of the parties hereto and are not an aid in the interpretation of this Agreement or any part thereof.

Section 9.7. Counterparts.

This Agreement may be executed **in** any number of counterparts and by the parties hereto on separate counterparts, each of which when so executed and delivered shall be an original, but all of which shall together constitute one and the same Agreement.

Section 9.8. Time is of the Essence.

The parties agree that time shall be of the essence in interpreting each and every term and condition contained herein.

Section 9.9. Waiver of Trial by Jury.

The Borrower and the Lender knowingly, voluntarily and intentionally waive any right they may have to a trial by jury in respect of any litigation. based hereon, or arising out of, under or in connection with the Loan Documents and any agreement contemplated to be executed in conjunction therewith, or any course of conduct, course of dealing, statements (whether verbal or written) or actions of any party. This provision is a material inducement for the Lender entering into the loan evidenced by the Loan Documents.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties have executed this Agreement the day and year first above written.

Signed, sealed and delivered in the presence of:	HCW BIOLOGICS INC., a Delaware Corporation
/s/ *** /s/***	By: /s/ Hing C. Wong Name: Hing C. Wong, Chief Executive Officer "Borrower"

COGENT BANK, a State Chartered Bank

/s/ ***
Name: ***

By: /s/ ***
Name: ****, SVP
"Lender"

/s/***
Name: ***

EXHIBIT "A" LEGAL DESCRIPTION

A PORTION OF TRACT D, MIRAMAR PARK OF COMMERCE, ACCORDING TO THE PLAT THEREOF, RECORDED IN PLAT BOOK 122, AT PAGE 24, OF THE PUBLIC RECORDS OF BROWARD COUNTY, FLORIDA, MORE PARTICULARLY DESCRIBED AS FOLLOWS:

COMMENCE AT THE NORTHEAST CORNER OF SAID TRACT D; THENCE SOUTH 02°09'31" EAST, 218 .52 FEET ALONG THE EASTERLY LINE OF SAID TRACT D AND THE WESTERLY RIGHT-OFWAY LINE OF CORPORATE WAY AS SHOWN ON SAID PLAT; THENCE SOUTHEASTERLY ALONG THE ARC OF A TANGENT CURVE BEING CONCAVE TO THE NORTHEAST, HAVING A RADIUS OF 405.70 FEET, A CENTRAL ANGLE OF 06°10'12" AND AN ARC LENGTH OF 43.69 FEET TO THE POINT OF BEGINNING; THENCE CONTINUE SOUTHEASTERLY ALONG THE ARC OF SAID CURVE BEING CONCAVE TO THE NORTHEAST, HAVING A RADIUS OF 405.70 FEET, A CENTRAL ANGLE OF 38°48'20" AND AN ARC LENGTH OF 274.78 FEET TO THE MOST EASTERLY CORNER OF SAID TRACT D (THE LAST THREE (3) COURSES DESCRIBED BEING COINCIDENT WITH THE EASTERLY LINE OF SAID TRACT D AND THE WESTERLY RIGHT-OF-WAY LINE OF SAID CORPORATE WAY); THENCE SOUTH 42°50'19" WEST, 350.44 FEET ALONG THE SOUTHERLY LINE OF SAID TRACT D TO THE SOUTHWEST CORNER OF SAID TRACT (SAID POINT BEING ON THE ARC OF A NON-TANGENT CURVE, RADIAL LINE THROUGH SAID POINT BEARS SOUTH 48°30'11" WEST); THENCE NORTHWESTERLY ALONG THE ARC OF SAID CURVE BEING CONCAVE TO THE NORTHEAST, HAVING A RADIUS OF 754.32 FEET, A CENTRAL ANGLE OF 39°20'18" AND AN ARC LENGTH OF 517.90 FEET ALONG THE WESTERLY LINE OF SAID TRACT D; THENCE NORTH 02°09'31" WEST, 12.80 FEET ALONG THE WEST LINE OF SAID TRACT D; THENCE NORTH 87°50'29" EAST, 302.35 FEET TO THE POINT Of BEGINNING.

SAID LAND LYING AND BEING IN THE CITY OF MIRAMAR, BROWARD COUNTY, FLORIDA.

EXHIBIT 10.2

THIS DOCUMENT PREPARED BY:
[***]
Winderweedle, Haines, Ward
& Woodman, P.A.
Post Office Box 880
Winter Park, Florida 32790-0880

MORTGAGE AND SECURITY AGREEMENT
("Mortgage")

THIS MORTGAGE AND SECURITY AGREEMENT (the "Mortgage"), made as of the 15th day of August, 2022, between HCW BIOLOGICS INC., a Delaware corporation, whose mailing address is 2929 North Commerce Parkway, Miramar, Florida 33025 (the "Borrower"), and COGENT BANK, a State Chartered Bank, whose mailing address is 420 South Orange Avenue, Suite 150, Orlando, Florida 32801 (the "Lender");

WITNESSETH:

WHEREAS, the Borrower is indebted to Lender in the principal sum of SIX MILLION FIVE HUNDRED THOUSAND AND 00/100 DOLLARS ($6,500,000.00), together with
interest thereon, as evidenced by that certain promissory note of even date herewith, executed by Borrower and delivered to Lender, (the "Note"), which by reference is made a part hereof to the same extent as though set out in full herein. The Note, this Mortgage, and all other documents executed in connection therewith, now or hereafter, are herein referred to as the "Loan Document(s)".

NOW, THEREFORE, to secure the performance and observance by Borrower of all covenants and conditions in the Note and all renewals, extensions and modifications thereof and in this Mortgage and in all other Loan Documents, and in order to charge the properties, interests and rights hereinafter described with such payment, performance and observance, and for and in consideration of the sum of ONE DOLLAR ($1.00) paid by Lender to Borrower this date, and for other valuable considerations, the receipt of which is acknowledged, Owner does hereby grant, bargain, sell, alien, remise, release, convey, assign, transfer, mortgage, hypothecate, pledge, deliver, set over, warrant and confirm unto Lender, its successors and assigns forever:

THE MORTGAGED PROPERTY

(A) **THE LAND.** All the land located in the County of Broward, State of Florida, (the "Land"), described as follows, to-wit:

A PORTION OF TRACT D, MIRAMAR PARK OF COMMERCE, ACCORDING TO THE PLAT THEREOF, RECORDED IN PLAT BOOK 122, AT PAGE 24, OF THE PUBLIC RECORDS OF BROWARD COUNTY, FLORIDA, MORE PARTICULARLY DESCRIBED AS FOLLOWS:

COMMENCE AT THE NORTHEAST CORNER OF SAID TRACT D; THENCE SOUTH 02°09'31" EAST, 218 .52 FEET ALONG THE EASTERLY LINE OF SAID TRACT D AND THE WESTERLY RIGHT-OFWAY LINE OF CORPORATE WAY AS SHOWN ON SAID PLAT; THENCE SOUTHEASTERLY ALONG THE ARC OF A TANGENT CURVE BEING CONCAVE TO THE NORTHEAST, HAVING A RADIUS OF 405.70 FEET, A CENTRAL ANGLE OF 06°10'12" AND AN ARC LENGTH OF 43.69 FEET TO THE POINT OF BEGINNING; THENCE CONTINUE SOUTHEASTERLY ALONG THE ARC OF SAID CURVE BEING CONCAVE TO THE NORTHEAST, HAVING A RADIUS OF 405.70 FEET, A CENTRAL ANGLE OF 38°48'20" AND AN ARC LENGTH OF 274.78 FEET TO THE MOST EASTERLY CORNER OF SAID TRACT D (THE LAST THREE (3) COURSES DESCRIBED BEING COINCIDENT WITH THE EASTERLY LINE OF SAID TRACT D AND THE WESTERLY RIGHT-OF-WAY LINE OF SAID CORPORATE WAY); THENCE SOUTH 42°50' 19" WEST, 350.44 FEET ALONG THE SOUTHERLY LINE OF SAID TRACT D TO THE SOUTHWEST CORNER OF SAID TRACT (SAID POINT BEING ON THE ARC OF A NON-TANGENT CURVE, RADIAL LINE THROUGH SAID POINT BEARS SOUTH 48°30'11" WEST); THENCE NORTHWESTERLY ALONG THE ARC OF SAID CURVE BEING CONCAVE TO THE NORTHEAST, HAVING A RADIUS OF 754.32 FEET, A CENTRAL ANGLE OF 39°20' 18" AND AN ARC LENGTH OF 517.90 FEET ALONG THE WESTERLY LINE OF SAID TRACT D; THENCE NORTH 02°09'31" WEST, 12.80 FEET ALONG THE WEST LINE OF SAID TRACT D; THENCE NORTH 87°50'29" EAST, 302.35 FEET TO THE POINT Of BEGINNING.

SAID LAND LYING AND BEING IN THE CITY OF MIRAMAR, BROWARD COUNTY, FLORIDA.

(B) **THE IMPROVEMENTS.** TOGETHER WITH all buildings, structures and improvements of every nature whatsoever now or hereafter situated on the Land, and all fixtures now or hereafter owned by Borrower and located in or on, or attached to, or used or intended to be used in connection with or with the operation of, the Land, buildings, structures or other improvements, or in connection with any construction being conducted or which may be conducted thereon, and owned by Borrower, including all extensions, additions, improvements, betterments, renewals, substitutions, and replacements to any of the foregoing and all of the right, title and interest of Borrower in and to any such fixtures (subject to any lien, security interest or claim) together with the benefit of any deposits or payments now or hereafter made on such fixtures by Borrower or on its behalf (the "Improvements").

(C) **EASEMENTS OR OTHER INTERESTS.** TOGETHER WITH all easements, rights of way, gores of land, streets, ways, alleys, passages, sewer rights, waters, water courses, water rights and powers, and all estates, rights, titles, interests, privileges, liberties, tenements, hereditaments and appurtenances whatsoever, in any way belonging, relating or appertaining to any of the property hereinabove described, or which hereafter shall in any way belong, relate or

be appurtenant thereto, whether now owned or hereafter acquired by Borrower, and the reversion and reversions, remainder and remainders, rents, issues and profits thereof, and all the estate, right, title, interest, property, possession, claim and demand whatsoever, at law as well as in equity, of Borrower of, in and to the same, including but not limited to all judgments, awards of damages and settlements hereafter made resulting from condemnation proceedings or the taking of the property described in paragraphs (A), (B) and (C) (the "Property") hereof or any part thereof under the power of eminent domain, or for any damage (whether caused by such taking or otherwise) to the Property hereof or any part thereof, or to any rights appurtenant thereto, and all proceeds of any sales or other dispositions of the Property or any part thereof.

(D) **ASSIGNMENT OF RENTS.** TOGETHER WITH all rents, royalties, issues, profits, revenue, income and other benefits derived from the rental of the Property to be applied against the indebtedness and other sums secured hereby, provided, however, that permission is hereby given to Borrower so long as no default has occurred hereunder, to collect, receive, take, use and enjoy such rents, royalties, issues, profits, revenue, income and other benefits as they become due and payable, but not in advance thereof, to enforce all Borrower's rights under any lease now or hereafter affecting the Property. The foregoing assignment shall be fully operative without any further action on the part of either party and specifically Lender shall be entitled, at its option upon the occurrence of a default hereunder, to all rents, royalties, issues, profits, revenue, income and other benefits from the Property whether or not Lender takes possession of the Property. Upon any such default hereunder, the permission hereby given to Borrower to collect such rents, royalties, issues, profits, revenue, income and other benefits from the Property shall terminate and such permission shall not be reinstated upon a cure of the default without Lender's specific consent. Neither the exercise of any rights under this paragraph by Lender nor the application of any such rents, royalties, issues, profits, revenue, income or other benefits to the indebtedness and other sums secured hereby, shall cure or waive any default or notice of default hereunder or invalidate any act done pursuant hereto or to any such notice, but shall be cumulative of all other rights and remedies.

(E) **ASSIGNMENT OF LEASES.** TOGETHER WITH all right, title and interest of Borrower in and to any and all leases now or hereafter on or affecting the Property together with all security therefor and all monies payable thereunder, subject, however, to the conditional permission hereinabove given to Borrower to collect the rentals and enforce its rights under any such lease. The foregoing assignment of any lease shall not be deemed to impose upon Lender any of the obligations or duties of Borrower provided in any such lease, and Borrower agrees to fully perform all obligations of the lessor under all such leases. Upon Lender's request, Borrower agrees to send to Lender a list, or copy, of all leases covered by the foregoing assign ment and as any such lease shall expire or terminate or as any new lease shall be made, Borrower shall so notify Lender in order that at all times Lender shall have a current list of all leases affecting the Property. Lender shall have the right, at any time and from time to time, to notify any lessee of the rights of Lender as provided by this paragraph. From time to time, upon request of Lender, Borrower shall specifically assign to Lender as additional security hereunder, by an instrument in writing in such form as may be approved by Lender, all right, title and

interest of Borrower in and to any and all leases now or hereafter on or affecting the Mortgaged Property, together with all security therefor and all monies payable thereunder, subject to the conditional permission hereinabove given to Borrower to collect the rentals and enforce its rights under any such lease. Borrower shall also execute and deliver to Lender any notification, financing statement or other document reasonably required by Lender to perfect the foregoing assignment as to any such lease. Upon the reasonable request of the Lender, the Borrower shall provide the Lender with estoppel letters or certificates from the various tenants, if any, occupying the Mortgaged Property, stating in detail, the current status of their lease and/or occupancy of the Mortgaged Property.

This instrument constitutes an absolute and present assignment of the rents, royalties, issues, profits, revenue, income and other benefits derived from the rental of the Mortgaged Property, subject, however, to the conditional permission given to Borrower to collect, receive, take, use and enjoy the same and enforce its rights as provided hereinabove; provided, further, that the existence or exercise of such right of Borrower shall not operate to subordinate this assignment to any subsequent assignment, in whole or in part, by Borrower, and any such subsequent assignment by Borrower shall be subject to the rights of Lender hereunder.

(F) **FIXTURES.** TOGETHER WITH a security interest in (i) all property and fixtures affixed to or located on the Property which, to the fullest extent permitted by law shall be deemed fixtures and a part of the Property; (ii) all materials delivered to the Property for use in any construction being conducted thereon, and owned by Borrower; (iii) all proceeds, products, replacements, additions, substitutions, renewals and accessions of any of the foregoing; (iv) all contract rights, general intangibles, water and sewer payments, leases and lease payments, eminent domain awards, insurance policies and proceeds, actions and rights in action, as all of the same may relate to the Property; (v) all contracts, agreements, licenses and permits, now or hereafter in existence, used by the Borrower in connection with the occupancy of the Land; and (vi) all instruments, documents, chattel papers and general business intangibles relating to or arising from the collateral described in this paragraph (F) and all cash and non-cash proceeds and products thereof. The foregoing items (i), (ii) and (iii) excluding all intellectual property of Borrower (hereinafter the "Tangible Property") include (a) all rights, title and interest of Borrower in and to the minerals, soil, flowers, shrubs, crops, trees, timber and other emblements now or hereafter on the Property or under or above the same or any part or parcel thereof; (b) all machinery, apparatus, equipment, fittings, fixtures, actually or constructively attached to the Property and used in the operation of the building located on the Property, including all domestic and ornamental fixtures of every kind and nature whatsoever now or hereafter located in, upon or under the Property or any part thereof and used or usable in connection with any present or future operation of the building located on the Property and now owned or hereafter acquired by Borrower; together with all building materials and equipment now or hereafter delivered to the Property and intended to be installed therein, including but not limited to lumber, plaster, cement, shingles, roofing, plumbing, fixtures, pipe, lath, wallboard, cabinets, nails, sinks, toilets, furnaces, heaters, brick, tile, water heaters, screens, window frames, glass doors, flooring, paint, lighting fixtures and heating and ventilating equipment; together

with all proceeds, additions and accessions thereto and replacements thereof, For clarity, the items noted in the preceding sub-section (b) specifically exclude any manufacturing, research and development and other laboratory equipment utilized by Borrower or any subsidiary of Borrower in connection with Borrower's business operations; (c) all of the water, sanitary and storm sewer systems now or hereafter owned by the Borrower which are now or hereafter located by, over and upon the Property or any part and parcel thereof, and which water system includes all water mains, service laterals, hydrants, valves and appurtenances, and which sewer system includes all sanitary sewer lines, including mains, laterals, manholes, sewer and water tap units, and appurtenances thereto; and (d) all paving for streets, roads, walkways or entrance ways now or hereafter owned by Borrower and which are now or hereafter located on the Property or any part or parcel thereof. The foregoing items (iv), (v) and (vi) (hereinafter the "Intangible Collateral") include (aa) all sewer permits, connection fees, impact fees, reservation fees, and other deposits or payments made in connection with the reservation, allocation, permitting or providing of wastewater treatment and potable water to the Property and any and all claims or demands relating thereto, now owned or which may hereafter be acquired by Borrower, together with all right, title, interest, equity, estate, demand or claim to the provision of wastewater treatment and potable water to the Property, now existing or which may hereafter be acquired by Borrower; (bb) all of Borrower's interest as lessor in and to all leases or rental arrangements of the Property or any part thereof, heretofore made and entered into, and in and to all leases or rental arrangements hereafter made and entered into by Borrower during the life of the security agreements or any extension or renewal thereof, together with all rents and payments in lieu of rents, together with any and all guarantees of such leases or rental arrangements and including all present and future security deposits and advance rentals; (cc) any and all awards or payments, including interest thereon and the right to receive the same, as a result of (a) the exercise of the right of eminent domain, (b) the alteration of the grade of any street, or (c) any other injury to, taking of or decrease in the value of the Property; (dd) all of the right, title and interest of the Borrower in and to all unearned premiums accrued, accruing or to accrue under any and all hazard, flood, if applicable, and general liability insurance policies now or hereafter provided pursuant to the terms of security agreements, and all proceeds or sums payable for the loss of or damage to the Property herein, or rents, revenues, income, profits or proceeds derived from leases of or on any part of the Property, but not derived from Borrower's manufacturing or research and development; (ee) all contracts and contract rights of Borrower arising from contracts entered into in connection with development, construction upon or occupancy of the Property, including but not limited to, all deposits held by or on behalf of the Borrower and all management and service agreements related to occupancy of the Property; and (ff) all of Borrower's interest in all utility security deposits or bonds on the Property or any part or parcel thereof. Borrower (Debtor) hereby grants to Lender (Creditor) a security interest in all of the foregoing items (i) through (vi).

(G) **SECURITY AGREEMENT.** To the extent any of the property described above encumbered by this Mortgage from time to time constitutes the type of property subject to the provisions of the Florida Uniform Commercial Code (the "Code"), this Mortgage constitutes a "Security Agreement", "Financing Statement" and "Fixture Filing" for all purposes under the

Code. Without limitation, Lender, at its election, upon Borrower's default under this Mortgage continuing beyond any applicable curative period, will have all rights, powers, privileges, and remedies from time to time available to a secured party under the provisions of the Code with respect to such property. Notwithstanding any provision of this Mortgage to the contrary, Borrower and Lender agree that, unless and until Lender affirmatively elects otherwise, all property described above in any manner used, useful, or intended to be used for the improvement of, or production of leasing income from, the Property is, and at all times and for all purposes and in all proceedings both legal or equitable shall be, regarded as part of the real estate irrespective of whether (i) any such items are physically attached to the Improvements; (ii) serial numbers are used for the better identification of certain equipment; or (iii) any such item is referred to or reflected in any financing statement filed or recorded at any time. Similarly, the mention in any financing statement of the rights in, or the proceeds of, any fire and/or hazard insurance policy, or any award in eminent domain proceedings for a taking or for loss of value, or Borrower's interest as lessor in any present or future lease or rights to income growing out of the use of the Mortgage Property, whether pursuant to a lease or otherwise, shall not be construed as altering any of Lender's rights as determined by this Mortgage, or otherwise available at law or in equity, or impugning the priority of this Mortgage, or the Loan Documents, or both, but such mention in any financing statement is declared to be for Lender's protection if, as, and when any court holds that notice of Lender's priority of interest, to be effective against a particular class of persons, including the Federal government and any subdivisions or entity of the Federal government, must be perfected in the manner required by the Code. Borrower agrees to execute and deliver on demand and does hereby appoint Lender as its attorney-in-fact to execute, deliver, record, and file such other security agreements, financing statements and other instruments as Lender may request in order to perfect its security interest or to impose the lien hereof more specifically upon any of such property.

Everything referred to in paragraphs (A), (B), (C), (D), (E), (F) and (G) hereof and any additional property hereafter acquired by Borrower to be used in connection with the Property and subject to the lien of this Mortgage or intended to be so is herein referred to as the "Mort gaged Property".

TO HAVE AND TO HOLD the same, together with all and singular the tenements, hereditaments and appurtenances thereunto belonging or in anywise appertaining, and the rever sion and reversions, remainder or remainders, rents, issues, and profits thereof, and also all the estate, right, title, interest, homestead, dower and right of dower, separate estate, possession, claim and demand whatsoever, as well in law as in equity, of the said Borrower in and to the same, and every part thereof, with the appurtenances of the said Borrower in and to the same, and every part and parcel thereof unto the said Lender in fee simple.

And the Borrower hereby covenants with the Lender, that the Borrower is indefeasibly seized of the Land in fee simple; that the Borrower has full power and lawful right to convey the same in fee simple as aforesaid; that the Land is and will remain free from all encumbrances except taxes for the current year; that said Borrower will make such further assurances to prove

the fee simple title to the Land in said Borrower as may be reasonably required, and that said Borrower does hereby fully warrant the title to the Land, and every part thereof, and will defend the same against the lawful claims of all persons whomsoever.

PROVIDED ALWAYS, that if the Borrower shall well and truly pay said indebtedness unto the Lender, and any renewals or extensions thereof, and the interest thereon, together with all costs, charges and expenses, including a reasonable attorney's fee, which the Lender may incur or be put to in collecting the same by foreclosure, or otherwise, and shall duly, promptly, and fully perform, discharge, execute, effect, complete, and comply with and abide by each and every stipulation, agreement, condition, and covenant of the Note and of this Mortgage, then this Mortgage and the estate hereby created shall cease and be null and void.

And the Borrower hereby further covenants as follows:

1. **Payment.** That Borrower will pay all and singular the principal and interest and the various and sundry sums of money payable by virtue of the Note and this Mortgage, each and every, promptly on the days respectively the same severally become due. If any payment hereunder (other than the final payment) is not made within ten (10) days after it is due, the Borrower shall pay to Lender a late charge equal to five percent (5%) of the late payment. It is further agreed that any sums, including without limitation payments of principal and interest on said Note, which shall not be paid when due, subject to any applicable grace and/or cure periods and whether becoming due by lapse of time or by reason of acceleration under the provisions herein stated, shall bear interest at the Default Rate, as defined in the Note, and shall be secured by the lien of this Mortgage.

2. **Taxes, etc.** That Borrower will pay, when due and before any penalty attaches, all real estate taxes, other taxes associated with the Mortgaged Property, assessments, water rates, and other governmental or municipal charges, fines, or impositions, on the Mortgaged Property for which provision has not been made hereinbefore, and in default thereof the Lender may pay the same, and all such sums so paid by the Lender shall be immediately due and payable, and shall be secured by the lien of this Mortgage; and the Borrower will promptly deliver the official receipts therefor to the Lender. On or before March 1st of each year during the term of this Mortgage, the Borrower shall provide the Lender with paid receipts evidencing the payment of all real estate and all other taxes with respect to the Mortgaged Property.

3. **Waste; Repairs.** That Borrower will permit, commit, or suffer no waste, impair- ment, or deterioration of the Mortgaged Property or any part thereof; and in the event of the failure of the Borrower to keep any buildings on said premises and those to be erected on the Mortgaged Property or improvements thereon, in good repair, the Lender may, after giving the Borrower written notice and ten (10) days to cure any such defects, make such repairs, as in its discretion, it may deem necessary for the proper preservation thereof, and the full amount of each and every such payment shall be immediately due and payable, and shall be secured by the lien of this Mortgage. Borrower will notify Lender in writing within five (5) days of any injury,

damage or impairment of or occurring on the Mortgaged Property including, but not limited to, serious injury or loss by death or otherwise occurring on the Mortgaged Property

4. **Use and Alteration of Mortgaged Property.** Unless required by applicable law or unless Lender has otherwise agreed in writing, Borrower shall not allow changes in the nature of the occupancy for which the Mortgaged Property was intended at the time this Mortgage was executed. Borrower shall not initiate or acquiesce in a change in the zoning classification of the Mortgaged Property without Lender's written consent. Borrower shall not make any change in the use of the Mortgaged Property which will create a fire or other hazard not in existence on the date hereof, nor shall Borrower in any way increase any hazard. Without the prior written consent of Lender, which consent shall not be unreasonably withheld or delayed, Borrower may not remove or demolish any building or improvement, nor may Borrower materially structurally alter any building or improvement that would change the use of the Mortgaged Property or that would otherwise decrease its value, nor shall any fixture or chattel covered by this Mortgage be removed at any time unless simultaneously replaced by an article of equal kind, quality and value owned by Borrower, and which is unencumbered except by the lien of this Mortgage and other instruments of security securing the Note.

5. **Surface Alteration and Mineral Rights.** Borrower shall not consent to, permit or indulge in any entry, either by itself or by any others, upon the surface of the Land for the purpose of exploration, drilling, prospecting, mining, excavation or removal of any earth, sand, dirt, rock, minerals, oil or any other substance without the Lender's approval and written consent.

6. **Collection Expenses.** All parties liable for the payment of the Note agree to pay the Lender all costs incurred by the Lender, whether or not an action be brought, in collecting the sums due under the Note, enforcing the performance and/or protecting its rights under the Loan Documents and in realizing on any of the security for the Note. Such costs and expenses shall include, but are not limited to, reasonable attorneys' fees, filing fees, costs of publication, deposition fees, stenographer fees, witness fees, title search or abstract costs and other court and related costs incurred or paid by Lender in any action, proceeding or dispute in which Lender is made a part or appears as a party plaintiff or party defendant because of the failure of the Borrower promptly and fully to perform and comply with all conditions and covenants of this Mortgage, the Note secured hereby, or any other Loan Document, including but not limited to, the foreclosure of this Mortgage, condemnation of all or part of the Mortgaged Property, or any action to protect the security thereof. Sums advanced by the Lender for the payment of collec tion costs and expenses shall accrue interest at the Default Rate, as defined in the Note, from the time they are advanced or paid by the Lender, and shall be due and payable upon payment by Lender without notice or demand and shall be secured by the lien of the Mortgage.

7. **Attorneys' Fees.** All parties liable for the payment of the Note agree to pay the Lender reasonable attorneys' fees incurred by the Lender, whether or not an action be brought, in collecting the sums due under the Note, enforcing the performance and/or protecting its rights under the Loan Documents and in realizing on any of the security for the Note. Such reasonable

attorneys' fees shall include, but not be limited to, fees for attorneys, paralegals, legal assistants, and expenses incurred in any and all judicial, bankruptcy, reorganization, administrative receivership, or other proceedings affecting creditor's rights and involving a claim under the Note or any Loan Document, which such proceedings may arise before or after entry of a final judgment. Such fees shall be paid regardless whether suit is brought and shall include all fees incurred by Lender at all trial and appellate levels including bankruptcy court. Sums advanced by the Lender for the payment of attorneys' fees shall accrue interest at the Default Rate, as defined in the Note, from the time they are advanced by the Lender, and shall be due and payable upon payment by Lender without notice or demand and shall be secured by the lien of the Mortgage.

8. **Insurance.**

(a) **Insurance Requirements.** Borrower shall keep the Mortgaged Property insured for the benefit of Lender against loss or damage by fire, lightning, windstorm, hail, explosion, riot, riot attending a strike, civil commotion, aircraft, vehicles and smoke; and such other hazards, including, but not limited to, prior to commencement of leasing activity, six (6) months business interruption insurance covering loss of rents, revenues, income, profits or proceeds from leases, franchises, concessions or licenses of or on any part of the Mortgaged Property, as Lender may from time to time require; all in amounts approved by Lender not less than one hundred percent (100%) of full replacement value; all insurance herein provided for shall be in form and underwritten by companies approved by Lender; and, regardless of the types or amounts of insurance required and approved by Lender.

(b) **Public Liability Insurance.** The Borrower shall at all times maintain public liability insurance and Workers Compensation policies insuring against all claims for personal or bodily injury, death or property damage occurring upon, in or about the Mortgaged Property in amounts not less than $1,000,000.00 for bodily injury and property damage combined arising out of any one occurrence, and $1,000,000.00 for personal injury and damages arising out of any one occurrence, with a general aggregate limit of not less than $2,000,000.00. Such insurance coverage shall be in form and with companies approved by the Lender. Borrower shall furnish to Lender evidence that such insurance is in effect, upon request, at no cost to Lender. All such policies shall name Lender as an additional insured.

(c) **Flood Insurance.** If required, insurance under the Federal Flood Insurance program shall be maintained at all times within the minimum requirements and amounts required under said program for federally financed or assisted loans under the Flood Disaster Protection Act of 1973, as amended. Borrower shall maintain insurance on the Property as required by the Lender and shall otherwise comply with the requirements as set forth in the Loan Agreement.

(d) **Minimum Insurance Coverage.** In the absence of written direction from Lender, the insurance amount required herein shall not be less than such amount as may be

required to prevent Borrower from becoming co-insurer under the terms of any applicable policy, or the amount of the indebtedness secured hereby, whichever is greater.

(e) **Renewal.** Not less than thirty (30) days prior to the expiration date of each policy of insurance required of Borrower pursuant to this paragraph, and of each policy of insurance held as additional collateral to secure the indebtedness secured hereby, Borrower shall deliver to Lender a renewal policy or policies marked "premium paid" or accompanied by other evidence of payment satisfactory to Lender.

(f) **Notice of Cancellation.** All policies of insurance shall provide that no cancellation, reduction in amount or material change in coverage thereof shall be effective until at least thirty (30) days after receipt by Lender and Borrower of written notice thereof.

(g) **Assignment to Lender; Application of Payments.** All policies of insurance and renewals thereof which insure against any loss or damage to the Mortgaged Property, shall be held by the Lender and shall contain a non-contributory standard Mortgagee's endorsement making losses payable to the Lender as its interest may appear. Borrower shall furnish to Lender evidence of insurable value, upon request, at no cost to Lender. The delivery of the insurance policies shall constitute, as further security for the payment of the Note, an assignment of the benefits, but not the obligations, of such policies and an assignment of all unearned premiums existing from time to time thereon. In event of loss, Borrower will give immediate notice by mail to Lender, and Lender may make proof of loss if not made promptly by Borrower, and each insurance company concerned is hereby authorized and directed to make payment for such loss directly to Lender instead of to Borrower and Lender jointly, and the insurance proceeds, or any part thereof, may be applied by Lender either to the repayment of monies paid or advanced by Lender on behalf of the Borrower, or to the payment of interest due on the Note, or to the payment of principal due under the Note or to the restoration or repair of the Mortgaged Property as the Lender, at its sole option, may elect.

(h) **Foreclosure; Successor in Interest.** In the event of a foreclosure of this Mortgage, or other transfer of title to the Mortgaged Property in extinguishment of the indebtedness secured hereby, the purchaser of the Mortgaged Property shall succeed to all the rights of Borrower, including any right to unearned premiums, in and to all policies of insurance assigned and delivered to Lender, with respect to all property herein encumbered.

(i) **Failure to Provide Insurance.** Should Borrower fail to provide the insurance required by the Loan Documents, or fail to continue any previously provided insurance in full force and effect, Borrower acknowledges and agrees that Lender may obtain any required insurance at Borrowers expense. The cost of any such insurance paid by the Lender shall accrue interest at the Default Rate, as defined in the Note, from the time they are advanced or paid by the Lender and shall be immediately due and payable and shall be secured by the lien of this Mortgage. Borrower acknowledges that if Lender purchases any such insurance, the insurance may provide only limited protection against physical damage to the real property up to the

outstanding principal balance of the Note; however, Borrower's equity in the Property may not be insured. Further, any such insurance purchased by the Lender may not provide any liability or property damage indemnification and may not meet the requirements of any financial responsibility laws.

9. **Event of Default.** The occurrence of any of the following constitutes an Event of Default by Borrower under this Mortgage and, at the option of the Lender, under the Loan Documents:

(a) **Scheduled Payment.** Subject to any applicable graced and/or cure periods, Borrower's failure to make any other payment required by the Note on or before the date it is due, without further notice or demand.

(b) **Monetary Default.** Borrower's failure to make any other payment required by this Mortgage, or the other Loan Documents, or one or more of the foregoing, within fifteen (15) days after written demand therefore.

Other. Borrower's continued failure to duly observe or perform any other covenant, condition, agreement or obligation imposed upon Borrower by any Loan Document, for a period of thirty (30) days after written demand; provided (i) if Borrower reasonably cannot perform within such thirty (30) day period, and in Lender's judgment, Lender's security reasonably will not be impaired and Borrower is proceeding in good faith to cure, perform and observe such covenant, condition, agreement or obligation, Borrower may have such additional time to perform as Borrower reasonably may require; and (ii) if Lender's security reasonably will be materially impaired if Borrower does not perform in less than thirty (30) days, Borrower will have only such period following written demand in which to perform as Lender reasonably may specify.

(c) **Representation.** Any verbal or written representation, statement or warranty of Borrower, any co-signer, endorser, surety or guarantor of the Note, contained in the Note, this Mortgage or any other Loan Document, or in any certificate delivered pursuant hereto, or in any other instrument or statement made or furnished in connection herewith, proves to be incorrect or misleading in any material respect as of the time when the same shall have been made, including, without limitation, any and all financial statements furnished by Borrower to Lender as an inducement to Lender's making the loan evidenced by the Note or pursuant to any provision of this Mortgage.

(d) **Dissolution.** The dissolution of the Borrower.

(e) **Insolvency.** If (i) a petition is filed by the Borrower seeking or acquiescing in any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any law relating to bankruptcy or insolvency, or (ii) a petition is filed against the Borrower, which is not dismissed within sixty (60) days after filing, seeking any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any law relating to bankruptcy or insolvency, or (iii) Borrower seeks or consents to or acquiesces in the appointment of any trustee, receiver, master or liquidator of itself or of all of the rent, revenues, issues, earnings, profits or income of any part of the Mortgaged Property, or
(iv) Borrower makes any general assignment for the benefit of creditor, or (v) Borrower makes any admission in writing of its inability to pay its debts generally as they become due, or (vi) Borrower is "insolvent", as hereafter defined; or (vii) any trustee, receiver or liquidator of Borrower or of all or any part of the Mortgaged Property or of any or all of the Rents thereof is appointed who is not discharged within sixty (60) days after its appointment. For purposes of this paragraph, a person or entity shall be deemed to be insolvent, if they are unable to pay their debts as they become due and/or if the fair market value of their assets does not exceed their aggregate liabilities.

(f) **Foreclosure Proceedings.** The filing of a foreclosure proceeding by the owner and holder of any mortgage or lien affecting the Mortgaged Property, regardless of whether same is or is asserted to be prior or inferior in dignity and enforceability to the lien and security interest of this Mortgage.

10. **Remedies.** Upon the occurrence of any default continuing beyond any applicable curative period under this Mortgage or any other Loan Document, as provided in the preceding paragraph, Lender may exercise any one or more of the following rights and remedies, in addition to all other rights and remedies otherwise available at law or in equity:

(a) **Other Documents.** To pursue any right or remedy provided by the Loan Documents including the right to sue for collection of all sums due and payable of the indebted ness secured hereby.

(b) **Collect Rents.** To collect all rents, issues, profits, revenues, income, proceeds or other benefits derived from leasing of the Mortgaged Property.

(c) **Acceleration.** To declare the entire unpaid amount of the indebtedness secured hereby immediately due and payable.

(d) **Foreclosure.** To foreclose the lien of this Mortgage, and obtain possession of the Mortgaged Property, or either, by any lawful procedure.

(e) **Code Rights.** To exercise any right or remedy available to Lender as a secured party under the Code, as it from time to time is in force and effect, with respect to any portion of the Mortgaged Property or the Intangible Collateral then constituting property subject

to the provisions of the Code; or Lender, at its option, may elect to treat the Mortgaged Property or the Intangible Collateral, or any combination, as real property, or an interest therein, for remedial purposes.

(f) **Receiver.** To apply, on *ex parte* motion to any court of competent juris- diction, for and obtain the appointment of a receiver to take charge of, manage, preserve, protect, complete construction of, and operate the Mortgaged Property, and any business or businesses situated thereon, or any combination; to collect the rents; to make all necessary and needed repairs; to pay all taxes, assessments, insurance premiums, and all other costs incurred in connection with the Mortgaged Property; and, after payment of the expenses of the receivership, including reasonable attorneys' and legal assistants' fees, and after compensation to the receiver for management and completion of the Mortgaged Property, to apply all net proceeds derived therefrom in reduction of the indebtedness secured hereby or in such other manner as the court shall direct. The appointment of such receiver shall be a matter of strict right to Lender, regardless of the adequacy of the security or of the solvency of any party obligated for payment of the indebtedness secured hereby. All expenses, fees, and compensation incurred pursuant to any such receivership shall be secured by the lien of this Mortgage until paid. The receiver, personally or through agents, may exclude Borrower wholly from the Mortgaged Property and have, hold, use, operate, manage, and control the Mortgaged Property, and may in the name of Borrower exercise all of Borrower's rights and powers to maintain, construct, operate, restore, insure, and keep insured the Mortgaged Property in such manner as such receiver deems appropriate.

(g) **Relief from Stay.** In the event the Borrower shall default under the terms of Paragraph 9(f) of this Mortgage the Lender shall thereupon be entitled to relief from any automatic stay imposed by Title XI of the U.S. Code, as amended, or otherwise, on or against the exercise of the rights and remedies otherwise available to the Lender as provided in the Loan Documents and as otherwise provided by law.

(h) **Other Security.** Lender may proceed to realize upon any and all other security for the indebtedness secured hereby in such order as Lender may elect; and no such action, suit, proceeding, judgment, levy, execution, or other process will constitute an election of remedies by Lender, or will in any manner alter, diminish, or impair the lien and security interest created by this Mortgage, unless and until the indebtedness secured hereby is paid in full.

(i) **Advances.** To advance such monies, and take such other action, as is authorized by Paragraphs 2, 3 and 8 above. All such advances shall bear interest at the Default Rate, as defined in the Note, and shall be immediately due and payable by Borrower to Lender without demand therefor, and such advances together with interest and costs accruing thereon shall be secured by this Mortgage.

11. **Exercise of Remedies.** The remedies of Lender as provided in the Loan Docu- ments, shall be cumulative and concurrent and may be pursued singly, successively or together,

at the sole discretion of Lender, and may be exercised as often as occasion therefor shall arise. No act, or omission or commission or waiver of Lender, including specifically any failure to exercise any right, remedy or recourse, shall be effective unless set forth in a written document executed by Lender and then only to the extent specifically recited therein. A waiver or release with reference to one event shall not be construed as continuing, as a bar to, or as a waiver or release of, any subsequent right, remedy or recourse as to any subsequent event.

12. **Eminent Domain.** If all or any material part of the Mortgaged Property shall be damaged or taken through condemnation (which term when used herein shall include any damage taking by any governmental authority or any other authority authorized by applicable laws to so damage or take, and any transfer by private sale in lieu thereof), either temporarily or permanently, then the entire indebtedness and other sums secured hereby shall, at the option of the Lender, become immediately due and payable. Lender shall be entitled to all compensation awards, damages, claims, rights of action and proceeds of, or on account of any damage or taking through condemnation is hereby authorized, at its option, to commence, appear in and prosecute, in its own or Borrower's name, any action or proceeding relating to any condemnation, and to settle or compromise any claim in connection therewith. All such compensation awards, damages, claims, rights of action and proceeds, and any other payments or relief, and the right thereto are hereby assigned by Borrower to Lender, who, after deducting therefrom all its expenses, including attorneys' fees, may release any money received by it without affecting the lien of this Mortgage or may apply the same, in such manner as Lender shall determine, to the reduction of the sum secured hereby.

13. **Consent to Transfer.** In the event the Borrower, without the prior written consent of the Lender, (a) shall sell, convey, transfer (including a transfer by agreement for deed or land contract) the Mortgaged Property or any part thereof or any interest therein, or (b) shall be divested of title or any interest in the Mortgaged Property in any manner or way, whether voluntary or involuntary, or (c) enters into an oral or written agreement to lease the entire fee simple interest of the Mo1tgaged Property (and not simply the improvements or buildings located thereon) not in the ordinary course of business or (d) further encumbers the Mortgaged Property then the entire balance of the indebtedness evidenced by the Note shall be accelerated and become immediately due and payable, at the option of the Lender upon ten (10) days written notice to the Borrower. In the event the Lender elects to accelerate the entire balance of the indebtedness, the Lender shall have no obligation to allege or show any impairment of its security and may pursue any legal or equitable remedies for default in such payment without allegation or showing. It is specifically understood by the parties that as a condition of granting its approval required by this paragraph, the Lender may adjust the interest rate stated in the Note.

14. **Future Advances.** Upon request of Borrower, Lender, at Lender's option, within fifteen (15) years from date of this Mortgage, may make future advances to Borrower. It is hereby specifically agreed that any sum or sums which may be loaned or advanced by the Lender to the Borrower at any time after the recording of this indenture, together with interest thereon at the rate agreed upon at the time of such loan or advance, shall be equally secured with and have

the same priority as the original indebtedness and be subject to all the terms and provisions of this Mortgage, providing that the aggregate amount of principal outstanding at any time shall not exceed an amount equal to two (2) times the principal amount originally secured hereby.

15. **Loan Agreement.** This Mortgage is subject to and secures the terms, provisions and conditions of that certain Loan Agreement (the "Loan Agreement") of even date entered into between the Borrower and the Lender herein, which is by reference incorporated herein and made a part hereof.

16. **Financial Information.** The Borrower will keep its books of account in accordance with generally accepted accounting practices, or other recognized accounting principles acceptable to Lender, and will furnish the Lender with the financial information as set forth in the Loan Agreement.

17. **Environmental Agreement.** Borrower hereby represents that neither Borrower nor any other person has ever used the Mortgaged Property as a storage facility for any "Hazardous Substances".

Borrower hereby agrees to indemnify Lender and hold Lender harmless from and against any and all losses, liabilities, including strict liability, damages, injuries, expenses, including reasonable attorneys' fees, costs of any settlement or judgment and claims of any and every kind whatsoever paid incurred or suffered by, or asserted against, Lender by any person or entity or governmental agency for, with respect to, or as a direct or indirect result of, the presence on or under, or the escape, seepage, leakage, spillage, discharge, emission, discharging or release from the premises of any Hazardous Substance (including, without limitation, any losses, liabilities, including strict liability, damages, injuries, expenses, including reasonable attorneys' fees, costs of any settlement or judgment or claims asserted or arising under the Comprehensive Environmental Response, Compensation and Liability Act, any so called federal, state or local "Superfund" "Superlien" laws, statutes, law ordinance, code, rule, regulation, order or decree regulating, with respect to or imposing liability, including strict liability, substances or standards of conduct concerning any Hazardous Substance), regardless of whether within the control of Lender, so long as the act or omission in question occurs prior to the sale of the Mortgaged Property pursuant to the provisions of paragraph 10 hereof and complete dispossession of Borrower thereunder.

For purposes of this Mortgage, "Hazardous Substances" shall mean and include those elements or compounds which are contained in the list of hazardous substances adopted by the United States Environmental Protection Agency ("EPA") and the list of toxic pollutants designated by Congress or the EPA or defined by any other federal, state or local statute, law, ordinance, code, rule, regulation, order or decree regulating, relating to, or imposing liability or standards of conduct concerning, any hazardous, toxic or dangerous waste, substance or material as now or at any time hereafter in effect.

If Borrower receives any notice of (i) the happening of any material event involving the spill, release, leak, seepage, discharge or clean-up of any Hazardous Substance on the Mortgaged Property or in connection with Borrower's operations thereon or (ii) any complaint, order, citation or material notice with regard to air emissions, water discharges, or any other environmental, health or safety matter affecting Borrower (an "Environmental Complaint") from any person or entity (including without limitation the EPA) then Borrower shall immediately notify Lender orally and in writing of said notice.

Lender shall have the right but not the obligation, and without limitation of Lender's rights under this Mortgage, to enter onto the Mortgaged Property or to take such other actions as it deems necessary or advisable to clean up, remove, resolve or minimize the impact of, or otherwise deal with, any such Hazardous Substance or Environmental Complaint following receipt of any notice from any person or entity (including, without limitation, the EPA) asserting the existence of any Hazardous Substance or an Environmental Complaint pertaining to the Mortgaged Property or any part thereof which, if true, could result in an order, suit or other action against Borrower and/or which, in the sole opinion of Lender, could jeopardize its security under this Mortgage. All reasonable costs and expenses incurred by Lender in the exercise of any such rights shall be secured by this Mortgage and shall be payable by Borrower upon demand.

Lender shall have the right, in its reasonable discretion to require Borrower to periodically (but not more frequently than annually unless an Environmental Complaint is then outstanding) perform (at Borrower's expense) an environmental audit and, if deemed necessary by Lender, an environmental risk assessment, each of which must be satisfactory to Lender, of the Mortgaged Property, hazardous waste management practices and/or hazardous waste disposal sites used by Borrower. Said audit and/or risk assessment must be by an environmental consultant satisfactory to Lender. Should Borrower fail to perform said environmental audit or risk assessment within 30 days of the Lender's written request, Lender shall have the right but not the obligation to retain an environmental consultant to perform said environmental audit or risk assessment. All costs and expenses incurred by Lender in the exercise of such rights shall be secured by this Mortgage and shall be payable by Borrower upon demand or charged to Borrower's loan balance at the discretion of Lender.

Any breach of any warranty, representation or agreement contained in this Section shall be a default hereunder and shall entitle Lender to exercise any and all remedies provided in this Mortgage or otherwise permitted by law.

The provisions of this paragraph will survive the foreclosure of this Mortgage or any deed in lieu of foreclosure delivered to Lender by Borrower.

18. **After Acquired Property.** Without the necessity of any further act of Borrower or Lender, the lien of, and security interest created by, this Mortgage automatically will extend to and include (i) any and all renewals, replacements, substitutions, accessions, proceeds, or

physical additions of or to the Mortgaged Property, the Rents, and the Intangible Collateral, excluding Borrower's intellectual property and (ii) any and all monies and other property that from time to time may, either by delivery to Lender or by any instrument (including this Mortgage) be subjected to such lien and security interest by Borrower, or by anyone on behalf of Borrower, or with the consent of Borrower, or which otherwise may come into the possession or otherwise be subject to the control of Lender pursuant to this Mortgage, or the Loan Documents, or both.

19. **Appraisal.** Notwithstanding any term or provision hereof to the contrary, if at any time the Lender in its sole discretion reasonably believes that the value of the Mortgaged Property may have declined or that the value of the Mortgaged Property is less than the value utilized by the Lender at the time of loan approval or renewal, within thirty (30) days from Lender's written request to Borrower therefor, Borrower shall provide Lender, at Borrower's sole cost and expense, a current appraisal of the Mortgaged Property to be ordered by the Lender from an appraiser designated by Lender and in form and content as required by Lender. Borrower shall cooperate fully with any such appraiser and provide all such documents and information as such appraiser may request in connection with such appraiser's performance and preparation of such appraisal. Borrower's failure to promptly and fully comply with Lender's requirements under this paragraph shall, without further notice, constitute an Event of Default under this Mortgage, the Note and the other Loan Documents.

20. **Inspection.** Lender shall be entitled to inspect the Mortgaged Property and Borrower agrees to permit Lender, or its agents or employees, access to the Mortgaged Property for such purpose, all at such reasonable time upon reasonable notice to Borrower of the date and time of such inspection and as often as the Lender may request.

21. **Choice of Law and Venue.** This Mortgage shall be governed by the Laws of the State of Florida, and the United States of America, whichever the context may require or permit. The Borrower expressly agrees that proper venue for any action which may be brought under this Mo1tgage in addition to any other venue permitted by law shall be any county in which property encumbered by the Mortgage is located as well as Orange County, Florida. Should Lender institute any action under this Mortgage, the Borrower hereby submits itself to the jurisdiction of any court sitting in Florida.

22. **Debtor-Creditor Relationship Only.** It is understood by and between Lender and its successors, or assigns and the Borrower, that the funds received on the Note which are secured by this Mortgage, create the relationship of Lender and Borrower and it is not the intention of the parties to create the relationship of a partnership, a joint venture or syndicate, or mutual enterprise or endeavor.

23. **Taxes on Note and Mortgage.** Borrower agrees to pay any and all taxes which may be levied or assessed directly or indirectly upon the Note and this Mortgage (except for income taxes payable by the holder thereof) or the debt secured hereby without regard to any

law which may be hereafter enacted imposing payment of the whole or any part thereof upon the Lender, its successors or assigns. Upon violation of this agreement, or upon the rendering by any court of competent jurisdiction of a decision that such an agreement by the Borrower is legally inoperative, or if any court of competent jurisdiction shall render a decision that the rate of said tax when added to the rate of interest provided for in said Mortgage Note exceeds the then maximum rate of interest allowed by law, then, and in any such event, the debt hereby secured shall, at the option of the Lender, its successors or assigns, become immediately due and payable, anything contained in this Mortgage or in the Mortgage Note secured hereby notwith standing, without the imposition of premium or penalty. The additional amounts which may become due and payable hereunder shall be part of the debt secured by this Mortgage.

24. **Time of the Essence.** Time is of the essence with respect to each provision of this Mortgage where a time or date for performance is stated. All time periods or dates for performance stated in this Mortgage are material provisions of this Mortgage.

25. **Captions and Pronouns.** The captions and headings of the various sections of this Mortgage are for convenience only, and are not to be construed as confining or limiting in any way the scope or intent of the provisions hereof. Whenever the context requires or permits, the singular shall include the plural, the plural shall include the singular, and the masculine, feminine and neuter shall be freely interchangeable.

26. **Corporate Authority.** The Board of Directors of the Borrower have duly authorized the execution and delivery of this Mortgage and the Note, and there is no provision in the Articles of Incorporation or Bylaws of the Borrower requiring the consent of its shareholders to the execution and delivery of this Mortgage.

27. **Indemnification Agreement.** The Borrower hereby indemnifies the law firm of Winderweedle, Haines, Ward & Woodman, P.A., and all of its attorneys, including, but not limited to [***] Esquire, from any and all loss, cost, expense, damage or claim, whether or not valid, including attorneys' fees and disbursements, arising under or in any way connected with Section 697.10 of the Florida Statutes or any similar law. The Borrower hereby verifies and confirms all factual information in this Mortgage, including the accuracy and correctness of the legal description set forth herein. In the event any factual errors are found in this Mortgage or in the legal description, the Borrower shall, at its own cost and expense, promptly correct or cause to be corrected subsequent to the date hereof any and all such errors with no further liability incurred by counsel for either the Borrower or the Lender. The Borrower shall promptly pay or cause to be paid all damages, claims or any other costs whatsoever arising out of any impairment of title due to or caused by any inaccuracy or incorrectness of the legal description set forth herein. Notwithstanding the foregoing, all rights are preserved against the Lender's title insurer, the surveyor, the engineer, if any, and the appraiser, if any, and after payment is made by the Borrower, the Borrower shall be subrogated to such rights.

28. **Notice.** Any written notice, demand or request that is required to be made in any of the Loan Documents shall be served in person, or by registered or certified mail, return receipt requested, or by express mail or similar courier service, addressed to the party to be served at the address set forth in the first paragraph hereof. The addresses stated herein may be changed as to the applicable party by providing the other party with notice of such address change in the manner provided in this paragraph. In the event that written notice, demand or request is made as provided in this paragraph, then in the event that such notice is returned to the sender by the United States Postal Service because of insufficient address or because the party has moved or otherwise, other than for insufficient postage, such writing shall be deemed to have been received by the party to whom it was addressed on the date that such writing was initially placed in the United States Postal Service or courier service by the sender.

29. **Waiver of Trial By Jury. The Borrower and the Lender knowingly, volun- tarily and intentionally waive the right either may have to a trial by jury in respect of any litigation based hereon, or arising out of, under or in connection with this Mortgage and any agreement contemplated to be executed in conjunction herewith, or any course of conduct, course of dealing, statements (whether verbal or written) or actions of either party. This provision is a material. inducement for the Lender entering into the loan evidenced by this Mortgage.**

The covenants herein contained shall bind, and the benefits and advantages shall inure to, the respective heirs, executors, administrators, successors, and assigns of the parties hereto. Whenever used, the singular number shall include the plural, the plural the singular, and the use of any gender shall include all genders.

[Remainder of page intentionally blank]

IN WITNESS WHEREOF, the said Borrower has executed these presents as of the day and year first above written in manner and form sufficient to be binding.

Signed, sealed and delivered in the presence of:	HCW BIOLOGICS INC., a Delaware Corporation
/s/ *** Name: ***	By: /s/ Hing C. Wong Name: Hing C. Wong, Chief Executive Officer "Borrower"
/s/*** Name: ***	

STATE OF FLORIDA COUNTY OF BROWARD

The foregoing instrument was acknowledged before me by means of: (please check one)
[☑] physical presence; or
[___] online notarization
this 11th day of August, 2022, by HING C. WONG, as Chief Executive Officer of HCW BIOLOGICS INC., a Delaware corporation, on behalf of the corporation. He: (please check one)
[___] is personally known to me known to me;
[☑] has produced a *Florida* driver's license as identification; or
[___]has produced _____ as identification.

/s/ ***
Notary Public
My Commission Expires: ***

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, 2022;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

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

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

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

/s/ Hing C. Wong

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

Date: November 7, 2022

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, 2022;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

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

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

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

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

Date: November 7, 2022

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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 7, 2022

By: /s/ Hing C. Wong

Hing C. Wong
Chief Executive Officer
(Principal 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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 7, 2022

By: /s/ Rebecca Byam

Rebecca Byam
Chief Financial Officer
(Principal Financial and Accounting Officer)