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, 2025

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 11, 2025, the registrant had 2,701,607 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, 2024	September 30, 2025 Unaudited
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,674,572	$ 1,096,909
Accounts receivable, net	582,201	30,667
Prepaid expenses	328,181	210,661
Other current assets	113,528	250,340
Total current assets	5,698,482	1,588,577
Investments	1,599,751	1,326,329
Property, plant and equipment, net	22,909,869	22,502,158
Other assets	28,476	28,476
Total assets	$ 30,236,578	$ 25,445,540
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Liabilities		
Current liabilities:		
Accounts payable	$ 22,332,261	$ 18,968,173
Accrued liabilities and other current liabilities	981,940	1,084,602
Short-term debt, net	6,314,684	6,807,431
Total current liabilities	29,628,885	26,860,206
Debt, net	7,377,865	—
Contingent liability - related party	—	692,531
Total liabilities	37,006,750	27,552,737
Commitments and contingencies (Note 11)		
Stockholders' deficit:		
Common stock:		
Common, $0.0001 par value; 250,000,000 shares authorized and 1,113,532 shares issued at December 31, 2024; 250,000,000 shares authorized and 2,621,607 shares issued at September 30, 2025	111	262
Additional paid-in capital	93,785,854	107,127,619
Accumulated deficit	(100,556,137)	(109,235,078)
Total stockholders' deficit	(6,770,172)	(2,107,197)
Total liabilities and stockholders' deficit	$ 30,236,578	$ 25,445,540

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,	
	2024	2025	2024	2025
Revenues:				
Revenues	$ 426,423	$ 15,606	$ 2,171,988	$ 27,222
Cost of revenues	(341,138)	(12,485)	(1,291,546)	(21,777)
Net revenues	85,285	3,121	880,442	5,445
Operating expenses:				
Research and development	1,186,913	1,404,247	5,339,383	4,109,782
General and administrative	1,633,457	1,884,994	4,788,558	6,187,296
Legal expenses (recoveries), net	949,455	6,006	15,761,531	(1,590,945)
Nonoperating loss	—	—	1,300,000	—
Total operating expenses	3,769,825	3,295,247	27,189,472	8,706,133
Loss from operations	(3,684,540)	(3,292,126)	(26,309,030)	(8,700,688)
Interest expense	(229,058)	(127,070)	(393,908)	(632,923)
Change in fair value of investment and contingent liability, net	—	(966,284)	—	782,404
Loss on sale of put shares	—	(182,146)	—	(182,146)
Other income, net	11,310	13,290	52,397	54,412
Net loss	$ (3,902,288)	$ (4,554,336)	$ (26,650,541)	$ (8,678,941)
Equity dividend to investor	—	—	—	(10,153,799)
Net loss attributable to Common Stockholders	$ (3,902,288)	$ (4,554,336)	$ (26,650,541)	$ (18,832,740)
Net loss per share, basic and diluted	$ (4.13)	$ (2.02)	$ (28.33)	$ (11.34)
Weighted average shares outstanding, basic and diluted	945,585	2,260,068	940,586	1,661,332

See accompanying notes to the unaudited condensed interim financial statements.

HCW Biologics Inc.
Condensed Statements of Changes in Stockholders' Equity (Deficit)
For the Nine Months Ended September 30, 2024 and 2025
(Unaudited)

	Stockholders' Equity (Deficit)				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance, January 1, 2024	900,628	$ 90	$ 83,993,950	$ (70,532,323)	$ 13,461,717
Issuance of Common Stock upon exercise of stock options	314	1	2,254	—	2,255
Issuance of Common Stock upon equity subscription	44,643	4	2,500,001	—	2,500,005
Stock-based compensation	—	—	244,685	—	244,685
Net loss	—	—	—	(7,468,061)	(7,468,061)
Balance, March 31, 2024	**945,585**	**$ 95**	**$ 86,740,890**	**$ (78,000,384)**	**$ 8,740,601**
Issuance of Common Stock upon exercise of stock options	—	—	—	—	—
Stock-based compensation	—	—	239,821	—	239,821
Net loss	—	—	—	(15,280,191)	(15,280,191)
Balance, June 30, 2024	**945,585**	**$ 95**	**$ 86,980,711**	**$ (93,280,575)**	**$ (6,299,769)**
Issuance of Common Stock upon exercise of stock options	—	—	—	—	—
Stock-based compensation	—	—	232,433	—	232,433
Net loss	—	—	—	(3,902,288)	(3,902,288)
Balance, September 30, 2024	**945,585**	**$ 95**	**$ 87,213,144**	**$ (97,182,863)**	**$ (9,969,624)**

	Stockholders' Deficit				
	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance, January 1, 2025	1,113,532	$ 111	$ 93,785,854	$ (100,556,137)	$ (6,770,172)
Issuance of Common Stock upon exercise of stock options	205	—	1,654	—	1,654
Issuance of Common Stock to Square Gate	9,616	1	149,999	—	150,000
Issuance cost of Common Stock	—	—	(22,297)	—	(22,297)
Stock-based compensation	—	—	275,642	—	275,642
Net loss	—	—	—	(2,196,875)	(2,196,875)
Balance, March 31, 2025	**1,123,353**	**$ 112**	**$ 94,190,852**	**$ (102,753,012)**	**$ (8,562,048)**
Issuance of Common Stock	194,242	20	1,592,784	—	1,592,804
Issuance of pre-funded warrants	—	—	4,207,718	—	4,207,718
Issuance of common stock warrants	—	—	9,650,404	—	9,650,404
Exercise of pre-funded warrants	513,140	51	-	—	51
Issuance cost of Common Stock	—	—	(70,094)	—	(70,094)
Issuance cost of pre-funded warrants	—	—	(504,862)	—	(504,862)
Issuance cost of common stock warrants	—	—	(227,646)	—	(227,646)
Equity dividend to investor	—	—	(10,153,799)	—	(10,153,799)
Issuance of Common Stock to extinguish restructured debt	253,083	25	1,774,087	—	1,774,112
Issuance of common stock warrants to extinguish restructured debt	—	—	544,249	—	544,249
Gain on conversion of debt with related parties, net	—	—	3,346,562	—	3,346,562
Stock-based compensation	—	—	278,307	—	278,307
Adjustment for reverse stock split	62,783	7	(7)	—	—
Net loss	—	—	-	(1,927,730)	(1,927,730)
Balance, June 30, 2025	**2,146,601**	**$ 215**	**$ 104,628,555**	**$ (104,680,742)**	**$ (51,972)**
Issuance of common stock under Standby Equity Purchase Agreement (SEPA)	475,000	47	2,357,073	—	2,357,120
Issuance cost of Common Stock	—	—	(63,501)	—	(63,501)
Stock-based compensation	—	—	205,492	—	205,492
Adjustment for reverse stock split	6	—	—	—	—
Net loss	—	—	—	(4,554,336)	(4,554,336)
Balance, September 30, 2025	**2,621,607**	**$ 262**	**$ 107,127,619**	**$ (109,235,078)**	**$ (2,107,197)**

See accompanying notes to the unaudited condensed interim financial statements.

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

	Nine Months Ended September 30,	
	2024	2025
Cash flows from operating activities:		
Net loss	$ (26,650,541)	$ (8,678,941)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and accretion	501,882	884,831
Stock-based compensation	716,940	759,441
Commitment fee	—	150,000
Change in fair value of investment and contingent liability, net	—	(782,404)
Loss on sale of put shares	—	182,146
Loss on conversion of debt with related parties	—	(131,135)
Changes in the carrying amount of right-of-use asset	(418)	—
Changes in operating assets and liabilities:		
Accounts receivable	883,917	551,534
Prepaid expenses and other assets	829,043	162,903
Accounts payable and other liabilities	12,383,171	(3,134,475)
Operating lease liability	(56,541)	—
Net cash used in operating activities	(11,392,547)	(10,036,100)
Cash flows from investing activities:		
Purchases of property and equipment	(148,205)	—
Net cash used in investing activities	(148,205)	—
Cash flows from financing activities:		
Proceeds from issuance of Common Stock	2,502,260	1,475,939
Proceeds from issuance of Common Stock under SEPA, net	—	1,992,779
Proceeds from issuance of pre-funded warrants	—	3,822,894
Proceeds from issuance of debt	6,530,000	150,000
Issuance costs for Common Stock and pre-funded warrants	—	(888,399)
Debt repayment	(88,388)	(94,776)
Net cash provided by financing activities	8,943,872	6,458,437
Net decrease in cash and cash equivalents	(2,596,880)	(3,577,663)
Cash and cash equivalents at the beginning of the period	3,595,101	4,674,572
Cash and cash equivalents at the end of the period	$ 998,221	$ 1,096,909
Supplemental disclosure of cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 340,988	$ 496,268
Noncash investing activities:		
Capital expenditures accrued, but not yet paid	$ 1,910,698	$ —
Purchases of property and equipment included in accounts payable	$ 829,207	$ 23,000
Noncash financing activities:		
Put shares issued but not priced under SEPA	$ —	$ 182,195
Extinguishment of restructured debt	$ —	$ 7,440,462
Issuance of Common Stock, warrants and other rights upon extinguishment of restructured debt	$ —	$ 3,962,766
Gain on extinguishment of debt with related parties	$ —	$ 3,477,696
Equity dividend to investor	$ —	$ 10,153,799

See accompanying notes to the unaudited condensed interim financial statements.

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

1. Organization and Summary of Significant Accounting Policies

Organization

HCW Biologics Inc. (the "Company") is a biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen healthspan by disrupting the link between chronic, low-grade inflammation and age-related diseases. The Company believes age-related low-grade chronic inflammation, or "inflammaging," is a significant contributing factor to several chronic diseases and conditions, such as cancer, cardiovascular disease, diabetes, neurodegenerative diseases, and autoimmune diseases. The Company is located in Miramar, Florida and was incorporated in the state of Delaware in April 2018.

Reverse Stock Split

On March 31, 2025, at a Special Meeting of the Stockholders (the "Special Meeting"), the stockholders of the Company approved a reverse stock split of all outstanding shares of the Common Stock, and the Board approved a reverse stock split of the Common Stock at a final ratio of one-for-forty (1::40) (the "Reverse Stock Split"). The Reverse Stock Split was effective at 12:01 a.m. Eastern Time on April 11, 2025. The Common Stock commenced trading on a reverse split-adjusted basis when the markets opened on April 11, 2025, under the existing trading symbol "HCWB."

In addition to the Reverse Stock Split, the stockholders approved two other proposals at the Special Meeting: (1) use of the Company's equity line of credit to raise up to $40.0 million through sales of shares of the Company's Common Stock thereunder and (2) execution of the principal terms for the conversion of up to approximately $6.9 million of the outstanding principal of Secured Notes into shares of Common Stock. See Note 3. Debt, net -- Senior Secured Notes.

All authorized, issued, and outstanding shares of common stock, preferred stock, stock option awards, and per share data included in these financial statements have been recast to give retrospective effect to the adjusted authorized shares and Reverse Stock Split for all periods presented. The Reverse Stock Split did not have any effect on the stated par value of the Company's Common Stock or the rights and privileges of the holders of shares of Common Stock. Options, warrants and convertible securities outstanding immediately prior to the Reverse Stock Split were appropriately adjusted to reflect the Reverse Stock Split.

Liquidity and Going Concern

In accordance with ASC 205-40, Presentation of Financial Statements – Going Concern ("Topic 205-40"), we are required to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern for at least 12 months from the issuance date of the Company's condensed interim financial statements. This evaluation does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented or are not within control of the Company as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

As of September 30, 2025, 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. During its development activities, the Company has sustained operating losses, experienced negative operating cash flows and negative working capital position and it expects to continue to incur operating losses for the foreseeable future. Since inception to September 30, 2025, the Company incurred cumulative net losses of $106.5 million. These losses reflect a $5.3 million reserve for credit losses and a $1.3 million nonoperating losses reported in prior periods.

To date, the Company has funded operations primarily through the sale of stock and warrants, issuance of Secured Notes and other debt, and revenues generated from the Company's exclusive worldwide license and development supply agreement with Wugen Inc. ("Wugen"), pursuant to which Wugen licensed limited rights to develop, manufacture, and commercialize cell-based therapy treatments for cancer based on two of our internally-developed, multi-cytokine fusion protein molecules, HCW9201 and HCW9206. Since inception, the Company has recognized $16.2 million of revenues derived from the Wugen License, including upfront license fees in cash and shares of Wugen common stock, payments for vials of materials, and for manufacturing of development supplies for clinical trials. On May 29, 2025, the Company agreed to a request from Wugen to suspend the Wugen License, including Wugen's clinical trial due diligence obligations and its obligation to pay up to $500,000 annually to reimburse the Company for certain research and development expenses. The suspension will run for a period of one year from the effective date of the suspension and will end on May 29, 2026. During the suspension, the Company has the exclusive right to seek alternate licensees and terminate the Wugen license in order to enter other business development transactions related to the ex vivo use of the licensed molecules.

The Company and WY Biotech Co., Ltd. ("WY Biotech") are currently finalizing the terms of an amendment to an exclusive worldwide license agreement ("WY Biotech License") that the parties first entered on November 17, 2024. The subject of the license is the use of in vivo rights to one of the Company's preclinical molecules, HCW11-006. The Company had extended the date for payment of the $7.0 million upfront license fee due under the WY Biotech License while WY Biotech worked to finalize agreements with their contract development and manufacturing organization ("CDMO") and investors. On September 5, 2025, WY Biotech proposed further revisions and additions to the terms of the WY Biotech License. Negotiations between the parties to restructure the terms of the WY Biotech License are ongoing. Pursuant to the terms currently being negotiated, the Company will retain its payment-free, milestone-free, and royalty-free option to recapture the development and commercialization in vivo rights of the licensed molecule for the United States, Canada, Central America, and South America (Opt-in Territory) after the conclusion of the Phase 1 clinical trial. WY Biotech is financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the molecule. The Company will be responsible for costs associated with clinical development, regulatory approval, and commercialization in the Opt-in Territory, if it exercises its opt-in rights.

During the nine months ended September 30, 2025, the Company extinguished $7.7 million of debt through restructuring or conversion of debt. This was accomplished by restructuring $7.4 million of Senior Secured Notes, including accumulated accretion of a fixed bonus payable upon maturity through the Second Amendment to the Amended and Restated Note Purchase Agreement (the "Conversion Agreement") and converting $270,000 of unsecured promissory notes according to the terms of the note purchase agreement. Both transactions include providing the former noteholders with the right to a portion of the proceeds received on the liquidation or sale of the Company's Wugen shares. The Company maintains ownership of the Wugen shares included in these transactions and has recorded a contingent liability to account for the right of the former noteholders to receive a portion of the proceeds upon liquidation or sale of the Wugen shares. See Note 1 - Organization and Summary of Significant Accounting Policies – Investments for further details on the Company's investment in Wugen shares. The former noteholders for this debt consisted of officers, directors and other significant stockholders. Due to the related party nature of the conversion transaction, the gain on restructuring and loss on conversion were recorded to additional paid-in capital, which is presented as a gain on conversion of debt with related parties, net in the accompanying interim condensed statements of changes in stockholders' equity (deficit) for the three months ended June 30, 2025, the period in which the conversion occurred. As of September 30, 2025, the Company's short-term debt includes $382,652 held by Senior Note noteholders who did not elect to convert. The Maturity Date of the Secured Notes is August 30, 2026, at which time the Company will repay $435,500, inclusive of the fixed bonus due upon the Maturity Date. The Company also has a short-term debt obligation with a carrying value of $189,722 as of September 30, 2025. This debt has a Maturity Date of February 7, 2026, at which time the Company will repay $225,000.

On August 15, 2022, the Company entered into a loan and security agreement (the "2022 Loan Agreement") with Cogent Bank, pursuant to which it received $6.5 million in proceeds to purchase a property at which the Company planned to build a facility to manufacture biologics and upgrade its research laboratory facilities. The loan is secured by a first priority lien on the property. As of September 30, 2025, the general contractor and certain subcontractors filed mechanics liens related to unpaid invoices issued in connection with construction of the Company's new manufacturing facilities and upgraded research laboratories. The 2022 Loan Agreement contains a provision for a discretionary default in the event that the Company fails to pay sums due in connection with construction of any improvements. As of September 30, 2025, the Company has reported the $6.2 million remaining balance of this loan as Short-term debt, net, to reflect that the lender has the right to accelerate the loan under a discretionary default provision. As discussed below, on October 24, 2025, the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure mechanics liens.

In connection with the mechanics liens filed by the general contractor and certain subcontractors which triggered the discretionary acceleration provision under the 2022 Loan Agreement, on January 22, 2025, the Company entered into a forbearance agreement with BE&K Building Group ("BE&K"), its general contractor, to allow the Company until March 31, 2025 to continue efforts to find the financing required to complete the construction and renovation of the property. Pursuant to the forbearance agreement, the Company made an initial payment of $1.0 million in partial satisfaction of amounts owing to BE&K and its subcontractors. As the Company reported in a Form 8-K, on April 17, 2025, the Company received a summons and a copy of a complaint filed by BE&K in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "BE&K Complaint"). Other Defendants named in the BE&K Complaint who are subcontractors elected to file counterclaims and cross-claims as part of their responses to the BE&K Complaint. Cogent Bank, also named as a Defendant in the BE&K Complaint, has not elected to take legal action at this time. In addition, on April 28, 2025, the Company received a summons and a copy of a complaint filed by Fisk Electric Company (which is a defendant in the BE&K Complaint) in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "Fisk Complaint") against the Company, BE&K, and the other defendants in the BE&K Complaint. On August 8, 2025, B&I Contractors, Inc., one of the defendants in the BE&K Complaint, filed a motion for summary judgment (the "MSJ") as to the Count I (Foreclosure of Construction Lien). The Company has responded to the BE&K and Fisk Complaints and cross-claims as well as the B&I MSJ. The parties are engaged in discovery and the court has set the case for trial in early December 2026.

On October 24, 2025, the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure the mechanics liens no later than thirty (30) days after receipt of this letter in strict compliance with Section 7.2(3) of the Loan Agreement by: (i) paying and discharging all of the Claims of Lien and causing satisfactions to be recorded in the Public Records of Broward County, Florida for all of the Claims of Lien, and (ii) resolving all litigation against the Borrower and the mortgaged property described in the Mortgage and causing such claims in the Foreclosure Actions to be dismissed and all related notices of lis pendens to be released. The Company and Cogent Bank are in negotiations to come to terms for a forbearance agreement to provide additional time for the Company to comply with the demands it made in the demand letter.

As of July 13, 2024, the Company and Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, entered into a confidential Settlement Agreement and Release (the "Settlement Agreement") with ImmunityBio and its affiliates. The Settlement Agreement includes mutual general releases by and among the parties thereto. No party was required to make any monetary payments to any other party or person under the Settlement Agreement and each party will bear its own expenses incurred in connection with the matter. The Arbitration and related Complaint were dismissed with prejudice on or about December 24, 2024. With the execution of the Settlement Agreement, the Company resolved the attendant uncertainties for the outcome of the Arbitration and additional complexities, and it launched its new financing plan.

In the accompanying condensed balance sheet as of September 30, 2025, the Company reported a balance of $12.1 million for legal fees incurred but not yet paid that were included within Accounts payable. The Company is in discussions with the law firms involved with this matter to establish a reasonable payment plan for the related legal fees. During the nine months ended September 30, 2025, the Company received an insurance reimbursement of $2.0 million, which was paid directly to the law firm who represented Dr. Wong in connection with his defense in the Arbitration. The insurance recovery is reported within Legal expenses (recoveries), net in the condensed interim statement of operations for the nine months ended September 30, 2025.

During the nine months ended September 30, 2025, the Company raised gross proceeds of $7.0 million through the issuance of equity securities. These include sale of shares of Common Stock through the Company's Standby Equity Purchase Agreement ("SEPA") and issuance of equity securities through a follow-on public offering to one institutional investor (the "Investor"). The Investor was also the sole investor in the Company's $6.9 million equity offering which closed on November 20, 2024.

On February 20, 2025, the Company entered into an Equity Purchase Agreement, which qualified as a SEPA, and a related Registration Rights Agreement with Square Gate Capital Master Fund, LLC - Series 4 ("Square Gate"), pursuant to which the Company will have the right, but not the obligation, to sell to Square Gate, and Square Gate will have the obligation to purchase from the Company, up to $20.0 million (the "Maximum Commitment Amount") worth of the Company's shares of Common Stock, at the Company's sole discretion, over the next 36 months (the "Put Shares"), subject to certain conditions precedent and other limitations. On April 16, 2025, the U.S. Securities and Exchange Commission ("SEC") declared a registration statement effective to register shares required to sell up to $40.0 million of the Company's shares to Square Gate, according to provisions of the Equity Purchase Agreement. On August 14, 2025, the parties agreed to amend the SEPA to allow for intraday trading. In the three months ended September 30, 2025, the Company issued 475,000 shares of Common Stock through the SEPA for net proceeds of $2.2 million, $2.0 million of which settled as of September 30, 2025. See Note 7. Standby Equity Purchase Agreement.

On November 20, 2024, the Company closed a $6.9 million registered direct offering and a concurrent private placement of common stock and warrants with an offering priced above market under Nasdaq rules. On May 15, 2025, the Company closed on a $5.0 million in a follow-on public offering with an offering priced at the market under Nasdaq rules. Contemporaneously with the May 2025 financing, the Company entered into an agreement with the Investor to set a new exercise price, of $7.45 per share, with respect to certain Common Stock Warrants to purchase 167,925 shares of the Company's Common Stock which were issued in the November 2024 financing. See Note 4. Sale of Common Stock and Warrants**.**

An important part of the Company's future financing plans is the ability to access the public markets for the sale of securities. This requires that the Company remain in compliance with all Nasdaq Listing Rules, and it is currently deficient in meeting the requirements of Listing Rule 5550(b)(1), or the Equity Rule, related to the minimum requirements to maintain a $2.5 million balance in stockholders' equity. The Company was recently granted an extension to regain compliance with the Equity Rule until December 31, 2025, as discussed in more detail below.

In the first quarter of 2025, following a hearing before a Nasdaq Hearings Panel (the "Panel"), the Panel granted the Company an extension until June 30, 2025 to regain compliance with all Nasdaq Listing Rules The Company had been deficient in three areas: Listing Rule 5550(a)(2), or requirements for the minimum bid price; Listing Rule 5550(a)(4), or requirements for the public float requirement in and the market value of publicly held shares, and the Equity Rule. On June 26, 2025, the Company announced that it received a formal notice from the Listing Qualifications Staff (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") that the Company was in compliance with the Equity Rule for continued listing on the Nasdaq Capital Market (the "Exchange"). At that time, the Company was also notified that it will remain subject to a "Panel Monitor," as that term is defined in Nasdaq Listing Rule 5815(d)(4)(B), for a period of one year from the date of the Nasdaq notice, through June 23, 2026. While the Company successfully completed several elements of its compliance plan including the Reverse Stock Split, the restructuring or conversion of $7.7 million of debt, putting a Standby Equity Purchase Agreement in place, and completing a $5.0 million equity financing by June 30, 2025, as previously reported, the Company's upfront license fee from WY Biotech did not meet the criteria for revenue recognition for the period ended June 30,2025. As a result, as of June 30, 2025, the Company did not meet the requirements of the Equity Rule.

The Company filed its Form 10-Q for quarter ended June 30, 2025 on August 18, 2025. On August 19, 2025, the Company received written notice from the Staff that as of June 30, 2025, the Company was non-compliant with the Equity Rule for continued listing on the Exchange. The Company made a timely request for a hearing before the Panel and was granted a hearing. On October 13, 2025, the Panel granted the Company an extension in which to regain compliance with all continued listing rules of the Exchange. The Panel's determination follows the Company's hearing on September 25, 2025, at which the Company presented, and the Panel considered, the Company's plan to regain compliance with the Equity Rule. The Panel granted the Company's request for continued listing on the Exchange, subject to, among other things, the Company demonstrating compliance with the Equity Rule by December 31, 2025, and with all other Exchange continued listing rules by February 16, 2026. The Company was advised that February 16, 2026, represents the full extent of the Panel's discretion to grant continued listing while the Company is non-compliant with the Nasdaq Listing Rules. The Panel also required that the Company provide prompt notification of any significant events that occur during the exception period that may affect the Company's compliance with Nasdaq requirements. In addition, the Company must timely file Form 10-Q for the third quarter, and provide notice of the status of certain elements of the Company's compliance plan. Any compliance documentation submitted by the Company will be subject to review by the Panel, which may, in its discretion, request additional information before determining that the Company has complied with the terms of the exception. The Panel has discretion to review its decision to grant an exception period within 45 calendar days after issuance of the written decision.

As of September 30, 2025, the conclusion of a going concern assessment, before consideration of our financing plans, was that there is substantial doubt about the Company's ability to continue as a going concern. Future financial transactions planned in the next twelve months consist of business development transactions for out licenses and corporate partnering, as well as the sale of Common Stock through the Standby Equity Purchase Agreement. The Company considered future elements of its financing plan that were probable and likely to be implemented within the next year to determine if financing activities currently underway are sufficient to mitigate the substantial doubt in the going concern analysis, in addition to considering continued operating losses and the burden of obligations for expenses incurred in connection with past legal proceedings. Management concluded that there were no mitigating circumstances which alleviated the substantial doubt over its ability to continue as a going concern. If the Company is not successful in raising additional capital through these activities, management intends to revise its business plan and reduce costs. If such revisions are insufficient, the Company may have to curtail or cease operations.

The accompanying condensed interim financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above. The Company believes that substantial doubt exists regarding its ability to continue as a going concern for at least 12 months from the date of issuance of the Company's financial statements and that the substantial doubt that existed in its going concern analysis was not alleviated.

Summary of Significant Accounting Policies

Basis of Presentation

Unaudited Interim Financial Information

The accompanying unaudited condensed interim financial statements as of September 30, 2025 and for the three and nine months ended September 30, 2024 and 2025 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, 2025 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The condensed interim balance sheet at December 31, 2024 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, 2024 which appear in our Annual Report on Form 10-K for the year ended December 31, 2024 filed with the Securities and Exchange Commission (the "SEC") on March 28, 2025 (the "Annual Report") and in other filings with the SEC.

Segment Reporting

The Company operates and manages its business as one reportable and operating segment, which is the business of developing and commercializing novel immunotherapies for diseases promoted by chronic inflammation, especially age-related diseases. The Company's chief executive officer, who is the chief operating decision maker ("CODM"), reviews financial information on an aggregate basis for allocating and evaluating financial performance. In addition, our CODM is regularly provided with detailed results of preclinical and clinical data which is considered in his decision for the allocation of resources. See Note 10. Segment Reporting for further details. The single operating segment constitutes all of the Company activity, the CODM regularly reviews the entity-wide operating results and performance. All long-lived assets are maintained in the United States of America.

Reclassification of Prior Period Presentation of Legal Expenses

Certain prior period amounts have been reclassified to distinguish between General and administrative expenses in the ordinary course of business and legal expenses incurred in connection with the Arbitration and Settlement Agreement described in Liquidity and Going Concern in this Note 1. Reclassification of legal expenses incurred in connection with legal proceedings impacts the condensed interim statements of operations. There is no effect on reporting results of operations from prior periods. Legal expenses related to the Arbitration are presented in Legal expenses (recoveries), net in the accompanying condensed statements of operations.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Management must apply significant judgment in this process. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from estimates.

Fair Value Measurements

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

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require a reporting entity to develop its own assumptions.

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values takes into account the market for the Company's financial assets and liabilities, the associated credit risk, and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

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. The Wugen License 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 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. 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. For each in process SOW, amounts are billed in the same quarter the costs are incurred.

For the three months ended September 30, 2024 and September 30, 2025, the Company recognized $426,423 and $15,606 in revenue, respectively, related to sale of development supply materials to the Company's licensee, Wugen. In the nine months ended September 30, 2024 and September 30, 2025, the Company recognized $2.2 million and $27,222 in revenue, respectively, related to sale of clinical materials to Wugen. In the nine months ended September 30, 2025, the Company agreed to Wugen's request to suspend the Wugen License for a period of one year, ending on May 29, 2026. Wugen has made the strategic decision to focus its ongoing pivotal clinical trials for its CAR-T clinical program which received regenerative medicine advanced therapy (RMAT) designation by the FDA and priority medicines (PRIME) designation by the European Medicines Agency for the treatment of patients with relapsed/refractory T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL). During this time, Wugen will not be purchasing additional clinical materials for the licensed molecules as its clinical program based on these molecules has been paused however the Company continues to earn revenue from related ancillary services such as storage and insurance.

Investments

As part of its financing strategy, the Company may enter into licensing or collaboration agreements under which it receives consideration in the form of a minority equity interest in a counterparty, in lieu of or in addition to cash payments. These financial instruments are presented within Investments in the accompanying condensed interim balance sheets.

When consideration is an equity interest in a private entity whose equity has limited marketability with no readily determinable fair value and for which the Company does not have significant influence over the investee, the Company has elected to measure the equity interest using the measurement alternative, at cost less impairment, adjusted for observable price changes in orderly transactions for the identical or similar investment of the same issuer (ASC Topic 321, Investments - Equity Securities), unless the fair value method is otherwise elected. If the Company elects to measure an equity security at fair value, the entity shall measure all identical or similar investments of the same issuer, including future purchases of identical or similar investments of the same issuer, at fair value. The election to measure those securities at fair value shall be irrevocable. Any resulting gains or losses on the securities for which that election is made shall be recorded in earnings at the time of the election. See Note 8. Fair Value of Financial Instruments.

In the period ended June 30, 2025, the Company elected to account for its Wugen shares, previously accounted for under the measurement alternative, at fair value as determined using financial valuation techniques and market information available. Further, the Company will remeasure the change in fair value of the Wugen shares, and related contingent liability, in subsequent reporting periods and recognize the change in earnings.

The Company invests excess cash in U.S. Treasury bills and notes, which are classified as trading securities. As of December 31, 2024 and September 30, 2025, the Company had no short-term investments.

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 condensed interim 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. For short-term leases with a term of one year or less, the Company uses the practical expedient and does not record an ROU asset or lease liability for such short-term leases.

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.

During the current reporting period, the Company refined its methodology for calculating weighted average shares outstanding from a monthly average to a daily average. This change was implemented to improve the precision of the earnings (loss) per share calculations. The change does not represent a correction of an error, as both methodologies are permitted under ASC Topic 260, *Earnings per Share*. The change in methodology will be applied prospectively. As the effect of this refinement does not materially impact previously reported results and both approaches are consistent with U.S. GAAP, prior period net loss per share figures have not been recast.

Standby Equity Purchase Agreement

The Company and Square Gate Capital Master Fund, LLC - Series 4 ("Square Gate") entered a Standby Equity Purchase Agreement ("SEPA") providing for an equity line of credit with Square Gate on February 20, 2025. This agreement provides a mechanism for submission by the Company and acceptance by Square Gate of Put Notices under the SEPA pursuant to which Square Gate and the Company may agree to and execute one purchase and sale of Put Shares ("Standard Put Shares"). The Standard Put Notice has a pricing mechanism based on a volume-adjusted weighted average trading price over three days following the acceptance of the Standard Put.

On August 14, 2025, the parties entered into a First Amendment to the SEPA (the "First Amendment") to provide a mechanism for submission by the Company and acceptance by Square Gate of Put Notices under the SEPA pursuant to which Square Gate and the Company may agree to and execute multiple purchases and sales of Put Shares on the same trading day ("Intraday Put Shares"). Under the First Amendment, among other things, the purchase price of the Intraday Put Shares will be the lowest traded price during a specified valuation time period which begins with the acceptance of the Intraday Put and ends when trading volume reaches 1000% of the amount of shares included in the Intraday Put.

A SEPA is an equity-linked instrument for which an investor has the right, but not the obligation, to purchase shares of the entity's common stock over a specified period of time. The SEPA creates a purchase put option for the overarching arrangement which was determined to be a derivative. Economically, before the entity has elected to sell shares, a SEPA represents a purchased put option on the entity's own equity. However, once the entity "draws" on the SEPA, the related number of shares issued constitutes a financial instrument. Thus, a SEPA contains both a purchased put option element and a forward share issuance element. This generally means that a SEPA generally does not qualify for equity classification. Accordingly, entities must recognize an asset or liability for its SEPA. Such asset or liability must be measured at fair value, with changes in fair value recognized in net (loss) income. Further, individual draws must also be evaluated to determine if they meet criteria for equity classification.

With regards to the individual draws for a Standard Put under the SEPA, an individual draw would create a separate financial instrument with settlement criteria that does not meet indexation guidance. While the number of shares is known at inception and therefore not subject to the overarching share cap, there are two inputs into the settlement amount paid by the Investor which are not inputs into a fixed-for-fixed option: (1) the maximum amount to be funded under the SEPA of $20 million, which inherently limits the settlement amount regardless of the Company's stock price and (2) the discount which reduces the amount to be paid upon settlement.

With regards to the individual draws for an Intraday Put under the First Amendment to the SEPA, an individual draw would create a separate financial instrument with settlement criteria that does not meet the indexation guidance. While the number of shares is known at inception and therefore not subject to an overarching share cap, the only inputs into its settlement is the Company's stock price and trading volume during the pricing period.

Inputs noted above are not all inputs into a fixed-for-fixed option pricing model, thus the individual draw issuances are not eligible for equity classification in accordance with ASC 815-40, and therefore an asset or liability will be recorded and marked to market while the financial instrument is outstanding. Upon settlement of the financial instruments, the Company should recognize the following amounts in earnings:

- The gain (loss) for the excess (deficit) of (a) the carrying amount of the asset or liability for the financial instrument plus the proceeds received and (b) the fair value of the common shares.

- Any discount, issuance or transaction costs incurred in conjunction with the settlement of the put shares.

2. Accrued Liabilities and Other Current Liabilities

As of December 31, 2024, the Company had a balance of $981,940 included in Accrued liabilities and other current liabilities in the audited condensed balance sheet, consisting of $422,000 for construction expenses, $49,000 for manufacturing expenses, $155,000 for legal fees, $121,000 for clinical expenses, $5,000 for bonus expense, $202,000 for salary expenses and $28,000 for other liabilities.

As of September 30, 2025, the Company had a balance of $1.1 million included in Accrued liabilities and other current liabilities in the accompanying condensed interim balance sheet, consisting of $422,000 for construction expenses, $120,000 for property taxes, $49,000 for manufacturing expenses, $138,000 for legal fees, $137,000 for clinical expenses, $118,000 for salary expenses and $116,000 for other accrued expenses or current liabilities.

3. Debt, Net

Cogent Bank Loan

On August 15, 2022, the Company entered the 2022 Loan Agreement with Cogent Bank (the "2022 Loan Agreement"), pursuant to which it received $6.5 million in proceeds to purchase a property where the Company planned to construct a manufacturing facility for biologics and upgraded research laboratory facilities. The loan is secured by a first priority lien on the building.

As of September 30, 2025, the Company had $6.2 million in principal outstanding under the 2022 Loan Agreement. The interest-only period was one year followed by 48 months of equal payments of principal and interest beginning on September 15, 2023 based on a 25-year amortization rate. The unamortized balance is due on August 15, 2027 (the "2022 Loan Agreement Maturity Date"), and bears interest at a fixed per annum rate equal to 5.75%. Upon the 2022 Loan Agreement Maturity Date, a final payment of unamortized principal will be due. The Company is in compliance with covenants related to current payment of principal and interest as of September 30, 2025. The Company has the option to prepay the outstanding balance of the loan prior to the 2022 Loan Agreement Maturity Date without penalty.

As of December 31, 2024 and September 30, 2025, certain subcontractors filed mechanics liens related to unpaid invoices issued in connection with the Company's construction of its new manufacturing facilities and upgraded research laboratories. The 2022 Loan Agreement contains a provision for a discretionary default in the event that the Company fails to pay sums due in connection with construction of any improvements. As of December 31, 2024 and September 30, 2025, the Company has reported this loan as Short-term debt, net. On October 24, 2025, the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure the mechanics liens no later than thirty (30) days after receipt of this letter in strict compliance with Section 7.2(3) of the Loan Agreement by: (i) paying and discharging all of the Claims of Lien and causing satisfactions to be recorded in the Public Records of Broward County, Florida for all of the Claims of Lien, and (ii) resolving all litigation against the Borrower and the mortgaged property described in the Mortgage and causing such claims in the Foreclosure Actions to be dismissed and all related notices of lis pendens to be released. The Company and Cogent Bank are in negotiations to come to terms for a forbearance agreement to provide additional time for the Company to comply with the demands it made in the demand letter. See Note 11. Commitment and Contingencies -- Other Matters.

Senior Secured Notes

As of September 30, 2024, the Company received $6.5 million in funding from the issuance of Secured Notes, which is included within Debt, Net on the accompanying condensed interim balance sheet. Investors included Dr. Hing C. Wong, Founder and Chief Executive Officer, who invested $2.4 million; Rebecca Byam, Chief Financial Officer, who invested $220,000; Lee Flowers, Senior Vice President of Business Development, who invested $25,000; Scott T. Garrett, the Chairman of the Company's board of directors, who invested $140,000; Gary M. Winer, a former member of our board of directors, who invested $60,000; Rick S. Greene, a member of the board of directors, who invested $25,000, and other significant investors.

As of September 30, 2025, there was $325,000 of outstanding principal amount of Secured Notes reported in Short-term Debt, net in the accompanying condensed interim balance sheet. As of September 30, 2025, the Company restructured $6.6 million outstanding principal of Secured Notes by conversion to equity. On May 1, 2025, those noteholders who elected to convert their outstanding indebtedness to equity entered the Second Amendment to the Amended and Restated Note Purchase Agreement (the "Conversion Agreement"). On May 7, 2025, $6.6 million of outstanding principal amount of Secured Notes and the Company's obligation to pay these noteholders a fixed bonus on the Maturity Date were extinguished upon conversion. The Company pledged its equity ownership interest in Wugen which was 2.2 million shares of Wugen common stock as of September 30, 2025 ("Pledged Collateral"). The Pledged Collateral will be held and released according to the terms of the Escrow Agreement, as security for the Secured Notes.

The Secured Notes have a Mandatory Prepayment provision, according to which the Company is required to prepay the Secured Notes before the Maturity Date under certain circumstances. In the event of a Mandatory Prepayment, Secured Notes may receive a bonus payment based on the gross proceeds of the sale of the Pledged Collateral. The agreement also contains default provisions, according to which, following an event of default, the Company may be required to distribute the Pledged Collateral to the Purchasers on a pro rata basis based on a $10.0 million issuance of Secured Notes, in full satisfaction of the indebtedness evidenced by the Secured Notes.

If the Secured Notes are repaid on the Maturity Date, holders will receive their pro rata share of a fixed bonus payment of $3.4 million in addition to payment of outstanding principal and accrued and unpaid interest. If a bonus payment is paid, there is no prepayment penalty. In the three and nine months ended September 30, 2025, the Company recognized $15,502 and $390,810, respectively as an expense for accretion of the fixed bonus payment due in the event the Secured Notes are repaid on the Maturity Date, presented within General and administrative expenses in the accompanying condensed interim statements of operations. In the nine months ended September 30, 2025, the accumulated accretion balance of $860,462, related to the $6.6 million of Secured Notes that were restructured and converted, was derecognized. For those noteholders who converted to equity, the right to a fixed bonus payable on the Maturity Date was terminated and previously accumulated fixed bonus was waived. See section "Troubled Debt Restructuring of Secured Notes" below.

The Secured Notes were deemed to be a hybrid instrument, consisting of a debt host with embedded derivatives requiring bifurcation and accounting for separately. The embedded derivatives consist of the Mandatory Redemption, which depends on certain events occurring, and the fixed bonus payable upon the Maturity Date. The fair value of the embedded derivative, which incorporated the likelihood of certain events occurring, was immaterial. Thus, as of September 30, 2025, the Company did not recognize the embedded derivative in the accompanying condensed financial statements. The Company accounts for the fixed bonus payment to be paid if the Secured Notes are repaid on the Maturity Date by accreting the bonus payment to the full amount due on the Maturity Date, utilizing the effective interest rate method.

For those Secured Notes which remain outstanding, as of September 30, 2025, the Company reported $382,652 for the outstanding principal and accumulated accretion of a fixed bonus payment due upon maturity as a current liability in Short-term debt, net in the accompanying condensed interim balance sheet.

Troubled Debt Restructuring of Senior Secured Notes

The Company entered into the Second Amendment to its Secured Note in which certain Secured Note noteholders and the Company agreed to the terms to effectively extinguished $7.4 million of debt through the issuance of 253,083 shares of Common Stock, warrants to purchase 126,540 shares of Common Stock, and rights to receive a pro rata share of 49.11% of the proceeds or shares from the Company's investment in Wugen. The transaction was accounted for under ASC 470-60 as a troubled debt extinguishment, as the Company was experiencing financial difficulty and it was granted a concession by Secured Note noteholders whereby the fair value of consideration transferred was less than the carrying amount of the Secured Notes. The net carrying amount of the restructured Secured Notes at the time of the amendment was $7.4 million including principal of $6.6 million and accumulated accretion of a fixed bonus payable upon Maturity Date of $860,462. The fair value of consideration transferred including Common Stock, warrants to purchase Common Stock, and rights to proceeds of a portion of the Company's shares of Wugen common stock was $4.0 million, with the difference of $3.5 million being recognized as a troubled debt restructuring gain. Due to the related party nature of the converting noteholders, the gain was recorded to additional paid-in capital as of September 30, 2025.

Unsecured Promissory Notes

As of May 5, 2025, the Company issued a total of $270,000 principal amount of unsecured convertible promissory notes that mature on May 5, 2026 with paid in kind interest accruing thereon, payable quarterly in arrears at 10% per annum (the "Convertible Bridge Notes"). In accordance with their terms, following the completion of a qualified offering, the Convertible Bridge Notes were converted into shares of our Common Stock at the final offering price in an offering that closed on May 15, 2025. In addition, holders of the Convertible Bridge Notes have the right to receive a portion of the proceeds of the Company's shares of Wugen common stock, if and when such shares are ever sold, determined by the number of the Wugen shares equal to 0.25 multiplied by the original principal amount, in dollars, of the Convertible Bridge Notes. Investors included: $60,000 invested by Hing C. Wong, the Company's Founder and CEO; $100,000 invested by Scott T. Garrett, the Chairman of the Company's Board of Directors; and $10,000 invested by Gary M. Winer, who was a member of the Company's Board of Directors at the time of his investment.

As of May 15, 2025, the outstanding principal of Convertible Bridge Notes were converted. The fair value of consideration transferred including 36,242 shares of Common Stock and rights to proceeds of a portion of the Company's shares of Wugen common stock was $401,134, with the difference of $131,134 being recognized as a loss on conversion. Due to the related party nature of the converting noteholders, the loss was recorded to additional paid-in capital in the accompanying condensed interim financial statements as of and for the period ended September 30, 2025.

Promissory Note with Personal Guarantee

On May 8, 2025, the Company issued a promissory note for $150,000, secured by a personal guaranty and pledge given by the Company's Founder and CEO, Dr. Hing C. Wong ("Guarantor") in accordance with the provisions of that certain Guaranty and Pledge Agreement of even date herewith between the Company and the Holder. The promissory note was issued with an original issue discount of $75,000. On the Maturity Date of February 7, 2026, the Company will repay $225,000. There are provisions which allow the Company to prepay the promissory note before the Maturity Date. The proceeds of this promissory note were used to pay the expenses required to be paid prior to the equity financing which closed on May 15, 2025. The Company is accreting the original issue discount on a straight-line basis over the seven-month term. There is no current interest due on the promissory note with personal guarantee. As of September 30, 2025, the Company reported a balance of $189,722 in the accompanying condensed balance sheet. In the three and nine months ended September 30, 2025, the Company recognized accretion of original issue discount of $25,000 and $39,722, respectively, in Interest expense in the accompanying condensed interim statements of operations.

Contingent Liabilities

In connection with the Trouble Debt Restructuring and the conversion of the Unsecured Promissory Note discussed above, the converting noteholders have a right to receive proceeds of a portion of the Company' shares of Wugen common stock in the event of a liquidation or sale of these shares. The Company retained ownership of all of its Wugen shares which is presented in Investments on the accompanying condensed interim balance sheets. The Company recognized a contingent liability for the rights transferred to the converting noteholders presented in Contingent liability - related party on the accompanying interim condensed balance sheets. As of September 30, 2025, the carrying value of the Company's Wugen shares was $1.3 million, and carrying value for the Contingent liability - related party was $692,531 in the accompanying condensed interim balance sheets. See Note 8. Fair Value of Financial Instruments.

4. Sale of Common Stock and Warrants

Sale of Shares of Common Stock through SEPA

In the three months and nine months ended September 30, 2025, the Company submitted Put Shares to Square Gate which were accepted and resulted in the sale of 475,000 shares of Common Stock. See Note 7. Standby Equity Purchase Agreement.

May 2025 Equity Financing

On May 13, 2025, the Company entered into a securities purchase agreement with a single institutional investor (the "Investor") for the issuance and sale of (i) 158,000 shares (the "Shares") of the Company's Common Stock and (ii) pre-funded warrants to purchase up to 513,140 shares of Common Stock (the "Pre-Funded Warrants") in a follow-on public offering (the "Offering"), pursuant to a registration statement filed under Rule 424(b)(4) (File No. 333-287136), which was declared effective by the SEC on May 15, 2025. The Company also issued warrants to purchase up to an aggregate of 1,342,280 shares of Common Stock ("Common Stock Warrants") for $7.45 per share.

The Company sold the Common Stock and Pre-Funded Warrants with an accompanying two Common Stock Warrant, each of which may purchase one share of Common Stock, and the Common Stock and Pre-Funded Warrants were immediately separated from the Common Stock Warrants and issued separately. The combined purchase price for each Share and the two accompanying Common Stock Warrant was $7.45 per unit and the combined purchase price for each Pre-Funded Warrant and the two accompanying Common Stock Warrant was $7.4999 per unit. The Common Stock Warrants have an exercise price of $7.45 per share, are exercisable immediately, and expire on the five-year anniversary of the date of issuance. The Pre-Funded Warrants have an exercise price of $0.0001 per share, are exercisable immediately, and will not expire until exercised in full.

The gross proceeds to the Company from the Offering were approximately $5.0 million before deducting the placement agent's fees and other offering expenses of $802,602 payable by the Company. In this financing, the Company issued shares of Common Stock of Pre-Funded Warrants that may be exercised to purchase Common Stock in lieu thereof, and warrants that may be exercised to purchase Common Stock. In a contemporaneous private agreement entered into with the Investor, the Company agreed to reprice warrants to purchase up to 167,925 shares of Common Stock that were issued to the Investor in a financing that closed on November 20, 2024 to an exercise price of $7.45 per share. The fair value of the securities issued in this transaction was $15.2 million. This included a fair value of $1.3 million for the shares of Common Stock issued based on the number of shares issued times the closing price on May 15, 2025, or $8.20 per share. In addition, the fair value of the warrants issued in this transaction was estimated at $13.9 million using the Black-Scholes option pricing model with assumptions including a term of 5 - 10 years, volatility of 120.6% and a risk-free rate of 4.07% - 4.45% As this was a transaction with an existing stockholder, the difference between the gross proceeds and the fair value of securities issued, or $10.2 million, was deemed to be an equity dividend to the Investor which was recorded in additional-paid-in capital as of September 30, 2025.

The Investor may not exercise any portion of the Common Stock Warrants or Pre-Funded Warrants to the extent it would beneficially own more than the limits defined in the respective Warrant Purchase Agreement. The exercise price and number of shares of Common Stock issuable upon the exercise of the Common Stock Warrants and Pre-Funded Warrants are subject to adjustment in the event of any stock dividends and distributions, stock splits, stock combinations or stock reclassifications, as described in the respective warrant agreements. Under certain circumstances, the warrants may be exercised on a "cashless" basis.

Both the Common Stock Warrants and Pre-Funded Warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date. The Common Stock Warrants and Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of shares of Common Stock upon exercise, are indexed to the Company's Common Stock and meet the equity classification criteria. In addition, the Common Stock Warrants and the Pre-Funded Warrants do not provide any guarantee of value or return.

As of September 30, 2025, the Investor exercised all of the Pre-Funded Warrants by delivering a notice of exercise to the Company and paying the exercise price. As a result, the Company issued 513,140 shares of registered Common Stock to the Investor as of September 30, 2025.

As of September 30, 2025, none of the Common Stock Warrants issued on May 15, 2025 had been exercised.

November 2024 Equity Financing

On November 18, 2024, the Company entered into a securities purchase agreement with the Investor for the issuance and sale of (i) 104,000 shares (the "Shares") of the Company's common stock, par value $0.0001 per share (the "Common Stock") and (ii) pre-funded warrants to purchase up to 63,925 shares of Common Stock (the "Pre-Funded Warrants") in a registered direct offering (the "Registered Offering"), pursuant to a shelf registration statement on Form S-3 (File No. 333-266991), which was declared effective by the SEC on August 26, 2022. The Registered Offering was made by means of a prospectus supplement filed with the SEC on November 20, 2024 that forms a part of such registration statement. In a concurrent private placement (the "Private Placement" and together with the Registered Offering, the Company also issued unregistered warrants to purchase up to an aggregate of 167,925 shares of Common Stock ("Common Stock Warrants"). The Common Stock Warrants have an exercise price of $7.45 per share, are exercisable immediately, and expire on the five-year anniversary of the date of issuance.

The Company sold the Common Stock and Pre-Funded Warrants with an accompanying Common Stock Warrant to purchase one share of Common Stock, and the Common Stock and Pre-Funded Warrants were immediately separated from the Common Stock Warrants and issued separately. The combined purchase price for each Share and accompanying Common Stock Warrant was $41.20 per unit and the combined purchase price for each Pre-Funded Warrant and accompanying Common Stock Warrant was $41.1999 per unit. The Pre-Funded Warrants have an exercise price of $0.0001 per share, are exercisable immediately, and will not expire until exercised in full.

The gross proceeds to the Company from the offering were approximately $6.9 million before deducting the placement agent's fees and other offering expenses of $638,045 payable by the Company. It closed on November 20, 2024.

The Investor may not exercise any portion of the Common Stock Warrants or Pre-Funded Warrants to the extent it would beneficially own more than the limits defined in the respective Warrant Purchase Agreement. The exercise price and number of shares of Common Stock issuable upon the exercise of the Common Stock Warrants and Pre-Funded Warrants are subject to adjustment in the event of any stock dividends and distributions, stock splits, stock combinations or stock reclassifications, as described in the respective warrant agreements. Under certain circumstances, the warrants may be exercised on a "cashless" basis.

Both the Common Stock Warrants and Pre-Funded Warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date. The Common Stock Warrants and Pre-Funded Warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of shares of Common Stock upon exercise, are indexed to the Company's Common Stock and meet the equity classification criteria. In addition, the Common Stock Warrants and the Pre-Funded Warrants do not provide any guarantee of value or return.

On November 20, 2024, the Investor exercised all of the Pre-Funded Warrants by delivering a notice of exercise to the Company and paying the exercise price. The Company issued 63,925 registered shares of Common Stock to the Investor on November 21, 2024.

On April 16, 2025, the 167,925 shares of Common Stock underlying the Common Stock Warrants issued to the Investor on November 20, 2024 were registered in a registration statement filed pursuant to Rule 424(b)(3) (File No. 333-286409). On May 15, 2025, the Company entered into a privately negotiated agreement with the Investor for its Common Stock Warrants to reduce the exercise price of such warrants from $41.20 per share to $7.45 per share. The Company considered the change in fair value of this modification of the warrant as a deemed dividend to the Investor related to the equity offering that closed in May 2025 with the Investor.

As of September 30, 2025, none of the Common Stock Warrants issued on November 20, 2025 had been exercised.

5. Preferred Stock

As of December 31, 2024 and September 30, 2025, the Company had 10,000,000 shares of preferred stock authorized and no shares of preferred stock issued.

6. 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,	
	2024	2025	2024	2025
Numerator:				
Net loss	$ (3,902,288)	$ (4,554,336)	$ (26,650,541)	$ (8,678,941)
Equity dividend to investor	—	—	—	(10,153,799)
Net loss attributable to Common Stockholders	$ (3,902,288)	$ (4,554,336)	$ (26,650,541)	$ (18,832,740)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	945,585	2,260,068	940,586	1,661,332
Net loss per share, basic and diluted	$ (4.13)	$ (2.02)	$ (28.33)	$ (11.34)

The following table summarizes the outstanding potentially dilutive securities. At September 30, 2024 and 2025, these securities were excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive:

	September 30,	
	2024	2025
Common stock options	44,703	44,228
Common stock warrants	—	1,636,745
Potentially dilutive securities	44,703	1,680,973

During the current reporting period, the Company refined its methodology for calculating weighted average shares outstanding from a monthly average to a daily average. This change was implemented to improve the precision of the earnings (loss) per share calculations. The change does not represent a correction of an error, as both methodologies are permitted under ASC Topic 260, *Earnings per Share*. The change in methodology will be applied prospectively. As the effect of this refinement does not materially impact previously reported results and both approaches are consistent with U.S. GAAP, prior period net loss per share figures have not been recast.

7. Standby Equity Purchase Agreement

On February 20, 2025, the Company entered into an Equity Purchase Agreement (the "Equity Purchase Agreement") with Square Gate Capital Master Fund, LLC - Series 4 ("Square Gate"), which the Company deemed to be a Standby Equity Purchase Agreement ("SEPA"). Under the Equity Purchase Agreement, the Company will have the right, but not the obligation, to sell to Square Gate, and Square Gate will have the obligation to purchase from the Company, up to $20,000,000 (the "Maximum Commitment Amount") worth of the Company's shares of common stock, at the Company's sole discretion, over the next 36 months (the "Put Shares"), subject to certain conditions precedent and other limitations. Square Gate has covenanted not to cause or engage in any short sales or hedging transactions with respect to the shares of the Company's common stock. The Maxim Group LLC acted as the Company's exclusive Placement Agent in connection with this transaction.

Unless earlier terminated, the Equity Purchase Agreement will remain in effect until the earlier of February 18, 2028 (i.e., the expiry of the 36-month period commencing on the date of the Equity Purchase Agreement) or the date on which Square Gate has purchased the Maximum Commitment Amount (the "Commitment Period"). The Company has the right to terminate the Equity Purchase Agreement at any time, subject to certain provisions as set forth in the Equity Purchase Agreement. Square Gate has the right to terminate the Equity Purchase Agreement under certain provisions as set forth in the Equity Purchase Agreement, including the continued listing of the Company's common stock on an Eligible Market.

The Equity Purchase Agreement and Registration Rights Agreement contain customary representations, warranties and agreements by the Company and customary conditions to Square Gate's obligation to purchase the Put Shares. Actual sales of shares of our common stock, if any, to Square Gate under the Equity Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the Company's common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. The net proceeds to us from sales of our common stock to Square Gate under the Equity Purchase Agreement, if any, will depend on the frequency and prices at which the Company sells shares to Square Gate under the Equity Purchase Agreement. Any proceeds that the Company receives from sales of shares of our common stock to Square Gate under the Equity Purchase Agreement will be used to advance our clinical development programs and expand our discovery, research and preclinical activities in the near term and in the future.

During the Commitment Period, the Company will have the right, but not the obligation, to direct Square Gate to make a purchase of the Put Shares by delivering written notice (a "Put Notice") to Square Gate on any trading day (the "Put Date") to purchase a number of Put Shares pursuant to a formula set forth in the Equity Purchase Agreement. The number of Put Shares that the Company can issue to Square Gate from time to time under the Equity Purchase Agreement may not exceed 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares issuable pursuant to a Put Notice.

On March 12, 2025, the Company issued 9,616 shares of the Company's Common Stock (subject to adjustment for the Reverse Stock Split) to Square Gate in payment of the Commitment Fee ("Commitment Shares"). At the Special Meeting of Stockholders, stockholders approved the Company's use of the Equity Purchase Agreement. On April 16, 2025, the U.S. Securities and Exchange Commission ("SEC") declared a registration statement effective to register the Commitment Shares and shares required to sell up to $40.0 million of the Company's shares to Square Gate, according to provisions of the Equity Purchase Agreement.

As of September 30, 2025, the Company concluded that the Equity Purchase Agreement for Standard Put Shares does not qualify for equity classification. On the effective date, the Company concluded that the fair value of the Equity Purchase Agreement at inception was zero and no asset or liability was recorded. As a result, fees paid to Square Gate in excess of the fair value of the Equity Purchase Agreement were expensed as incurred. Any issuance costs or other transaction costs attributable to a freestanding equity-linked financial instrument that is classified as an asset or liability should be recognized in earnings in the period incurred. The Commitment Fee and issuance costs for the registration statement to register the underlying shares of Common Stock issued under the Equity Purchase Agreement were expensed in the nine months ended September 30, 2025.

In the nine months ended September 30, 2025, the Company expensed the $150,000 Commitment Fee which was incurred in the period ended March 31, 2025 and $74,887 of issuance costs incurred in the period ended June 30, 2025.

The Standby Equity Purchase Agreement ("SEPA") provide two mechanisms for submission by the Company and acceptance by the investor of Put Notices under the SEPA pursuant to which the investor and the Company may agree to and execute s single purchase and sale of Put Shares ("Standard Put Shares") or multiple purchases and sales of Put Shares on the same trading day ("Intraday Put Shares").

Standard Put Shares

For a Standard Put, the Company submits a put order to Square Gate on Day 0. After Square Gate accepts the Standard Put on Day 0, the Company issues the shares on Day 1. The amount that Square Gate will pay for the shares is determined in a pricing period that occurs from Day 1 – 3 trading days. The price to be paid by Square Gate is determined using the minimum volume-weighted trading price in one of the three trading days after the put order is accepted, less fixed discount. Under the terms of the SEPA, Square Gate is required to transfer proceeds to the Company for the Put Shares by Day 5. The Company accounts a Standard Put as a financial instrument with a gain or loss recognized in earnings upon settlement. The discount and cost of issuance for each put will be recognized in earnings upon settlement.

Intraday Put Shares

On August 14, 2025, the Company and the investor entered into a First Amendment to the SEPA (the "First Amendment") to provide a mechanism for submission by the Company and acceptance by Square Gate of Put Notices under the SEPA pursuant to which Square Gate and the Company may agree to and execute multiple purchases and sales of Put Shares on the same trading day ("Intraday Put Shares"). The Intraday Put Shares have a pricing period that is based on trading volume and a price that is lowest traded price during the pricing period. When there is a lag between the issuance of the shares and the pricing of the shares, the Company accounts for an Intraday Put as a financial instrument with a gain or loss recognized in earnings upon the settlement. The discount and cost of issuance for each put will be recognized in earnings upon settlement.

Put Shares Accepted by Square Gate

In the three and nine months ended September 30, 2025, the Company issued 475,000 shares of Common Stock through issuance of shares under the SEPA which resulted in net proceeds of $2.2 million, $2.0 million of which settled as of September 30, 2025. Loss on the sale of put shares was $182,146 and was presented in Loss on sale of put shares in the accompanying condensed interim statements of operations for the three and nine months ended September 30, 2025.

8. 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.

The Company measures its investment in shares of Wugen common stock and related contingent liability at fair value based on a combination of valuation techniques, consisting of the adjusted enterprise valuation method and the backsolve method, which are considered Level 3 inputs. No transfers between levels occurred during the periods presented.

The following table presents the Company's assets and liabilities which were measured at fair value at December 31, 2024 and September 30, 2025:

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 3,748,325	$ —	$ —	$ 3,748,325
Total	$ 3,748,325	$ —	$ —	$ 3,748,325

	September 30, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 959,578	$ —	$ —	$ 959,578
Investment	—	—	1,326,329	1,326,329
Liabilities:				
Contingent Liability	—	—	(692,531)	(692,531)
Total	$ 959,578	$ —	$ 633,798	$ 1,593,376

The Company holds a minority equity interest in Wugen as a result of an in-kind payment for a nonrefundable, upfront licensing fee paid in shares of Wugen common stock. Wugen is a private company, and there is limited marketability for the shares of common stock. The Wugen shares are subject to industry-standard restrictions for investments in venture-backed companies, such as restrictions on transferability in private sales and agreement to a lock-up period in the event of an initial public offering. Rights of common stockholders are subordinate to preferred stockholders, who control the Board of Directors. In the second quarter of 2025, the Company restructured or converted $7.7 million of debt, and part of the terms of restructuring or conversion included rights to receive a portion of the proceeds of the sale or liquidation of the Company's shares of Wugen common stock, if such an event occurs. The Company elected to account for the Wugen investment and related contingent liability at fair value beginning in the second quarter of 2025. As a result, the Company will remeasure the change in fair value of the Wugen shares and related contingent liability in each reporting periods and recognize the change in earnings.

Based on available market information and valuation techniques, the fair value of the Wugen investment declined from $3.3 million as of June 30, 2025 to $1.3 million as of September 30, 2025. Similarly, the fair value of the related contingent liability for the rights to proceeds from the sale or liquidation of Wugen shares declined from $1.7 million as of June 30, 2025 to $692,531 as of September 30, 2025. The Company recognized an unrealized loss of $966,284 in the three months ended September 30, 2025 and an unrealized net gain of $782,404 in the nine months ended September 30, 2025 presented within Change in fair value of investment and contingent liability, net in the accompanying condensed interim statements of operations.

9. Income Taxes

For the three and nine months ended September 30, 2025, 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, 2024 and September 30, 2025. The Company will continue to maintain a 100% valuation allowance on total deferred tax assets. The Company believes it is more likely than not that the related deferred tax assets will not be realized. As a result, the Company's effective tax rate will remain at 0.00% because no items either estimated or discrete items would impact the tax provision.

On July 4, 2025 the One Big Beautiful Bill Act was enacted into law in the United States. This legislation includes various tax provisions that may affect U.S. corporate taxpayers, including changes to the deductibility of interest expense, the treatment of research and development costs, and depreciation of certain property, among other items. The adoption of this standard did not have a significant impact on the Company's financial statements nor is it expected to have a material impact on future periods.

10. Segment Reporting

HCW Biologics, Inc. has one reportable segment: life science. The life science segment consists of operations focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation and diseases. The Company's CODM is the Chief Executive Officer.

The accounting policies of the life science segment are the same as those described in the summary of significant accounting policies. The CODM assesses performance for the life science segment based on net loss, which is reported on the statement of operations as net loss. The measure of segment assets is reported on the balance sheet as total assets.

The Company has not generated any product revenue from commercial product sales of internally-developed immunotherapeutic products for the treatment of diseases, as no products have been approved for commercial sale as of September 30, 2025. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances molecules through all stages of development and clinical trials and, ultimately, seek approval for commercial sale.

As such, the CODM uses cash forecast models in deciding how to invest into the life science segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance in conjunction with monitoring the results of research and development activities, including experiments for preclinical compounds and clinical trial data for clinical-stage compounds. The assessment of results of preclinical and clinical studies are critical to the allocation of resources by the CODM.

There were no material changes to the measures for segment revenue, profit or loss, and other metrics since June 30, 2025. The tables below summarize the significant expense categories regularly reviewed by the CODM for the three and nine months ended September 30, 2024 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2025	2024	2025
Revenues:				
Revenues	$ 426,423	$ 15,606	$ 2,171,988	$ 27,222
Cost of revenues	(341,138)	(12,485)	(1,291,546)	(21,777)
Net revenues	85,285	3,121	880,442	5,445
Operating expenses:				
Research and development expenses				
Salaries, benefits and related expenses	652,867	801,504	2,189,250	2,281,050
Manufacturing and materials	47,748	50,259	1,375,830	347,042
Preclinical expenses	144,746	315,725	688,310	639,785
Clinical trials	164,139	80,358	495,910	379,113
Overhead allocations	177,413	156,401	590,083	462,792
Total research and development expenses	1,186,913	1,404,247	5,339,383	4,109,782
General and administrative				
Salaries, benefits and related expenses	619,070	699,989	1,855,660	2,254,015
Professional services[(a)]	376,910	552,371	960,680	1,503,381
Facilities and office expenses	134,580	125,521	542,890	331,588
Depreciation expenses	69,370	58,451	203,050	178,849
Rent and occupancy expenses	49,160	39,633	155,860	151,911
Insurance	280,570	254,617	646,510	815,484
Taxes	59,890	39,607	156,090	133,775
Other expenses	43,907	99,303	267,818	427,484
Total general and administrative expenses	1,633,457	1,869,492	4,788,558	5,796,487
Other segment items[(b)]	1,167,203	1,283,718	17,403,042	(1,221,883)
Total operating expenses	3,987,573	4,557,457	27,530,983	8,684,386
Net segment loss	**$ (3,902,288)**	**$ (4,554,336)**	**$ (26,650,541)**	**$ (8,678,941)**

(a) Professional services consist primarily of audit and accounting advisory services, tax advisory services, corporate legal services and other services related to SEC compliance, and legal fees related to patent filings.

(b) Other segment items include the following unusual or nonrecurring item that comprise other segment items for the three and nine months ended September 30, 2024 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2025	2024	2025
Arbitration legal fees (recoveries), net	$ 949,455	$ 6,006	$ 15,761,531	$ (1,590,945)
Accretion of fixed bonus upon maturity of Secured Notes	—	15,502	—	390,809
Interest expense	229,058	127,070	393,908	632,923
Change in fair value of investment and contingent liability, net	—	966,284	—	(782,404)
Nonoperating loss	—	—	1,300,000	—
Loss on sale of put shares	—	182,146	—	182,146
Other income, net	(11,310)	(13,290)	(52,397)	(54,412)
Other segment items	**$ 1,167,203**	**$ 1,283,718**	**$ 17,403,042**	**$ (1,221,883)**

11. Commitments and Contingencies

Operating Leases

The Company has operating leases for approximately 12,250 square feet of space located in Miramar, Florida. On February 29, 2024, the lease on the Company's current location reached the end of its term and the Company entered a new one-year lease for the same location which commenced on March 1, 2024 and terminated on February 28, 2025. On January 27, 2025, the Company entered a new one-year lease for the same location which commenced on March 1, 2025 and terminates on February 28, 2026. As a lease of 12 months or less in duration and qualifies for a short-term lease exemption under ASC 842-20-25-2, the Company elected to account for this lease on a straight-line basis over the lease term and will not recognize a ROU asset and a lease liability as a result. The Company has no obligations under financing leases.

For the three months ended September 30, 2024 and 2025, rent expense recognized by the Company was $49,524 and $52,619 respectively, of which $25,936 and $27,557, respectively, are included in research and development in the accompanying condensed interim statements of operations. For the nine months ended September 30, 2024 and 2025, rent expense recognized by the Company was $146,431 and $155,794 respectively, of which $75,325 and $81,590, respectively are included in research and development in the accompanying unaudited condensed interim statements of operations.

Contractual Commitments

The Company has commitments with R&D outsourcing and development companies to supply us with clinical grade materials or other development services. As of September 30, 2025, it is under contract for future obligations of $245,900 it expects to pay during the year ending December 31, 2025.

Company Victim to Fraudulent Criminal Scheme

As reported in the Company's Form 8-K filed on May 1, 2024 with the SEC, the Company became aware that it was the victim of a criminal scheme involving the impersonation of a purchaser upon the default (the "Default") on a legally binding commitment to purchase $8.0 million of secured notes from the Company. The scheme resulted in the misdirection of approximately $1.3 million held in Company accounts to a fraudulent account controlled by a third party. The Company recognized a $1.3 million loss reported as a Nonoperating loss in the accompanying condensed interim statements of operations. The Company has pursued all available remedies to recover this loss, including reporting it to law enforcement.

Legal

Legal Proceedings

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

On December 23, 2022, ImmunityBio initiated an arbitration against Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, in California alleging breach of contract and fiduciary duty, among other claims. On that same date, ImmunityBio filed a lawsuit against the Company in federal court alleging misappropriation of trade secrets, inducement of breach of contract and breach of fiduciary duty, among other claims against the Company. On April 26, 2023, the parties stipulated that ImmunityBio's action against the Company would be consolidated with the ImmunityBio Arbitration demand against Dr. Wong. On April 27, 2023, the Court approved the parties' stipulation and ordered the parties to Arbitration. On May 1, 2023, ImmunityBio filed a demand against the Company before JAMS. On May 3, 2023, ImmunityBio dismissed the federal court action without prejudice and the Court ordered the case dismissed without prejudice and closed the case. ImmunityBio's proceeding against the Company proceeded in Arbitration before JAMS and consolidated with the Arbitration ImmunityBio initiated against Dr. Wong (the "Arbitration"). On March 26, 2024, ImmunityBio filed a complaint (the "Complaint") against the Company in the Chancery Court of the State of Delaware for the contribution of legal fees and expenses advanced to Dr. Wong.

As reported in the Company's Form 8-K filed on July 18, 2024 and described in Part II, Item 1. – "Legal Proceedings," as of July 13, 2024, the Company and Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, entered into a confidential Settlement Agreement with Altor BioScience, LLC ("Altor"), NantCell, Inc. ("NantCell"), and ImmunityBio, Inc. (the parent of Altor and NantCell, together with Altor and NantCell, "ImmunityBio"), to resolve the previously disclosed Arbitration before JAMS brought by Altor and NantCell as well as the Complaint Altor filed against the Company in the Chancery Court of the State of Delaware for the contribution of legal fees and expenses advanced to Dr. Wong. The Settlement Agreement includes mutual general releases by and among the parties thereto. No party is required to make any monetary payments to any other party or person under the Settlement Agreement and each party will bear its own expenses incurred in connection with the matter. The Arbitration and related Complaint were dismissed with prejudice on or about December 24, 2024.

Other Matters

As the Company reported in a Form 8-K, on April 17, 2025, the Company received a summons and a copy of a complaint filed by BE&K in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "BE&K Complaint"). Other Defendants named in the BE&K Complaint who are subcontractors elected to filed counterclaims and cross-claims in response to the BE&K Complaint. Cogent Bank, also named as a Defendant in the BE&K Complaint, has not elected to take legal action at this time. In addition, on April 28, 2025, the Company received a summons and a copy of a complaint filed by Fisk Electric Company (which is a defendant in the BE&K Complaint) in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "Fisk Complaint") against the Company, BE&K, and the other defendants in the BE&K Litigation. On August 8, 2025, B&I Contractors, Inc., one of the defendants in the BE&K Complaint, filed a motion for summary judgment (the "MSJ") as to the Count I (Foreclosure of Construction Lien). The Company has responded to the BE&K and Fisk Complaints and cross-claims as well as the B&I MSJ. The parties are engaged in discovery and the court has set the case for trial in early December 2026.

On October 24, 2025, the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure the mechanics liens no later than thirty (30) days after receipt of this letter in strict compliance with Section 7.2(3) of the Loan Agreement by: (i) paying and discharging all of the Claims of Lien and causing satisfactions to be recorded in the Public Records of Broward County, Florida for all of the Claims of Lien, and (ii) resolving all litigation against the Borrower and the mortgaged property described in the Mortgage and causing such claims in the Foreclosure Actions to be dismissed and all related notices of lis pendens to be released. The Company and Cogent Bank are in negotiations to come to terms for a forbearance agreement to provide additional time for the Company to comply with the demands it made in the demand letter.

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

The Company's operations have been affected by many headwinds, including inflationary pressures, including those brought about by tariffs and other economic policies, high interest rates, ongoing global supply chain disruptions resulting from increased geopolitical tensions such as the war in the Middle East, the conflict between Russia and Ukraine, China-Taiwan relations as well as U.S. trade policies, 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, we have been impacted by inflation when procuring materials required for the buildout of our new manufacturing and laboratory facilities, 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. The Company has used equity financing as a key element of its financing strategy, which relies on registration statements that must be declared effective by the SEC. On October 1, 2025 at 12:01 a.m. EDT, the federal government of the United States began a shutdown as a result of the failure by the U.S. Senate to pass appropriations legislation for the 2026 fiscal year, which began that day. During the shutdown, the SEC has only limited operations. As a result of the shutdown, the Company will have limited access to public markets through public offerings of our stock, which could negatively impact the Company's operations and ability to carry on clinical development programs. However, the extent and duration of such events and conditions, and resulting disruptions to our operations, are highly unpredictable.

12. Subsequent Events

Subsequent events have been evaluated through the date the financial statements were filed. In addition to the required recognition or disclosure disclosed in the footnotes herein, there were also the following subsequent events after the reporting date:

After the reporting date of September 30, 2025, the Company issued an additional 80,000 shares of Common Stock under the Standby Equity Purchase Agreement for net proceeds of $281,531.

As of September 30, 2025, the Company was deficient in meeting the requirements of Listing Rule 5550(b)(1), or the Equity Rule, related to the minimum requirements to maintain a $2.5 million balance in stockholders' equity. The Company was recently granted an extension to regain compliance with the Equity Rule until December 31, 2025.

On October 13, 2025, the Panel granted the Company an extension in which to regain compliance with all continued listing rules of the Exchange. The Panel's determination follows the Company's hearing on September 25, 2025, at which the Company presented, and the Panel considered, the Company's plan to regain compliance with the Equity Rule. The Panel granted the Company's request for continued listing on the Exchange, subject to, among other things, the Company demonstrating compliance with the Equity Rule by December 31, 2025, and with all other Exchange continued listing rules by February 16, 2026.

On October 13, 2025, the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida has set the BE&K Complaint for a five-day jury trial during the December 1-18, 2026 jury trial week. There will be a pretrial conference on November 20, 2026.

On October 24, 2025, the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure the mechanics liens no later than thirty (30) days after receipt of this letter in strict compliance with Section 7.2(3) of the Loan Agreement by: (i) paying and discharging all of the Claims of Lien and causing satisfactions to be recorded in the Public Records of Broward County, Florida for all of the Claims of Lien, and (ii) resolving all litigation against the Borrower and the mortgaged property described in the Mortgage and causing such claims in the Foreclosure Actions to be dismissed and all related notices of lis pendens to be released. The Company and Cogent Bank are in negotiations to come to terms for a forbearance agreement to provide additional time for the Company to comply with the demands it made in the demand letter.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (i) our unaudited condensed interim financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and (ii) our audited financial statements and related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" for the fiscal year ended December 31, 2024 included in the Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 28, 2025 (the "Annual Report"). Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to the "Company," "HCW Biologics," "HCWB", "we," "us" and "our" refer to HCW Biologics Inc.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this quarterly report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success of our clinical trials, plans and objectives of management for future operations, adequacy of our cash resources and working capital, future economic conditions or performance, 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. ("HCWB" or the "Company") is a clinical-stage biopharmaceutical company developing proprietary immunotherapies to treat diseases promoted by chronic inflammation, especially age-related and senescence-associated diseases. Our immunotherapeutics represent a new class of drug that we believe has the potential to fundamentally change the treatment of cancer and many other diseases and conditions that are promoted by chronic inflammation — and in doing so, improve patients' quality of life and possibly extend longevity. While chronic inflammation is possible at any age, it is more common as we age. In this case, the condition is known as inflammaging. 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 immune cells.

Chronic inflammation, including inflammaging, is believed to be a significant contributing factor to the cause for senescence-associated diseases and conditions that diminish health span, including many types of cancer, autoimmune diseases, and neurodegenerative diseases, as well as indications that impact quality-of-life that are not life-threatening. 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 Senescence-Associated Phenotype ("SASP") proinflammatory factors has been implicated as a major source of chronic sterile inflammation leading to many aging-related pathologies. SASP factors, including proinflammatory cytokines, chemokines, and proteinases, drive an inflammation cycle. Senescence is considered a stress response and can be induced by a wide range of intrinsic and extrinsic insults. Over time, these insults cause normal tissue cells to enter a senescent state of irreversible growth arrest accompanied by the release of SASP factors. The inflammation cycle promoted by SASP factors also activates immune cells. Similar to senescent cells, prolonged activation of immune cells promotes the release of highly proinflammatory cytokines. Unresolved activation of immune cells leads to chronic low-grade inflammation, which perpetuates this cycle.

Studies have shown that strategies to reduce or eliminate senescent cells can delay, prevent, and improve age-related dysfunctions, including cancer. Unfortunately, to date, there has been limited clinical success in targeting senescent cell accumulation or aberrant inflammasome activity using small molecule-based approaches. Preclinical research and preliminary results from first-in-human clinical trials indicate that our immunotherapeutic approach may achieve success for cancer indications, and many other age-related diseases and conditions. We believe our lead product candidates represent a novel immunotherapeutic approach and a clinically promising new class of senotherapeutic drugs for the treatment of age-related diseases.

The Company has developed two different drug discovery and development platforms, our legacy TOBI™ (Tissue factOr-Based fusIon) platform and our newly developed targeted platform technology – the T-cell Receptor β Chain constant region ("TRBC") platform:

- The TOBI platform is designed to engineer multi-functional fusion protein molecules and protein complexes. It employs a Tissue Factor ("TF") scaffold that can be packaged with multiple protein targets, including cytokines, chemokines, ligands, receptors, and single-chain antibodies.
- The Company invented its second-generation platform, the TRBC platform, to create novel immunotherapeutics designed to treat diseases, including cancer, as well as improve quality-of-life conditions. The immunotherapeutics created using the TRBC platform include multi-specific cytokines, targeted second-generation immune checkpoint inhibitors, and immune-cell engagers, which have the capabilities to activate subsets of immune cells that specifically target cancerous cells, infected cells, or senescent cells associated with age-related diseases.

As of July 13, 2024, the Company, Dr. Wong, Altor BioScience, LLC, NantCell, Inc. and ImmunityBio, Inc. (collectively, Altor BioScience, LLC, NantCell, Inc. and ImmunityBio Inc. will be referred to herein as "ImmunityBio"), entered into a Settlement Agreement that is described in Part II, Item 1. – "Legal Proceedings" below. The Settlement Agreement eliminated the uncertainty of the outcome of the previously disclosed Arbitration proceedings and provided clarity for the future direction and emphasis of our clinical development strategy. The settlement involved intellectual property the Company developed based on our proprietary TOBI® drug discovery platform and its unique Tissue-Factor scaffold used to create protein-fusion molecules.

With clarity on ownership of intellectual property, the Company reassessed its clinical development pipeline and the future direction of our Company. Our expertise is in immunotherapeutic treatments and our clinical development pipeline will remain so. Our focus continues to be to develop protein-based immunotherapies that are administered by subcutaneous injection. We remain focused on diseases promoted by chronic inflammation driven by senescence, including cancer, especially age-related diseases. The diseases we will target will have no curative FDA approved treatments. Finally, we have selected programs that include life-threatening diseases, such as pancreatic and ovarian cancer, as well as "quality-of-life" indications, such as alopecia areata and senile lentigo. HCW9302 will remain one of our lead product candidates. Future drug discovery and new drug development will be based on TRBC Molecules. There are several potential candidates in each class of TRBC Molecules from which the Company will select lead molecules for each program. Part of this selection will be to determine which TRBC molecules will be developed in-house and which are more appropriate to develop through business development transactions, such as out-licensing agreements.

Our clinical development program is based on a few select lead product candidates which will be evaluated in Company-sponsored clinical trials in autoimmune disorders, solid tumors and quality-of-life conditions. We have a large portfolio of non-core programs and assets and, for these, we anticipate that clinical development will be conducted through licensing agreements and other business development transactions.

HCWB has an experienced team led by Dr. Hing C. Wong, our Founder and CEO, who discovered and developed the immunotherapeutic Anktiva® (also known as ALT-803, an IL-15 agonist receptor) through pivotal trials. This blockbuster immunotherapeutic treatment for cancer was sold to ImmunityBio, Inc. in 2017 in a $1.0 billion acquisition. Anktiva® was approved by the U.S. Food and Drug Administration ("FDA") for a bladder cancer indication in 2024.

Business Highlights

Financing

Our financing strategy includes capital raising through the issuance of securities as well as business development transactions, especially out-licensing certain rights outside of our focus areas. The Company continues to evaluate its portfolio to identify compounds which may be good candidates for licensing or other collaborations, where it will be to our advantage to leverage the expertise and financial strength of a partner in the development of a compound or market.

WY Biotech License Agreement

The Company and WY Biotech Co., Ltd. ("WY Biotech") are currently finalizing the terms of an amendment to an exclusive worldwide license agreement ("WY Biotech License") that the parties first entered on November 17, 2024. The subject of the license is the use of in vivo rights to one of the Company's preclinical molecules, HCW11-006. The Company had extended the date for payment of the $7.0 million upfront license fee due under the WY Biotech License while WY Biotech worked to finalize agreements with their contract development and manufacturing organization ("CDMO") and investors. On September 5, 2025, WY Biotech proposed further revisions and additions to the terms of the WY Biotech License. Negotiations between the parties to restructure the terms of the WY Biotech License are ongoing. Pursuant to the terms currently being negotiated, the Company will retain its payment-free, milestone-free, and royalty-free option to recapture the development and commercialization in vivo rights of the licensed molecule for the United States, Canada, Central America, and South America (Opt-in Territory) after the conclusion of the Phase 1 clinical trial. WY Biotech is financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the molecule. The Company will be responsible for costs associated with clinical development, regulatory approval, and commercialization in the Opt-in Territory, if it exercises its opt-in rights.

$2.2 Million Raised through Issuance of Common Stock through Standby Equity Purchase Agreement

The Company has issued, and may issue additional, shares of Common Stock under its Standby Equity Purchase Agreement ("SEPA") as a means of accessing the public market. In the three and nine months ended September 30, 2025, the Company issued 475,000 shares of Common Stock through the SEPA, resulting in net proceeds of $2.2 million, $2.0 million of which settled as of September 30, 2025.

Compliance with Nasdaq Listing Rules

An important part of the Company's future financing plans is the ability to access the public markets for the sale of securities. This requires that the Company remain in compliance with all Nasdaq Listing Rules, and it is currently deficient in meeting the requirements of Listing Rule 5550(b)(1), or the Equity Rule, related to the requirement to maintain a minimum balance of $2.5 million in stockholders' equity. The Company was recently granted an extension to regain compliance with the Equity Rule until December 31, 2025, as discussed in more detail below.

In the first quarter of 2025, after a hearing with a Nasdaq Hearings Panel (the "Panel"), the Panel granted the Company an extension to June 30, 2025 to regain compliance with all Nasdaq Listing Rules. In particular, the Company was deficient in three areas: Listing Rule 5550(a)(2), or requirements for the minimum bid price; Listing Rule 5550(a)(4), or requirements for the public float requirement in and the market value of publicly held shares; and the Equity Rule. On June 26, 2025, the Company announced that it received a formal notice from the Listing Qualifications Staff (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") that the Company was in compliance with the Equity Rule for continued listing on the Nasdaq Capital Market (the "Exchange"). At that time, the Company was also notified that it will remain subject to a "Panel Monitor," as that term is defined in Nasdaq Listing Rule 5815(d)(4)(B), for a period of one year from the date of the Nasdaq notice, through June 23, 2026. While the Company successfully completed several elements of its compliance plan including the Reverse Stock Split, restructuring or converting $7.7 million of debt, putting a Standby Equity Purchase Agreement in place, and completing a $5.0 million equity financing by June 30, 2025, as previously reported, the Company's upfront license fee from WY Biotech did not meet the criteria for revenue recognition for the period ended June 30,2025. As a result, as of June 30, 2025, the Company did not meet the requirements of the Equity Rule.

The Company filed its Form 10-Q for the quarter ended June 30, 2025 on August 18, 2025. On August 19, 2025, the Company received written notice from the Staff that as of June 30, 2025, the Company was non-compliant with the Equity Rule for continued listing on the Exchange. The Company made a timely request for a hearing before the Panel and was granted a hearing. On October 13, 2025, the Panel granted the Company an extension in which to regain compliance with all continued listing rules of the Exchange. The Panel's determination follows the Company's hearing on September 25, 2025, at which the Company presented, and the Panel considered, the Company's plan to regain compliance with the Equity Rule. The Panel granted the Company's request for continued listing on the Exchange, subject to, among other things, the Company demonstrating compliance with the Equity Rule by December 31, 2025, and with all other Exchange continued listing rules by February 16, 2026. The Company was advised that February 16, 2026, represents the full extent of the Panel's discretion to grant continued listing while the Company is non-compliant with the Nasdaq Listing Rules. The Panel also required that the Company provide prompt notification of any significant events that occur during the exception period that may affect the Company's compliance with Nasdaq requirements. In addition, the Company must timely file Form 10-Q for the third quarter, and provide notice of the status of certain elements of the Company's compliance plan. Any compliance documentation submitted by the Company will be subject to review by the Panel, which may, in its discretion, request additional information before determining that the Company has complied with the terms of the exception. The Panel has discretion to review its decision to grant an exception period within 45 calendar days after issuance of the written decision.

Biologics Manufacturing Facility

The Company remains committed to establishing some control over our clinical supply of materials, and the supply of licensed molecules for our licensees, as well as other clinical-stage companies developing biologics. We have retained manufacturing rights for the licensed molecules under our license agreements. With the threat of pharmaceutical tariffs hanging over the biopharmaceutical industry and a push to "re-shore" manufacturing, especially pharmaceuticals, a growing list of major drug makers are bolstering their manufacturing footprints in the U.S.

On January 22, 2025, the Company entered a forbearance agreement with BE&K Building Group ("BE&K") and certain subcontractors filed mechanics liens related to unpaid invoices issued in connection with construction of the Company's new manufacturing facilities and upgraded research laboratories. The forbearance agreement terminated on March 31, 2025, and the Company did not have financing in place to satisfy the liens. On April 17, 2025, the Company received a summons and a copy of a complaint filed by BE&K in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "BE&K Complaint"). In addition, on April 28, 2025, the Company received a summons and a copy of a complaint filed by Fisk Electric Company (which is a defendant in the BE&K Complaint) in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "Fisk Complaint") against the Company, BE&K, and the other defendants in the BE&K Litigation. Subsequent to this filing date, certain other claims and cross claims were filed. See Part II, Item 1. – "Legal Proceedings." On August 8, 2025, B&I Contractors, Inc., one of the defendants in the BE&K Complaint, filed a motion for summary judgment (the "MSJ") as to the Count I (Foreclosure of Construction Lien). The Company has responded to the BE&K and Fisk Complaints and cross-claims as well as the B&I MSJ. The parties are engaged in discovery and the court has set the case for trial in early December 2026.

The Company entered a loan agreement with Cogent Bank ("2022 Loan Agreement") for $6.5 million on August 15, 2022, to provide a portion of the funds required to purchase this facility. The 2022 Loan Agreement contains discretionary acceleration provisions, one of which was triggered as a result of the mechanics liens discussed above. On October 24, 2025, the Company received a demand letter in which Cogent Bank gave notice that the loan was in default and the Company had thirty (30) days after receipt of the demand letter to cure the mechanics liens. The Company and Cogent Bank are negotiating for the terms of a forbearance agreement to provide the Company more time to comply with the demand made by Cogent Bank.

The Company has continued to pursue financing alternatives to provide the funding needed to come current in past amounts due and complete the construction and renovation of the property.

Clinical Development

The following compounds have been identified by the Company as our product candidates for clinical development. The Company has constructed over 50 proprietary compounds, of which only a select few will be developed through internal programs and Company-sponsored clinical trials. Other compounds may be selected by the Company to develop through corporate partners who will advance clinical development and commercialization through business development transactions, such as licensing agreements.

HCW9302

HCW9302 is the lead product candidate for the Company's clinical development program for autoimmune disorders. In the fourth quarter of 2025, the Company expects to dose the first patient in a Company-sponsored, multi-center Phase 1 dose-escalation clinical trial (NCT07049328) to evaluate HCW9302 in patients with alopecia areata, a common autoimmune disease in humans that currently has no curative FDA approved treatments. The Company currently has two clinical sites open, one at The Ohio State University Wexner Medical Center ("The Ohio State University") and one at the Tampa James A. Haley Veterans' Hospital ("Tampa VA Hospital"). Both sites are actively screening patients.

HCW9302 is a fusion protein molecule that contains two IL-2 domains linked by an extracellular tissue factor domain. IL-2 signaling is essential for homeostasis of T_{reg} cells. Unfortunately, recombinant IL-2 has an unfavorable pharmacokinetic profile and induces cytokine release syndrome limiting its therapeutic use. HCW9302 provides a potential solution to this problem. It is designed to have the therapeutic advantages of IL-2 while being well tolerated. In our preclinical and non-human primate studies, we found that HCW9302 exhibited a longer serum half-life with an approximately 1,000-fold higher affinity for the IL2Rα than IL-2. In addition, preclinical studies have shown HCW9302 can be administered at a dosing range that expanded and activated T_{reg} cells but not $CD4^+$ effector T cells. $CD4^+$ effector T cells (also known as helper T cells) are crucial for immune responses, but under certain conditions, their excessive activation can lead to negative effects like inflammation, tissue damage, and autoimmune reactions, particularly when they become dysregulated and target self-antigens, contributing to conditions like multiple sclerosis, rheumatoid arthritis, and inflammatory bowel disease.

Second-Generation Multi-Specific T-Cell Engagers

The Company has developed second-generation, multi-specific T-cell engagers against solid tumors, particularly for pancreatic cancer, using its novel proprietary TRBC product discovery and development platform technology. The Company has selected its T-Cell Engager program as a candidate for clinical development through a business development transaction with a large pharmaceutical company.

T-cell engagers revolutionized the immunotherapeutic approach against cancer. Currently, T-cell engagers have approval from the FDA to be used in the treatment of a small number of indications, including various hematological and solid tumors. The Company believes that it has created potentially highly effective T-cell engagers against difficult-to-treat solid tumors by using exceptional targets while managing immunosuppression.

The TRBC technology enabled the Company to construct T-cell engagers that not only target cancer antigens and CD3 activation of effector T cells, but also simultaneously reduce immunosuppression in the tumor microenvironment. Such immunosuppression plays a pivotal role in reducing effector T-cell infiltration and anti-tumor efficacy in solid tumors. The Company's two lead T-cell engagers target tissue factor and mesothelin, which are proven solid tumor antigens. These product candidates exhibit potent and antigen-specific anti-pancreatic cancer activities both in vitro and in humanized mouse models at dose levels that are well tolerated.

On November 7, 2025, the Company presented a poster at the 40th annual meeting of the Society for Immunotherapy of Cancer ("SITC") entitled, "A novel multi-functional bispecific T-cell engager molecule for cancer therapy." Highlights of the data presented include the unique features of the Company's T-cell engager:

- Broad coverage for human solid tumor indications by targeting tissue factor, with high potency and precision, shown in xenograft models including Patient-Derived Xenograft (PDX) tumor.
- Tetra-valent construct to address immunosuppressive tumor microenvironment.
- Activates tumor-infiltrated exhausted T cells.
- Favorable tolerability profile in non-human primates at dosing levels significantly higher than the efficacious level.
- Long serum half-life and favorable pharmacokinetics shown in non-human primate studies, without using the Fc fusion technology commonly found in bi-specific or tri-specific fusion molecules.
- Streamlined GMP manufacturing process similar to the process used for therapeutic monoclonal antibody.
- Subcutaneous administration to improve safety and quality-of-life for patients.

Second-Generation Immune Checkpoint Inhibitors

The Company has developed second-generation, pembrolizumab-based immunotherapeutics against solid tumors, particularly for pancreatic and ovarian cancer, using its novel proprietary TRBC product discovery and development platform technology. Pembrolizumab, known as KEYTRUDA® (a registered trademark of Merck Sharp & Dohme LLC), is the leading FDA-approved immune checkpoint inhibitor ("ICI").

Since their introduction to the treatment of cancer in 2011, immune checkpoint inhibitors ("ICIs") have been hailed as a breakthrough cancer therapy. Immune checkpoint proteins are expressed on the surface of T cells as the acting regulators for inhibiting the over-activation of T cells. By using ICIs, the immune response of T cells can be largely activated to re-establish the immune effects of anti-tumor exhausted T cells. However, there is vast evidence in preclinical and clinical studies suggesting that the lack of immune-cell costimulatory activities on ICIs diminishes their anti-tumor efficacy.

The Company's pembrolizumab-based fusion molecules have been selected as leading clinical product candidates because they exhibit potent anti-pancreatic cancer activities and outperform pembrolizumab as monotherapy for cancer both *in vitro* and in humanized mouse models at dose levels that are well tolerated. This novel fusion immunotherapeutic blocks the checkpoint receptors and engages the costimulatory receptors, analogous to taking the foot off the brake and simultaneously hitting the gas, thus, representing a breakthrough second-generation ICI which revives anti-tumor function of T cells.

On November 8, 2025, the Company presented a poster at SITC entitled, "A novel tetra-specific pembrolizumab-based immunotherapeutic." The Company's lead product candidate is HCW11-040, a second-generation immune checkpoint inhibitor that is a unique combination of cytokines in a multi-functional fusion protein molecule, constructed with a unique combination IL-15 and IL-7 domains and a Transforming Growth Factor β ("TGF-β") trap. It demonstrates PD-1/PD-L1 blocking activity equivalent to pembrolizumab (generic form of Keytruda®) in preclinical studies. Results of these preclinical studies also highlight the advantages of HCW11-040 over the first generation immune checkpoint inhibitors:

- To improve efficacy, HCW11-040 is equipped with other moieties in addition to pembrolizumab which neutralizes the immunosuppressive cytokine, TGF-β, and activates effector immune cell responses.
- The mouse homologue of HCW11-040 expands progenitor exhausted T (TPEX) cells significantly better than mouse ICI or pembrolizumab alone. TPEX cells are a key subset of T cells that respond to ICIs. TPEX cells have self-renewal capabilities and are considered a primary driver for the success of ICI therapies, making them a target for improving treatment outcomes.
- HCW11-040 expands and activates human peripheral blood lymphocytes ("PBMCs") significantly better than pembrolizumab alone.
- HCW11-040 exhibits significantly better anti-tumor activity of human PBMCs than pembrolizumab alone against human pancreatic cancer and leukemia cells in organoid models.
- No evidence of inducing cytokine release syndrome.
- Subcutaneous administration expected to improve safety and quality-of-life for patients.
- Streamlined GMP manufacturing process is similar to the process used for therapeutic monoclonal antibodies.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc. and the company is not affiliated with HCW Biologics Inc.

HCW9206

We have an opportunity to enter into a new license agreement based on using HCW9206 as a reagent in the manufacture of CAR-T products. On May 29, 2025, the Company agreed to a request from Wugen Inc. ("Wugen") to suspend the Wugen License. The suspension will run for a period of one year from the effective date of suspension and will end on May 29, 2026. During the suspension, the Company has the exclusive right to seek alternate licensees and terminate the license in order to enter other business development transactions related to the *ex vivo* use of the licensed molecules.

In research conducted with two leading research institutions, studies have shown that HCW9206 has the potential to provide a solution for key challenges facing chimeric antigen receptor T-cell ("CAR-T") therapies. While CAR-T therapy is a revolutionary technology that continues to play a pivotal role in treatment of cancer, autoimmune diseases, and age-related diseases, it faces significant challenges. In the results of the studies shared by the Company, we demonstrated that HCW9206 has the potential to significantly reduce costs and improve clinical efficacy of engineered effector T cells.

At the 2025 Annual Meeting of the American Association of Immunologists, our collaborator gave a poster presentation demonstrating that HCW9206 is not only a better reagent than the current anti-CD3/anti-CD28/IL-2 method for CAR-T viral transduction, but it also effectively expanded stem cell-like memory T cells (T_{scm}) carrying the CAR constructs. It is well known that the T_{scm} subset of T cells exhibits better targeted cell killing and persistence than other subsets of T cells, including memory T cells, following adoptive transfer into patients. In experimental humanized models in mice, adoptively transferred HCW9206-generated HIV- and CD19-specific CAR-Ts displayed more potency in the suppression of HIV-1 and leukemic cells with enhanced persistence, respectively, when compared with the same CAR-Ts generated with the standard methods. The results of these studies represent a novel alternative strategy for CAR-T cell production with the advantage of generating a large population of CAR-Ts with a T_{scm} cell phenotype, which should enhance the persistence of CAR-Ts in patients. This strategy will likely improve long-term survival of disease-specific CAR-Ts following adoptive transfer and enable sustained suppression of malignancies, chronic infections and autoimmune diseases.

The GMP master cell bank of HCW9206 and its manufacturing process have been established, and its drug master file as an *ex vivo* reagent has been filed with the FDA. The Company has commenced a search to identify a strong commercial partner for the sale and/or integration of HCW9206 as a reagent for incorporation into CAR-T based manufacturing processes.

HCW11-006

HCW11-006 is one of the molecules constructed using the Company's novel TRBC platform. HCW11-006 is part of the group of compounds the Company classifies as Class I, Multi-Functional Immune Cell Stimulators. The Company continues to hold worldwide exclusive *ex vivo* rights to HCW11-006. WY Biotech has licensed HCW11-006 for *in vivo* applications. Our preclinical studies demonstrated that this multi-functional product candidate is highly effective at inducing anti-tumor $CD8^+$ T cell and NK cell responses without triggering unwanted side effects in relevant solid tumor animal models. It appears to be a potent immunostimulatory agent and should combine well with other therapies, including immune checkpoint inhibitors, immune cell engagers, therapeutic antibodies, and CAR-T therapies. In *ex vivo* applications, the Company has studied the benefit of using HCW11-006 as a reagent useful in the manufacture of CAR-T therapies. In these studies, the Company has seen that HCW11-006 has the potential to significantly reduce costs and improve clinical efficacy of engineered effector T cells.

On November 8, 2025, the Company presented a poster at SITC entitled, "Enhancing immune cell expansion, checkpoint inhibitor synergy, and in vivo CAR-T and lymphocyte support using HCW11-006 -- a novel cytokine fusion molecule."

Trends and Uncertainties

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

The Company's operations have been affected by many headwinds, including inflationary pressures, including those brought about by tariffs and other economic policies, high interest rates, ongoing global supply chain disruptions resulting from increased geopolitical tensions such as the war in the Middle East, the conflict between Russia and Ukraine, China-Taiwan relations as well as U.S. trade policies, 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, we have been impacted by inflation when procuring materials required for the buildout of our new manufacturing and laboratory facilities, 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. The Company has used equity financing as a key element of its financing strategy, which relies on registration statements that must be declared effective by the SEC. On October 1, 2025 at 12:01 a.m. EDT, the federal government of the United States began a shutdown as a result of the failure by the U.S. Senate to pass appropriations legislation for the 2026 fiscal year, which began that day. During the shutdown, the SEC has only limited operations. As a result of the shutdown, the Company will have limited access to public markets through public offerings of our stock, which could negatively impact the Company's operations and ability to carry on clinical development programs. 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 Item 1A. “Risk Factors” in our Annual Report.

Components of our Results of Operation

Revenues

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

We derive revenue from license agreements. The Company entered the Wugen License in December 2020. In the second quarter of 2025, the Company agreed to a request from Wugen to suspend the Wugen License for a period of one-year. During this time, the Company may seek other business development transactions and may choose to terminate the Wugen License.

Since inception, the Company has recognized $16.2 million of revenues derived from the Wugen License, including upfront license fees in cash and shares of Wugen common stock, payments for vials of materials, and for manufacturing of development supplies for clinical trials. Consideration under our contract included a nonrefundable upfront payment, development, regulatory and commercial milestones, and royalties based on net sales of approved products. Additionally, HCW Biologics retained manufacturing rights and has agreed to provide Wugen with clinical and research grade materials for clinical development and commercialization of licensed products under separate agreements. We assessed which activities in the Wugen License should be considered distinct performance obligations that should be accounted for separately. We develop assumptions that require judgement to determine whether the license to our intellectual property is distinct from the research and development services or participation in activities under the Wugen License.

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

The Company and WY Biotech Co., Ltd. (“WY Biotech”) are currently finalizing the terms of an amendment to an exclusive worldwide license agreement (“WY Biotech License”) that the parties first entered on November 17, 2024. The subject of the license is the use of in vivo rights to one of the Company’s preclinical molecules, HCW11-006. The Company had extended the date for payment of the $7.0 million upfront license fee due under the WY Biotech License while WY Biotech worked to finalize agreements with their contract development and manufacturing organization (“CDMO”) and investors. On September 5, 2025, WY Biotech proposed further revisions and additions to the terms of the WY Biotech License. Negotiations between the parties to restructure the terms of the WY Biotech License are ongoing. Pursuant to the terms currently being negotiated, the Company will retain its payment-free, milestone-free, and royalty-free option to recapture the development and commercialization in vivo rights of the licensed molecule for the United States, Canada, Central America, and South America (Opt-in Territory) after the conclusion of the Phase 1 clinical trial. WY Biotech is financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the molecule. The Company will be responsible for costs associated with clinical development, regulatory approval, and commercialization in the Opt-in Territory, if it exercises its opt-in rights.

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 in connection with CMOs, which produce cGMP materials for clinical trials on our behalf;
- Expenses associated with preclinical activities, including research and development and other IND-enabling activities;
- Expenses incurred in connection with clinical trials; and
- Other expenses, such as facilities-related expenses, direct depreciation costs for capitalized scientific equipment, and allocation for overhead.

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

We expect research and development expenses to increase substantially for the foreseeable future as we continue the development of our product candidates. We cannot reasonably determine the nature, timing, and costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. Product candidates in later stages of development generally have higher development costs than those in earlier stages. See "Risk Factors -- Risks Related to the Development and Clinical Testing of Our Product Candidates," in our Annual Report for 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 fees in the ordinary course of business, accounting advisors, auditing and tax services, facilities administrative costs, expenses related to maintaining our listing on Nasdaq and remaining in compliance with SEC filings, and other expenses.

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

Legal Expenses (Recoveries), Net

Legal expenses (recoveries), net include legal fees incurred by the Company for its own defense and for the defense of Dr. Hing C. Wong, our Founder and Chief Executive Officer, net of insurance reimbursements in connection with the Arbitration brought by ImmunityBio and its affiliates against the Company and Dr. Wong. The Arbitration and related Complaint were dismissed with prejudice as of December 31, 2024. See Part II, Item 1, "Legal Proceedings."

Nonoperating Loss

As reported in the Company's Form 8-K filed on May 1, 2024 with the SEC, the Company became aware that it was the victim of a criminal scheme involving the impersonation of a purchaser upon the default on a legally binding commitment to purchase $8.0 million of secured notes from the Company. The scheme resulted in the misdirection of approximately $1.3 million held in Company accounts to a fraudulent account controlled by a third party. The Company is pursuing all available remedies to recover this loss. Given the limited success that these efforts have had to date for the recovery of funds, the Company recognized a loss of $1.3 million in the nine-month period ended September 30, 2024.

Interest Expense

Interest expense includes interest paid on debt. This includes interest due on the Cogent Bank loan, Secured Notes issued by the Company and accretion of original issue discount and accretion of debt issuance costs.

On August 15, 2022, we entered into a loan and security agreement with Cogent Bank to partially fund our purchase of the property we acquired on that same date (the "2022 Loan"). We borrowed $6.5 million under this agreement. Amounts outstanding on the term loan accrue interest at a rate per annum equal to 5.75%. We were obligated to make interest-only payments on this loan from September 2022 through August 2023 and principal and interest payments in 48 equal monthly installments, based on a 25-year maturity schedule, commencing September 15, 2023.

From March 31, 2024 to October 30, 2024, the Company issued $6.9 million in Secured Notes in multiple closings. During the second quarter of 2025, certain noteholders agreed to restructure amounts owed by the Company and convert to equity. Noteholders who purchased notes for $325,000 did not elect to convert their Secured Notes. The Secured Notes bear interest at an annual rate of 9%, payable quarterly in arrears. These noteholders are also entitled to a fixed bonus, payable on the Maturity Date, which is accreted on a straight line basis.

On May 8, 2025, the Company issued a $150,000 promissory note with a personal guarantee from the Company's Founder and Chief Executive Officer, which has an original issue discount of $75,000 which is accreted on a straight-line basis from the date of issuance to the Maturity Date of February 7, 2026 (the "Secured Promissory Note").

Change in Fair Value of Investment and Contingent Liability, net

The Company accounts for our investment in Wugen shares at fair value beginning in the second quarter of 2025. Similarly, the Company's contingent liability is recorded at fair value. A change in fair value of investment and contingent liability, net is recognized through earnings. Prior to that time, the Company accounted for the Wugen shares using the fair value measurement alternative. Therefore, the value of the investment in Wugen, and similarly the contingent liability, is recognized at fair value each reporting period based on available market information and valuation techniques.

Gain (Loss) on Sale of Put Shares

The Company recognizes an unrealized or realized gain or loss on put shares when we sell shares of Common Stock under the SEPA, which is recognized through earnings.

Other Income, Net

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, and other income and expenses related to non-operating activities.

Results of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2025	2024	2025
Revenues:				
Revenues	$ 426,423	$ 15,606	$ 2,171,988	$ 27,222
Cost of revenues	(341,138)	(12,485)	(1,291,546)	(21,777)
Net revenues	85,285	3,121	880,442	5,445
Operating expenses:				
Research and development	1,186,913	1,404,247	5,339,383	4,109,782
General and administrative	1,633,457	1,884,994	4,788,558	6,187,296
Legal expenses (recoveries), net	949,455	6,006	15,761,531	(1,590,945)
Nonoperating loss	—	—	1,300,000	—
Total operating expenses	3,769,825	3,295,247	27,189,472	8,706,133
Loss from operations	(3,684,540)	(3,292,126)	(26,309,030)	(8,700,688)
Interest expense	(229,058)	(127,070)	(393,908)	(632,923)
Change in fair value of investment and contingent liability, net	—	(966,284)	—	782,404
Loss on sale of put shares	—	(182,146)	—	(182,146)
Other income, net	11,310	13,290	52,397	54,412
Net loss	$ (3,902,288)	$ (4,554,336)	$ (26,650,541)	$ (8,678,941)

Comparison of the Three Months ended September 30, 2024 and September 30, 2025

Revenues

The Company recognized revenues of $426,423 and $15,606 for the three months ended September 30, 2024 and 2025, respectively. Revenues were derived exclusively from the sale of licensed molecules to Wugen and related ancillary services such as storage and insurance. As of September 30, 2025, the Company agreed to a request from Wugen to suspend the Wugen License, which will run for a period of one year from the effective date of the suspension, or until May 29, 2026. The Company expects to generate revenue for ancillary services provided to Wugen during this time, as provided for under the amended Wugen license. During the suspension, the Company is free to enter licenses with other parties for the molecules that are subject of the Wugen license. We are seeking a large biologics manufacturer who has a use for a reagent based on HCW9206 and like molecules to improve the efficacy of their manufacturing process of CAR-T products.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2024 and September 30, 2025:

	Three Months Ended September 30,			
	2024	2025	$ Change	% Change
Salaries, benefits and related expenses	$ 652,867	$ 801,504	$ 148,637	23%
Manufacturing and materials	47,748	50,259	2,511	5%
Preclinical expenses	144,746	315,725	170,979	118%
Clinical trials	164,139	80,358	(83,781)	(51)%
Other expenses	177,413	156,401	(21,012)	(12)%
Total research and development expenses	**$ 1,186,913**	**$ 1,404,247**	**$ 217,334**	18%

Research and development expenses increased by $217,334, or 18%, from $1.2 million for the three months ended September 30, 2024 to $1.4 million for the three months ended September 30, 2025. The increase was primarily due to increases in expenses related to salaries and benefits and preclinical expenses.

Salaries, benefits, and related expenses increased by $148,637, or 23%, from $652,867 for the three months ended September 30, 2024 to $801,504 for the three months ended September 30, 2025. This increase was primarily attributable to the suspension of the Wugen license and its obligation to reimburse certain research and development expenses. In the third quarter of 2024, the Company received $125,000 for reimbursement of certain research and development expenses, which did not occur in the same period in 2025.

Manufacturing and materials expense increased by $2,511, or 5%, from $47,748 for the three months ended September 30, 2024 to $50,259 for the three months ended September 30, 2025. For both periods, costs were related to ancillary costs, such as storage and insurance for drug supply that was already manufactured and ready for future use.

Expenses associated with preclinical activities increased by $170,979, or 118%, from $144,746 for the three months ended September 30, 2024 to $315,725 for the three months ended September 30, 2025. In the three months ended September 30, 2024, costs were incurred primarily for IND-enabling studies to prepare for the submission of an IND application to evaluate HCW9302 in a clinical study in patients with an autoimmune disease. In the three months ended September 30, 2025, the Company conducted preclinical studies for TRBC-based molecules, many of which were required to prepare the complete the package needed to launch the business development program to identify a corporate partner to advance the clinical development of the Company's T-cell engager lead product candidate. Also during this time, the Company narrowed down candidates in the group of compounds known as second-generation immune checkpoint inhibitors, to identify HCW11-040 as the lead product candidate with the greatest potential for treating large, unmet medical needs, especially in cancer and other aging-related diseases.

Expenses associated with clinical activities decreased by $83,781, or 51%, from $164,139 for the three months ended September 30, 2024 to $80,358 for the three months ended September 30, 2025 primarily because the Company completed two Phase 1/1b clinical trials in 2024, but the Company had no ongoing clinical trials in the three months ended September 30, 2025. The decrease in cost is primarily due to decreases of $41,125 for R&D outsourcing and other professional fees, $27,890 for start-up and Institutional Review Board ("IRB") fees, and $38,061 in patient fees, offset by an increase of $25,895 in fees for software licenses and data management. We anticipate clinical activities and related expenses to increase in the future. In the fourth quarter of 2025, the Company expects to dose the first patient in a Company-sponsored, multi-center Phase 1 clinical trial (NCT07049328) to evaluate HCWC9302 in an autoimmune disease. There are currently two clinical sites opened at The Ohio State University and the Tampa VA Hospital, both of which are actively screening patients. As clinical activities increase, the Company expect to incur increased expenses.

Other expenses, which include overhead allocations, decreased by $21,012, or 12%, from $177,413 for the three months ended September 30, 2024 to $156,401 for the three months ended September 30, 2025. This decrease is primarily attributable to a $21,634 decrease allocation of depreciation for scientific equipment.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2024 and September 30, 2025:

	Three Months Ended September 30,			
	2024	2025	$ Change	% Change
Salaries, benefits and related expenses	$ 619,070	$ 699,989	$ 80,919	13%
Professional services	376,910	552,371	175,461	47%
Facilities and office expenses	134,580	125,521	(9,059)	(7)%
Accretion of fixed bonus upon maturity of Secured Notes	—	15,502	15,502	NM
Depreciation	69,370	58,451	(10,919)	(16)%
Rent and occupancy expense	49,160	39,633	(9,527)	(19)%
Other expenses	384,367	393,527	9,160	2%
Total general and administrative expenses	**$ 1,633,457**	**$ 1,884,994**	**$ 251,537**	15%

NM = Not meaningful

General and administrative expenses increased $251,537, or 15%, from $1.6 million for the three months ended September 30, 2024 to $1.9 million for the three months ended September 30, 2025. The increase is primarily attributable to an increase in expenses for salaries and benefits and professional services.

Salaries, benefits and related expenses increased by $80,919, or 13%, from $619,070 for the three months ended September 30, 2024 to $699,989 for the three months ended September 30, 2025. There was a $116,337 increase in salaries, bonus payments and related taxes, partially offset by decreases of $25,415 in expense related to stock-based compensation and $11,445 in Board compensation, brought about by the resignation of Gary M. Winer from the Company's Board of Directors at the end of the second quarter of 2025.

Professional services increased by $175,461, or 47%, from $376,910 for the three months ended September 30, 2024 to $552,371 for the three months ended September 30, 2025. There was a $239,812 increase in fees paid for audit services, technical accounting advice, tax services, as well as the costs related to maintaining compliance with SEC and Nasdaq listing requirements, partially offset by a decrease of $69,183 for legal fees related to patent filings and other matters related to the Company's intellectual property portfolio.

Facilities and office expenses decreased by $9,059, or 7%, from $134,580 for the three months ended September 30, 2024 to $125,521 for the three months ended September 30, 2025, primarily due to a decrease of $28,353 in fees paid for licenses, software, partially offset by an increase of $21,060 in fees for IT services. In the three months ended September 30, 2025, the Company began a data migration project which is expected to yield significant improvements in cybersecurity.

Other expenses increased by $9,160, or 2%, from $384,367 for the three months ended September 30, 2024 to $393,527 for the three months ended September 30, 2025. There was a $62,255 increase in finance costs related to SEPA issuance costs, partially offset by decreases of $25,953 in insurance premiums and $20,283 in tax expenses.

Legal Expenses (Recoveries), Net

In the three months ended September 30, 2024, the Company incurred $949,455 in legal expenses in connection with the Arbitration. The Arbitration was settled on July 13, 2024, and the Arbitration and related Complaint were dismissed with prejudice as of December 31, 2024. In the three months ended September 30, 2025, the Company incurred legal expenses of $6,006 related to the Arbitration. Prospectively, we anticipate we will incur some expenses for costs of remaining in compliance with the terms of the Settlement Agreement.

As of September 30, 2025, the Company reported a balance of $12.1 million for legal fees incurred as a result of the Arbitration but not yet paid, and these are included within Accounts payable. The Company is engaged in discussions with the law firms involved with this matter to negotiate terms for a payment plan. See Part II, Item 1, "Legal Proceedings."

Interest Expense

Related to the 2022 Loan, in the three months ended September 30, 2024 and September 30, 2025, we paid $93,936 and $92,106, respectively, in cash for interest. For the three months ended September 30, 2024 and 2025, interest was expensed.

For the three months ended September 30, 2024 and September 30, 2025, the Company recognized interest of $87,386 and $7,373, respectively, related to the Secured Notes.

In the three months ended September 30, 2025, the Company recognized $25,000 of accretion expense for the Secured Promissory Note.

For the three months ended September 30, 2024 and 2025, the Company recognized $2,592 and $27,592, respectively, for the amortization of debt issuance costs included within Interest expense on the condensed interim statement of operations.

Change in Fair Value of Investment and Contingent Liability, Net

The Company recognized a $966,284 loss due to the change in fair value of the investment in Wugen shares and the related contingent liability, net for the three months ended September 30, 2025. During the three months ended September 30, 2025, the Company's investment in Wugen was diluted as a result of a new Wugen capital raise through the issuance of preferred stock; and therefore, the estimated fair value of the Company's investment was reduced as was the fair value of the related contingent liability. There was no change in fair value of the investment in Wugen shares and contingent liability, net in the comparable period in 2024. The net change in fair value was recognized through earnings on the accompanying condensed interim statements of operations.

Loss on Sale of Put Shares

In the three months ended September 30, 2025, the Company recognized $182,146 for a loss on the sale of put shares, related to the 475,000 shares sold using the Company's SEPA. The Company entered the SEPA agreement in the first quarter of 2025.

Other Income, Net

Other income, net had a de minimis increase from $11,310 for the three months ended September 30, 2024 to $13,290 for the three months ended September 30, 2025.

Comparison of the Nine Months ended September 30, 2024 and September 30, 2025

Revenues

The Company recognized $2.2 million and $27,222 of revenues for the nine months ended September 30, 2024 and 2025, respectively. Revenues were derived exclusively from the sale of licensed molecules to Wugen and related ancillary services such as storage and insurance. As of September 30, 2025, the Company agreed to a request from Wugen to suspend the Wugen License, which will run for a period of one year from the effective date of the suspension, or until May 29, 2026. The Company expects to generate revenue for ancillary services provided to Wugen during this time, as provided for under the amended Wugen license. During the suspension, the Company is free to enter licenses with other parties for the molecules that are subject of the Wugen license. We are seeking a large biologics manufacturer who has a use for a reagent based on HCW9206 and like molecules to improve the efficacy of their manufacturing process of CAR-T products.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2024 and September 30, 2025:

	Nine Months Ended September 30,			
	2024	2025	$ Change	% Change
Salaries, benefits and related expenses	$ 2,189,250	$ 2,281,050	$ 91,800	4%
Manufacturing and materials	1,375,830	347,042	(1,028,788)	(75)%
Preclinical expenses	688,310	639,785	(48,525)	(7)%
Clinical trials	495,910	379,113	(116,797)	(24)%
Other expenses	590,083	462,792	(127,291)	(22)%
Total research and development expenses	**$ 5,339,383**	**$ 4,109,782**	**$ (1,229,601)**	(23)%

Research and development expenses decreased by $1.2 million, or 23%, from $5.3 million for the nine months ended September 30, 2024 to $4.1 million for the nine months ended September 30, 2025. This decrease was primarily attributable to decreases in expenses related to manufacturing and materials and clinical trials.

Salaries, benefits, and related expenses increased by $91,800, or 4%, from $2.2 million for the nine months ended September 30, 2024 to $2.3 million for the nine months ended September 30, 2025. This increase was primarily attributable to the suspension of the Wugen license and its obligation to reimburse certain research and development expenses. In the nine months ended September 30, 2024, the Wugen reimbursement was $312,500 higher than it was in the nine months ended September 30, 2025. To partially offset the impact of the suspension of the Wugen reimbursement for certain research and development expenses, the Company reduced salaries by $146,884 and other benefits and related tax expenses by $78,476.

Manufacturing and materials expense decreased by $1.0 million, or 75%, from $1.4 million for the nine months ended September 30, 2024 to $347,042 for the nine months ended September 30, 2025. In the nine months ended September 30, 2024, costs were primarily attributable to the costs of production and materials related to manufacturing the high producing cell-line of HCW9101, which is used in the manufacturing process for all TOBI-based molecules. In the nine months ended September 30, 2025, decrease in manufacturing and materials costs were primarily attributable to decreases of $1.0 million in raw materials and other production costs and $26,579 in ancillary expenses such as shipping and storage costs, partially offset by an increase of $16,953 in insurance expenses.

Expenses associated with preclinical activities decreased by $48,525, or 7%, from $688,310 for the nine months ended September 30, 2024 to $639,785 for the nine months ended September 30, 2025. In the nine months ended September 30, 2024, toxicology and other IND-enabling studies were winding down, and the IND application to be granted authorization to conduct a clinical study to evaluate HCW9302 in an autoimmune disease was finalized and submitted for review. In the nine months ended September 30, 2025, there was a decrease of $195,830 in drug testing, partially offset by increases of $55,448 expenses for fees to collaborators and $91,857 for supply of experimental research materials for studies.

Expenses associated with clinical activities decreased by $116,797, or 24%, from $495,910 for the nine months ended September 30, 2024 to $379,113 for the nine months ended September 30, 2025. The decrease was primarily attributable to decreases of $144,715 for fees for collaborators and other professional fees and $111,293 in patient fees, partially offset by increases of $108,889 in other clinical expenses, such as start up costs and IRB fees, and $30,322 in software and data management expenses. In the nine months ended September 30, 2025, activities were focused on additional studies with collaborators and start up fees related to opening clinical sites in preparation for the initiation of a clinical trial for HCW9302. In the fourth quarter of 2025, the Company expects to dose the first patient in a Company-sponsored, multi-center Phase 1 clinical trial (NCT07049328) to evaluate HCWC9302 in an autoimmune disease. There are two sites open at The Ohio State University and the Tampa VA Hospital, both of which are actively screening patients. As clinical activities increase, the Company expect to incur increased expenses.

Other expenses, which include overhead allocations, decreased by $127,291, or 22%, from $590,083 for the nine months ended September 30, 2024 to $462,792 for the nine months ended September 30, 2025. The decrease in other expenses is primarily attributable to decreases of $109,351 in the allocation of depreciation and $16,924 in costs for repairs and maintenance.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2024 and September 30, 2025:

	Nine Months Ended September 30,			
	2024	2025	$ Change	% Change
Salaries, benefits and related expenses	$ 1,855,660	$ 2,254,015	$ 398,355	21%
Professional services	960,680	1,503,381	542,701	56%
Facilities and office expenses	542,890	331,588	(211,302)	(39)%
Accretion of fixed bonus upon maturity of Secured Notes	—	390,809	390,809	NM
Depreciation	203,050	178,849	(24,201)	(12)%
Rent expense	155,860	151,911	(3,949)	(3)%
Other expenses	1,070,418	1,376,743	306,325	29%
Total general and administrative expenses	**$ 4,788,558**	**$ 6,187,296**	**$ 1,398,738**	29%

NM = Not meaningful

General and administrative expenses increased by $1.4 million, or 29%, from $4.8 million for the nine months ended September 30, 2024 to $6.2 million for the nine months ended September 30, 2025. The increase is primarily attributable to increases in expenses related to salaries and benefits, professional services, accretion of the fixed bonus payable if Secured Notes are repaid on the Maturity Date, and financing activities.

Salaries, benefits and related expenses increased by $398,355, or 21%, from $1.9 million for the nine months ended September 30, 2024 to $2.3 million for the nine months ended September 30, 2025. In the nine months ended September 30, 2024, officers waived a $298,159 performance-based bonus payment that was earned in 2022, which effectively reduced the salaries, benefits and related expenses by that amount. Excluding the benefit of the waiver of the performance-based bonus, there was a $99,645 increase in salaries offset by decreases of $25,847 in expenses for employee benefits and $11,445 in Board compensation, due to the resignation of Gary M. Winer from the Board of Directors late in the second quarter of 2025.

Professional services increased by $542,701, or 56%, from $960,680 for the nine months ended September 30, 2024 to $1.5 million for the nine months ended September 30, 2025. The increase is primarily attributable to increases of $157,100 in fees for audit services, $169,443 in fees for technical accounting advice, $119,977 in legal fees and other services required for SEC filings, and $65,810 for fees for Nasdaq listing and preparation for a meeting with the Nasdaq Hearings Panel, partially offset by a decrease of $75,147 for legal fees related to patent filings and other matters related to the Company's intellectual property portfolio.

Facilities and office expenses decreased by $211,302, or 39%, from $542,890 for the nine months ended September 30, 2024 to $331,588 for the nine months ended September 30, 2025. The decrease is primarily due to a $199,176 decrease in fees paid for licenses, software and IT services, primarily due to the termination of certain software licenses required for the data management system utilized during the Arbitration. The Arbitration and related Complaint were dismissed with prejudice as of December 31, 2024.

Other expenses increased by $306,325, or 29%, from $1.1 million for the nine months ended September 30, 2024 to $1.4 million for the nine months ended September 30, 2025. The increase is primarily attributable to increases of $168,974 in insurance premiums and $159,714 related to expenses for financing costs, including the Commitment Fee and issuance costs for the SEPA, partially offset by decreases of $26,262 in travel-related expenses and $22,315 in tax expenses.

Legal Expenses (Recoveries), Net

In the nine months ended September 30, 2024, Legal expenses (recoveries), net were $15.8 million, incurred for preparations leading up to the Arbitration hearing, which was held from May 20 - 31, 2024, negotiations for the Settlement Agreement entered into on July 13, 2024, and other activities related to remediation necessary to comply with the terms of the Settlement Agreement.

As of September 30, 2025, the Company reported a balance of $12.1 million for legal fees incurred in connection to the Arbitration but not yet paid that were included within Accounts payable. We are engaged in discussions with the law firms involved to negotiate a reasonable payment plan. See Part II, Item 1, "Legal Proceedings."

In the nine months ended September 30, 2025, the Company received a $2.0 million insurance reimbursement for legal fees incurred on behalf of Dr. Hing Wong, the Company's Founder and Chief Executive Officer, for his defense costs associated with the Arbitration, in prior periods, which was paid directly to the law firm involved. The insurance reimbursement is included within Legal expenses (recoveries), net, along with legal fees related to the Arbitration of $409,055 incurred in the nine months ended September 30, 2025. For the nine months ended September 30, 2025, the Company reported a contra expense of $1.6 million in Legal expenses (recoveries), net in the accompanying condensed interim statement of operations.

Interest Expense

Related to the 2022 Loan, in the nine months ended September 30, 2024 and September 30, 2025, we paid $282,098 and $275,710, respectively, in cash for interest. For the nine months ended September 30, 2024, three months interest was capitalized and six months interest was expensed. For the nine months ended September 30, 2025, interest was expensed.

For the nine months ended September 30, 2024 and September 30, 2025, the Company recognized interest of $152,679 and $227,931, respectively, related to the Secured Notes.

In the nine months ended September 30, 2025, the Company recognized $39,722 of accretion expense for the Secured Promissory Note.

For the nine months ended September 30, 2024 and 2025, the Company recognized $7,775 and $47,497, respectively, for the amortization of debt issuance costs included within Interest expense on the condensed interim statement of operations.

Change in Fair Value of Investment and Contingent Liability, Net

The Company recognized a net gain of $782,404 as a result of the change in fair value of the investment in Wugen shares and the related contingent liability, net for the nine months ended September 30, 2025. There was no change in fair value of investment and contingent liability, net in the comparable period in 2024. The net change in fair value was recognized through earnings on the accompanying condensed interim statements of operations. During the nine months ended September 30, 2025, the Company's investment value of Wugen shares was impacted by (a) the Company made an election to fair value its investment in Wugen shares in the second quarter of 2025, whereas previously the Company was accounting for the investment under the measurement alternative and (b) during the third quarter of 2025, the Company's investment was diluted as a result of a new capital raise by Wugen through the issuance of preferred stock. The Company's contingent liability was similarly impacted by the dilution subsequent to the recognition of the liability during the second quarter of 2025.

Loss on Sale of Put Shares

In the nine months ended September 30, 2025, the Company recognized a $182,146 loss for a loss on the sale of put shares, related to the 475,000 shares sold using the Company's SEPA.

Other Income, Net

Other income, net increased from $52,397 for the nine months ended September 30, 2024 to $54,412 in the nine months ended September 30, 2025.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2025, our principal source of liquidity was $1.1 million in cash and cash equivalents, including money market investments, and as a result, there was substantial doubt over whether the Company had sufficient capital to operate for the next twelve months from the issuance date of this Quarterly Report. We considered elements of our financing plan that were probable and likely to be implemented within the next year. While we have already begun to successfully execute our financing plan, including raising $7.0 million in the nine months ended September 30, 2025 through issuance of equity securities. In addition, during the nine months ended September 30, 2025, the Company strengthened our balance sheet by extinguishing $7.7 million of debt through restructuring and conversion to equity, including restructuring $7.4 million of Secured Notes and accumulated accretion of a fixed bonus payable upon Maturity Date and converting $270,000 of unsecured promissory notes according to the terms in the agreement.

In the coming year, we believe we have some significant potential valuation inflection points related to the initiation of the Phase 1 clinical trial to evaluate HCW9302 in an autoimmune disease, licensing agreements, and disclosures of our discoveries regarding the lead product candidates among the new class of molecules the Company has created with our TRBC platform. These events could provide much needed momentum for successful financings. However, if the Company is not successful in raising additional capital through these activities, management may need to revise its business plan and reduce costs. If such revisions are insufficient, the Company may have to curtail or cease operations.

In the three and nine months ended September 30, 2025, the Company issued 475,000 shares of Common Stock through the SEPA for net proceeds of $2.2 million, $2.0 million of which were settled as of September 30, 2025. On February 20, 2025, the Company entered the SEPA and a related Registration Rights Agreement with Square Gate Capital Master Fund, LLC - Series 4 ("Square Gate"), pursuant to which the Company will have the right, but not the obligation, to sell to Square Gate, and Square Gate will have the obligation to purchase from the Company, up to $20.0 million (the "Maximum Commitment Amount") worth of the Company's shares of Common Stock, at the Company's sole discretion, over the next 36 months (the "Put Shares"), subject to certain conditions precedent and other limitations. On August 14, 2025, the parties agreed to amend the SEPA to allow for intraday trading. See Note 7. Standby Equity Purchase Agreement.

In the nine months ended September 30, 2025, the Company closed on a $5.0 million in a follow-on public offering with an offering priced at the market under Nasdaq rules. Contemporaneously with the May 2025 financing, the Company entered into an agreement with the Investor to set a new exercise price of $7.45 per share, with respect to certain Common Stock Warrants to purchase 167,925 shares of the Company's Common Stock which were issued in the November 20, 2024 financing. On November 20, 2024, the Company closed a $6.9 million registered direct offering and a concurrent private placement of common stock and warrants with an offering priced above market under Nasdaq rules. All of these transactions were all completed with one institutional investor. See Note 4. Sale of Common Stock and Warrants**.**

An important part of the Company's future financing plans is the ability to access the public markets for the sale of securities. This requires that the Company remain in compliance with all Nasdaq Listing Rules, and it is currently deficient in meeting the requirements of Listing Rule 5550(b)(1), or the Equity Rule, related to the minimum requirements to maintain a $2.5 million balance in stockholders' equity. The Company was recently granted an extension to regain compliance with the Equity Rule until December 31, 2025, as discussed in more detail below.

In the first quarter of 2025, following a hearing before the Panel, the Panel granted the Company an extension until June 30, 2025 to regain compliance with all Nasdaq Listing Rules The Company had been deficient in three areas: Listing Rule 5550(a)(2), or requirements for the minimum bid price; Listing Rule 5550(a)(4), or requirements for the public float requirement in and the market value of publicly held shares, and the Equity Rule. On June 26, 2025, the Company announced that it received a formal notice from the Listing Qualifications Staff (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") that the Company was in compliance with the Equity Rule for continued listing on the Nasdaq Capital Market (the "Exchange"). At that time, the Company was also notified that it will remain subject to a "Panel Monitor," as that term is defined in Nasdaq Listing Rule 5815(d)(4)(B), for a period of one year from the date of the Nasdaq notice, through June 23, 2026. While the Company successfully completed several elements of its compliance plan including the Reverse Stock Split, the restructuring or conversion of $7.7 million of debt, putting a Standby Equity Purchase Agreement in place, and completing a $5.0 million equity financing by June 30, 2025, as previously reported, the Company's upfront license fee from WY Biotech did not meet the criteria for revenue recognition for the period ended June 30,2025. As a result, as of June 30, 2025, the Company did not meet the requirements of the Equity Rule.

The Company filed its Form 10-Q for quarter ended June 30, 2025 on August 18, 2025. On August 19, 2025, the Company received written notice from the Staff that as of June 30, 2025, the Company was non-compliant with the Equity Rule for continued listing on the Exchange. The Company made a timely request for a hearing before the Panel and was granted a hearing. On October 13, 2025, the Panel granted the Company an extension in which to regain compliance with all continued listing rules of the Exchange. The Panel's determination follows the Company's hearing on September 25, 2025, at which the Company presented, and the Panel considered, the Company's plan to regain compliance with the Equity Rule. The Panel granted the Company's request for continued listing on the Exchange, subject to, among other things, the Company demonstrating compliance with the Equity Rule by December 31, 2025, and with all other Exchange continued listing rules by February 16, 2026. The Company was advised that February 16, 2026, represents the full extent of the Panel's discretion to grant continued listing while the Company is non-compliant with the Nasdaq Listing Rules. The Panel also required that the Company provide prompt notification of any significant events that occur during the exception period that may affect the Company's compliance with Nasdaq requirements. In addition, the Company must timely file Form 10-Q for the third quarter, and provide notice of the status of certain elements of the Company's compliance plan. Any compliance documentation submitted by the Company will be subject to review by the Panel, which may, in its discretion, request additional information before determining that the Company has complied with the terms of the exception. The Panel has discretion to review its decision to grant an exception period within 45 calendar days after issuance of the written decision.

In addition to equity financings, a key strategy in our financing plan is identifying candidates in our sizeable molecule portfolio that would be appropriate to develop through business development transactions, especially out-licensing. In the second quarter of 2025, we began our search for an appropriate partner to commercialize our Immune-Cell Engagers, including T-Cell Engagers, created using our TRBC drug discovery and development platform. Since the inception of the Wugen License in December 2020, the Company has recognized cumulative revenues of $16.2 million. During the nine months ended September 30, 2025, the Company agreed to a request from Wugen to suspend the Wugen License, including Wugen's clinical trial due diligence obligations and its obligation to pay $500,000 annually to reimburse the Company for certain research and development expenses. The suspension will run for a period of one year from the effective date and will end on May 29, 2026. During the suspension, the Company has the exclusive right to seek alternate licensees and terminate the license in order to enter other business development transactions related to the *ex vivo* rights of licensed molecules. We are actively engaged in discussions with several large biologics manufacturing companies with interest in a license for these molecules.

The Company and WY Biotech Co., Ltd. ("WY Biotech") are currently finalizing the terms of an amendment to an exclusive worldwide license agreement ("WY Biotech License") that the parties first entered on November 17, 2024. The subject of the license is the use of in vivo rights to one of the Company's preclinical molecules, HCW11-006. The Company had extended the date for payment of the $7.0 million upfront license fee due under the WY Biotech License while WY Biotech worked to finalize agreements with their contract development and manufacturing organization ("CDMO") and investors. On September 5, 2025, WY Biotech proposed further revisions and additions to the terms of the WY Biotech License. Negotiations between the parties to restructure the terms of the WY Biotech License are ongoing. Pursuant to the terms currently being negotiated, the Company will retain its payment-free, milestone-free, and royalty-free option to recapture the development and commercialization in vivo rights of the licensed molecule for the United States, Canada, Central America, and South America (Opt-in Territory) after the conclusion of the Phase 1 clinical trial. WY Biotech is financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the molecule. The Company will be responsible for costs associated with clinical development, regulatory approval, and commercialization in the Opt-in Territory, if it exercises its opt-in rights.

As reported in the Company's Form 8-K filed on July 18, 2024 and further described in Part II, Item 1. – "Legal Proceedings" below, as of July 13, 2024, the Company and Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, entered into a confidential Settlement Agreement with ImmunityBio and its affiliates. The Settlement Agreement includes mutual general releases by and among the parties thereto. No party was required to make any monetary payments to any other party or person under the Settlement Agreement and each party will bear its own expenses incurred in connection with the matter. The Arbitration and related Complaint were dismissed on December 24, 2024. With the execution of the Settlement Agreement, we resolved the attendant uncertainties for the outcome of the Arbitration and additional complexities, and we launched our new financing plan.

In the accompanying condensed interim balance sheet as of September 30, 2025, the Company reported a balance of $12.1 million for legal fees incurred but not yet paid that were included within Accounts payable. The Company is in discussions with the law firms involved with this matter to establish a reasonable payment plan for the related legal fees. During the nine months ended September 30, 2025, the Company received an insurance reimbursement of $2.0 million, which was paid directly to the law firm who represented Dr. Wong in connection with his defense in the Arbitration. The insurance recovery is reported within Legal expenses (recoveries), net in the condensed interim statement of operations for the nine months ended September 30, 2025.

The Company owns a property which we are renovating to create a biologics manufacturing facility to produce clinical trial quantities of material to serve our needs, the needs of our licensees, and other small clinical-stage immunotherapeutic companies. We are actively seeking financing to complete this project. On August 15, 2022, the Company entered into a loan and security agreement (the "2022 Loan Agreement") with Cogent Bank, pursuant to which it received $6.5 million in proceeds to purchase our property at which the Company planned to build a facility to manufacture biologics and upgrade its research laboratory facilities. The loan is secured by a first priority lien on the property. As of September 30, 2025, certain subcontractors had filed mechanics liens related to unpaid invoices issued in connection with construction. The 2022 Loan Agreement contains a provision for a discretionary default in the event that the Company fails to pay sums due in connection with construction of any improvements; however, as of the reporting date, the lender has not elected to do so. As of September 30, 2025, the Company has reported the balance $6.2 million for this loan as Short-term debt, net. As discussed below, on October 24, 2025, the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure mechanics liens.

On January 22, 2025, the Company entered into a forbearance agreement with BE&K Building Group ("BE&K"), its general contractor, to allow the Company until March 31, 2025 to continue efforts to find the financing required to complete the construction and renovation of the property. Pursuant to the forbearance agreement, the Company made an initial payment of $1.0 million in partial satisfaction of amounts owing to BE&K and its subcontractors. As the Company reported in a Form 8-K, on April 17, 2025, the Company received a summons and a copy of a complaint filed by BE&K in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "BE&K Complaint"). Other Defendants named in the BE&K Complaint who are subcontractors elected to file counterclaims and cross-claims as part of their responses to the BE&K Complaint. Cogent Bank, also named as a Defendant in the BE&K Complaint, has not elected to take legal action at this time. In addition, on April 28, 2025, the Company received a summons and a copy of a complaint filed by Fisk Electric Company (which is a defendant in the BE&K Complaint) in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "Fisk Complaint") against the Company, BE&K, and the other defendants in the BE&K Complaint. On August 8, 2025, B&I Contractors, Inc., one of the defendants in the BE&K Complaint, filed a motion for summary judgment (the "MSJ") as to the Count I (Foreclosure of Construction Lien). The Company has responded to the BE&K and Fisk Complaints and cross-claims as well as the B&I MSJ. The parties are engaged in discovery and the court set the case for trial in early December 2026.

On October 24, 2025, the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure the mechanics liens no later than thirty (30) days after receipt of this letter in strict compliance with Section 7.2(3) of the Loan Agreement by: (i) paying and discharging all of the Claims of Lien and causing satisfactions to be recorded in the Public Records of Broward County, Florida for all of the Claims of Lien, and (ii) resolving all litigation against the Borrower and the mortgaged property described in the Mortgage and causing such claims in the Foreclosure Actions to be dismissed and all related notices of lis pendens to be released. The Company and Cogent Bank are in negotiations to come to terms for a forbearance agreement to provide additional time for the Company to comply with the demands it made in the demand letter.

The accompanying condensed interim financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above. The Company believes that substantial doubt exists regarding its ability to continue as a going concern for at least 12 months from the date of issuance of the Company's condensed interim financial statements, without additional funding or financial support. After considering management's plan for financing and funds raised that are probable to occur within one year, as well as that the Company expects to continue to incur losses from operations for the foreseeable future, management concluded that the substantial doubt that existed in its going concern analysis as of September 30, 2025 was not alleviated.

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;
- costs, timing, and outcome of regulatory review of our product candidates;
- number of trials required for regulatory approval;
- whether we enter into any cooperative, collaboration or co-development agreements and the terms of such agreements;
- whether we raise additional funding through bank loan facilities, other debt arrangements, out-licensing or joint ventures, cooperative agreements or strategic collaborations;
- effect of competing technology and market developments;
- cost of maintaining, expanding, and enforcing our intellectual property rights;
- impact of future arbitration, litigation, regulatory inquiries, or investigations, as well as costs to indemnify our officers and directors against third-party claims related to our patents and other intellectual property:
- cost and timing of buildout of the Company's new manufacturing and laboratory facilities, including manufacturing for biologics and upgraded research and development facilities, including risks of cost overruns and delays, and ability to obtain additional financing, if needed;
- impact of legal actions taken by BE&K and other lien holders related to foreclosure and other claims; 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, 2024 and September 30, 2025

The following table summarizes our cash flows for the nine months ended September 30, 2024 and September 30, 2025:

	Nine Months Ended September 30,	
	2024	2025
Cash used in operating activities	$ (11,392,547)	$ (10,036,100)
Cash (used in) provided by investing activities	(148,205)	—
Cash provided by financing activities	8,943,872	6,458,437
Net decrease in cash and cash equivalents	**$ (2,596,880)**	**$ (3,577,663)**

Operating Activities

Net cash used in operating activities were $11.4 million for the nine months ended September 30, 2024 and $10.0 million for the nine months ended September 30, 2025.

Cash used in operating activities for the nine months ended September 30, 2024 consisted primarily of net loss for the period of $26.7 million, partially offset by a $12.4 million increase in accounts payable and other liabilities, a decrease of $883,917 in accounts receivable and a decrease of $829,043 in prepaid expenses and other current assets. Further offset to the use of cash resulted from noncash adjustments of $1.2 million, consisting primarily of $501,882 of cash provided by an adjustment for depreciation and accretion and $716,940 of cash provided by an adjustment for stock-based compensation.

Cash used in operating activities for the nine months ended September 30, 2025 consisted primarily of net loss for the period of $8.7 million, a decrease in accounts payable of $3.1 million and an adjustment for a noncash transaction of a change in fair value of investment and contingent liability, net of $782,404, partially offset by $551,534 of cash provided by a decrease in accounts receivable, $162,903 of cash provided from a decrease in prepaid expenses and other assets, and several adjustments to reconcile net loss to net cash used in operating activities. Adjustments for noncash transactions provided $2.0 million of cash by operating activities, including $884,831 in depreciation and accretion expense, $759,441 for stock-based compensation, $150,000 for a Commitment Fee paid in shares of the Company's Common Stock, and $182,146 for a loss on the sale of Put Shares issued under the provisions of the SEPA.

Investing Activities

Cash used in investment activities for the nine months ended September 30, 2024 consisted of $148,205 used for purchases of property and equipment. There was no cash used in or provided by investing activities in the nine months ended September 30, 2025.

Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2024 resulted from a $2.5 million private placement of the Company's common stock and $6.5 million from the issuance of Secured Notes, partially offset a $88,388 principal repayment under the 2022 Loan Agreement related to the acquisition financing used to purchase a building.

In the nine months ended September 30, 2024, there were noncash transactions of $1.9 million for capital expenditures accrued but not yet paid and $829,207 for purchases of property and equipment that were included in accounts payable.

During the nine months ended September 30, 2025, $6.5 million of cash provided by financing activities consisted of the following:

- $3.5 million of gross proceeds for the issuance of shares of the Company's Common Stock, $2.0 million of which were proceeds received from the sale of shares under the Company's Standby Equity Purchase Agreement.
- $3.8 million in gross proceeds for the issuance of Pre-Funded Warrants may be exercised to purchase shares of the Company's Common Stock.
- $150,000 in gross proceeds upon the issuance of a promissory note secured by a personal guarantee by the Company's Founder and Chief Executive Officer.

These were partially offset by cash used in financing activities consisted of $888,399 used for issuance costs and $94,776 used to repay debt.

In the nine months ended September 30, 2025, there were significant noncash transactions. The Company restructured and extinguished $7.4 million of Secured Notes and accumulated accretion for a fixed bonus payable upon Maturity Date, in exchange for shares of Common Stock, warrants to exercise for Common Stock, and the right to receive proceeds upon the liquidation or sale of a portion of the Company's shares of Wugen common stock. Because this was a transaction with related parties, the $4.0 million gain from restructuring was recorded to additional paid-in capital for the period ended September 30, 2025. Also during this period, the Company closed on a $5.0 million financing in which it issued shares of the Company's Common Stock and warrants to exercise to purchase shares of the Company's Common Stock and repriced previously issued warrants with an existing stockholder of the Company. The Company estimated fair value of the securities issued and repriced warrants was $15.2 million. The difference between the gross proceeds and fair value was recognized as an equity dividend to investor, as this transaction was with an existing stockholder of the Company. The Company recorded a $10.2 million dividend to additional paid-in capital as of September 30, 2025.

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.

Investments

As part of its financing strategy, the Company may enter into licensing or collaboration agreements under which it receives consideration in the form of a minority equity interest in a counterparty, in lieu of or in addition to cash payments. These financial instruments are presented within Investments in the accompanying condensed interim balance sheets.

When consideration is an equity interest in a private entity whose equity has limited marketability with no readily determinable fair value and for which the Company does not have significant influence over the investee, the Company has elected to measure the equity interest using the measurement alternative, at cost less impairment, adjusted for observable price changes in orderly transactions for the identical or similar investment of the same issuer (ASC Topic 321, Investments - Equity Securities), unless the fair value method is otherwise elected. If the Company elects to measure an equity security at fair value, the entity shall measure all identical or similar investments of the same issuer, including future purchases of identical or similar investments of the same issuer, at fair value. The election to measure those securities at fair value shall be irrevocable. Any resulting gains or losses on the securities for which that election is made shall be recorded in earnings at the time of the election. See Note 8. Fair Value of Financial Instruments.

In the period ended June 30, 2025, the Company elected to account for its Wugen common shares at fair value. The Company utilized a valuation report that used the adjusted enterprise valuation method to fair value the Wugen common shares, which is considered a Level 3 input. We believe are useful to consider in the amounts reported in the financial statements for the carrying value for the Wugen investment and the change in the carrying value recognized in earnings in the financial statements. The fair value of the Wugen common shares is also used to fair value the contingent liability the Company recognizes for rights granted to converting noteholders to a portion of the proceeds received in the liquidation or sale of the Wugen shares.

In the period ended September 30, 2025, Wugen has its first closing for a Series C Preferred Stock equity offering. While this closing was completed with only existing investors and was not widely marketed, we considered that these parties invested nearly $100.0 million through the purchase of shares in cash to through conversion of debt. In addition, they are sophisticated investors who are market participants with knowledge of the life sciences industry as well as Wugen. Therefore, we considered this first closing of the Series C Preferred Stock equity offering to be an orderly transaction. Wugen may have subsequent closings for this offering in the future, at which time the Company will assess the impact on our investment in Wugen common shares. During the period, the Company utilized a combination of valuation techniques, consisting of adjusted enterprise valuation method and the backsolve method (based on the capital raise described above) to estimate the fair value as of September 30, 2025. Wugen is a private company, and we have a limited amount of information available to us. We are aware of the sensitivity of the backsolve method to the quality of inputs, which can sometimes be subjective, especially when relying on a single recent funding event. To mitigate the risks of using a backsolve valuation approach, the Company used the adjusted enterprise valuation method in combination with the backsolve method.

The Company concluded that the fair value of the Wugen investment declined from $3.3 million as of June 30, 2025 to $1.3 million as of September 30, 2025. The fair value of the related contingent liability for the rights to proceeds from the sale or liquidation of Wugen shares declined from $1.7 million as of June 30, 2025 to $692,531 as of September 30, 2025. The Company recognized an unrealized loss of $966,284 in the three months ended September 30, 2025 and an unrealized net gain of $782,404 in the nine months ended September 30, 2025 presented within Change in fair value of investment and contingent liability, net in the accompanying condensed interim statements of operations.

Standby Equity Line of Credit

The Company and Square Gate Capital Master Fund, LLC - Series 4 (“Square Gate”) entered a Standby Equity Purchase Agreement (“SEPA”) providing for an equity line of credit with Square Gate on February 20, 2025. This agreement provides a mechanism for submission by the Company and acceptance by Square Gate of Put Notices under the SEPA pursuant to which Square Gate and the Company may agree to and execute one purchase and sale of Put Shares (“Standard Put Shares”). The Standard Put Notice has a pricing mechanism based on a volume-adjusted weighted average trading price over three days following the acceptance of the Standard Put.

On August 14, 2025, the parties entered into a First Amendment to the SEPA (the “First Amendment”) to provide a mechanism for submission by the Company and acceptance by Square Gate of Put Notices under the SEPA pursuant to which Square Gate and the Company may agree to and execute multiple purchases and sales of Put Shares on the same trading day (“Intraday Put Shares”). Under the First Amendment, among other things, the purchase price of the Intraday Put Shares will be the lowest traded price during a specified valuation time period which begins with the acceptance of the Intraday Put and ends when trading volume reaches 1000% of the amount of shares included in the Intraday Put.

A SEPA is an equity-linked instrument for which an investor has the right, but not the obligation, to purchase shares of the entity’s common stock over a specified period of time. The SEPA creates a purchase put option for the overarching arrangement which was determined to be a derivative. Economically, before the entity has elected to sell shares, a SEPA represents a purchased put option on the entity’s own equity. However, once the entity “draws” on the SEPA, the related number of shares issued constitutes a financial instrument. Thus, a SEPA contains both a purchased put option element and a forward share issuance element. This generally means that a SEPA generally does not qualify for equity classification. Accordingly, entities must recognize an asset or liability for its SEPA. Such asset or liability must be measured at fair value, with changes in fair value recognized in net (loss) income. Further, individual draws must also be evaluated to determine if they meet criteria for equity classification.

With regards to the individual draws for a Standard Put under the SEPA, an individual draw would create a separate financial instrument with settlement criteria that does not meet indexation guidance. While the number of shares is known at inception and therefore not subject to the overarching share cap, there are two inputs into the settlement amount paid by the Investor which are not inputs into a fixed for fixed option: (1) the maximum amount to be funded under the SEPA of $20 million, which inherently limits the settlement amount regardless of the Company’s stock price and (2) the discount which reduces the amount to be paid upon settlement.

With regards to the individual draws for an Intraday Put under the First Amendment to the SEPA, an individual draw would create a separate financial instrument with settlement criteria that does not meet the indexation guidance. While the number of shares is known at inception and therefore not subject to an overarching share cap, the only inputs into its settlement is the Company’s stock price and trading volume during the pricing period.

Inputs noted above are not all inputs into a fixed for fixed option pricing model, thus the individual draw issuances are not eligible for equity classification in accordance with ASC 815-40, and therefore an asset or liability will be recorded and marked to market while the financial instrument is outstanding. Up settlement of the financial instruments, the Company should recognize the following amounts in earnings:

- The gain (loss) for the excess (deficit) of (a) the carrying amount of the asset or liability for the financial instrument plus the proceeds received and (b) the fair value of the common shares.

- Any discount, issuance or transaction costs incurred in conjunction with the settlement of the put shares.

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. For all of the significant accounting policies see Note 1 to our Annual Report.

Recent Accounting Pronouncements

See Note 1 to our Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As of September 30, 2025, we had cash and cash equivalents of $1.1 million including cash, cash equivalents and market investments. 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 interim 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, 2025. Based on that evaluation, the CEO and CFO have concluded that, as of such date, our disclosure controls and procedures were effective.

Inherent Limitations of Internal Controls

While we strive to create a stronger control environment, we recognize that it is impossible for our internal controls over financial reporting to prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. While we are committed to continuously improve and strengthen our control environment, over time, our internal controls over financial reporting may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

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) under the Exchange Act during the three months ended September 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, the Company is a party to or otherwise involved in legal proceedings, including suits, assessments, regulatory actions and investigations generally arising out of the normal course of business. Such proceedings can be costly, time consuming, and unpredictable. Therefore, no assurance can be given on the outcome of any proceeding or the potential impact on our results of operations or financial condition.

Settlement and General Release: Arbitration

During the period ended December 31, 2022, Altor/NantCell initiated legal proceedings against Dr. Wong and the Company. On April 26, 2023, the parties stipulated that Altor/NantCell's action against the Company would be consolidated with the Altor/NantCell Arbitration demand against Dr. Wong. On April 27, 2023, the U.S. District Court for the Southern District of Florida (the "Court") with jurisdiction over the lawsuit against the Company approved the parties' stipulation and ordered the parties to Arbitration. On May 1, 2023, Altor/NantCell filed a demand against the Company before JAMS. On May 3, 2023, Altor/NantCell dismissed the federal court action without prejudice and the Court ordered the case dismissed without prejudice and closed the case. Proceedings against the Company and Dr. Wong were consolidated in the Arbitration before JAMS. The Arbitration hearing was held from May 20, 2024 to May 31, 2024, after which the parties entered into settlement negotiations.

As reported in the Company's Form 8-K filed on July 18, 2024, as of July 13, 2024, the Company and Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, entered into a confidential Settlement Agreement and Release (the "Settlement Agreement") with Altor BioScience, LLC ("Altor"), NantCell, Inc. ("NantCell"), and ImmunityBio, Inc. (the parent of Altor and NantCell, together with Altor and NantCell, "ImmunityBio"), to resolve the previously disclosed Arbitration before JAMS brought by Altor and NantCell (the "Arbitration") as well as a complaint Altor filed against the Company in the Chancery Court of the State of Delaware for the contribution of legal fees and expenses advanced to Dr. Wong ("Complaint"). The Settlement Agreement includes mutual general releases by and among the parties thereto. No party is required to make any monetary payments to any other party or person under the Settlement Agreement and each party will bear its own expenses incurred in connection with the matter. In accordance with the provisions of the Settlement Agreement, upon completion of remedial procedures, the parties stipulated that the Arbitration and Complaint should be dismissed. The Arbitration and related Complaint were dismissed with prejudice on or about December 24, 2024.

Pursuant to the Settlement Agreement, the Company transferred and assigned to ImmunityBio ownership of certain intellectual property (including issued patents, pending patent applications, and know-how) for TOBI-based molecules. The Company retains the worldwide, perpetual, irrevocable, fully paid-up, royalty-free, exclusive right and license to exploit HCW9218 for all age-related diseases other than cancer. The Company also retains the right to develop treatments for all indications with respect to HCW9302 and HCW9206, which, along with HCW9218, are the lead product candidates in the Company's clinical development pipeline. ImmunityBio has the exclusive right to pursue oncology indications with all of the TOBI-based molecules designed with a TGF-β domain, including HCW9218. Under the Settlement Agreement ImmunityBio also receives an exclusive license to exploit fusion proteins, molecules and/or antibodies created utilizing the TOBI platform directed to the receptors of PDL-1, IL-7, IL-12, IL-18, IL-15, and IL-21 in the oncology field. The Company's ownership and rights with respect to HCW9302, HCW9206 and HCW9201 are expressly excluded from the rights transferred to ImmunityBio for oncology indications. In addition, ImmunityBio received a non-exclusive license to exploit HCW9201 administered by injection for oncology indications.

The Company retains ownership and control of the TOBI platform and TOBI-based molecules, with no restrictions under the Settlement Agreement on our ability to use the TOBI platform for protein-fusion molecules for non-oncology indications. We have rights to pursue oncology indications, in particular using HCW9302, HCW9206 and HCW9201. Further, the Company retains ownership of the Wugen license and shares of Wugen common stock transferred to the Company as the upfront licensing fee from Wugen for granting the Wugen license. For our molecule, HCW9218, we maintain the exclusive rights for clinical development and use of HCW9218 in the treatment of all non-oncological diseases. We retain ownership of our lead molecule, HCW9302, which expands T_{reg} cells and is designed to treat autoimmune diseases and other proinflammatory diseases, including cancer, and the ownership of HCW9206, a preclinical molecule which we are developing for the treatment of cancer and other age-related diseases. The Company agreed to provide ImmunityBio with a right of first refusal to enter a licensing agreement for oncology indications for HCW9206. We have no restrictions on the development of HCW9206 for our own clinical development activities, including oncology indications. Under the terms of the Settlement Agreement, ImmunityBio will own the cell line and supply for HCW9218, and the parties agreed that within six months from the date of the Settlement Agreement they will enter into a supply agreement providing the Company with a continuing supply of HCW9218 molecules. However, as of the reported date, the supply agreement of HCW9218 is not yet in place. The Company also retains *in vivo* rights to HCW9201, a combination of IL-12, IL-15, and IL-18 in a single protein complex which is designed to stimulate activation and proliferation signals in human NK cells. The Company retains ownership of the cell lines for HCW9302, HCW9206 and HCW9201, and thus will retain independent control over manufacturing and supply for these compounds.

Other Matters

As the Company reported in a Form 8-K, on April 17, 2025, the Company received a summons and a copy of a complaint filed by BE&K in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "BE&K Complaint"). Other Defendants named in the BE&K Complaint who are subcontractors elected to filed counterclaims and cross-claims in response thereto. Cogent Bank, also named as a Defendant in the BE&K Complaint, has not elected to take legal action at this time. In addition, on April 28, 2025, the Company received a summons and a copy of a complaint filed by Fisk Electric Company (which is a defendant in the BE&K Litigation) in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "Fisk Complaint") against the Company, BE&K, and the other defendants in the BE&K Complaint. On August 8, 2025, B&I Contractors, Inc., one of the defendants in the BE&K Complaint, filed a motion for summary judgment (the "MSJ") as to the Count I (Foreclosure of Construction Lien). The Company has responded to the BE&K and Fisk Complaints and cross-claims as well as the B&IMSJ. The parties are engaged in discovery and the court set the case for trial in early December 2026.

On October 24, 2025, the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure the mechanics liens no later than thirty (30) days after receipt of this letter in strict compliance with Section 7.2(3) of the Loan Agreement by: (i) paying and discharging all of the Claims of Lien and causing satisfactions to be recorded in the Public Records of Broward County, Florida for all of the Claims of Lien, and (ii) resolving all litigation against the Borrower and the mortgaged property described in the Mortgage and causing such claims in the Foreclosure Actions to be dismissed and all related notices of lis pendens to be released. The Company and Cogent Bank are in negotiations to come to terms for a forbearance agreement to provide additional time for the Company to comply with the demands it made in the demand letter.

Item 1A. Risk Factors.

There have been no material changes to the risk factors previously disclosed by us in our Annual Report. The risk factors included our Annual Report continue to apply to us and describe risks and uncertainties that could cause actual results to differ materially from the results expressed or implied by the forward-looking statements contained in this Quarterly Report. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business, financial condition and results of operations.

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

Sale of Unregistered Shares of Common Stock

On February 20, 2024 (the "Purchase Date"), we entered into subscription agreements (the "Subscription Agreements") with certain officers and directors of the Company, including our Founder and Chief Executive Officer, our Chief Financial Officer and the Chairman of the Company's Board of Directors, pursuant to which the Company sold an aggregate of 1,785,718 shares (the "Shares") of our common stock, par value $0.0001 per share (the "Common Stock"), at a purchase price of $1.40 per share for an aggregate purchase price of $2.5 million. The per share purchase price represents a 25% premium to the per share closing price of the Common Stock as reported on the Nasdaq Global Market on the Purchase Date and a 19% premium to the 5-day volume weighted average closing price per share of the Common Stock as reported on the Nasdaq Global Market for the period ending on the Purchase Date.

The Shares issued pursuant to the Subscription Agreements were not registered under the Securities Act of 1933, as amended, in reliance upon exemptions provided by Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

Conversion of Senior Secured Notes for Unregistered Shares of Common Stock and Unregistered Warrants

On March 28, 2024, the Company entered into a senior secured note purchase agreement (the "Note Purchase Agreement") with the Purchasers (as defined in the Note Purchase Agreement), pursuant to which we agreed to issue senior secured notes in an aggregate principal amount of up to $10.0 million ("Secured Notes") to certain accredited investors, including unrelated parties as well as officers and directors of the Company. As of March 31, 2024, the Company had an initial closing and issued $2.0 million in Initial Secured Notes. As of June 30, 2024, all existing investors approved an Amended and Restated Note Purchase Agreement ("Amended and Restated Note Purchase Agreement"), with terms described below. As of September 30, 2024, the Amended and Restated Note Purchase Agreement was amended to extend the last closing date to issue Additional Secured Notes to October 31, 2024. See Exhibit 10.25. No other terms were amended. The material terms of the Additional Secured Notes are identical to the terms of the Initial Secured Notes.

As of October 31, 2024, the Company issued an aggregate of $6.9 million of Secured Notes, with $2.9 million from the Company's officers and members of the Board of Directors, including $2.4 million purchased by Dr. Hing C. Wong, Founder and Chief Executive Officer; $220,000 purchased by Rebecca Byam, Chief Financial Officer; $140,000 purchased by Scott T. Garrett, Chairman of the Board of Directors; $60,000 purchased by Gary M. Winer, who was a member of the Board of Directors at the time he made this investment; $25,000 purchased by Lee Flowers, Senior Vice President for Business Development; and $25,000 purchased by Rick S. Greene, member of the Board of Directors.

The Secured Notes bear interest at a rate of 9% per annum, payable quarterly in arrears, and mature on August 30, 2026 (the "Maturity Date"), on which date the principal balance, accrued but unpaid interest, and other amounts that may be due under the terms of the Amended and Restated Note Purchase Agreement shall be due and payable. The Secured Notes may be prepaid on or prior to December 31, 2024, but will be subject to a 5% prepayment penalty ("Premium Amount"). Thereafter, the Secured Notes may be repaid upon a Mandatory Redemption event or at the end of the term.

As a condition to entering into the Amended and Restated Note Purchase Agreement, the Company, Mercedes M. Sellek, P.A. ("Escrow Agent"), and the Purchasers entered into that certain Escrow Agreement and Amended and Restated Pledge Agreement, dated July 2, 2024, pursuant to which the Company agreed to pledge our equity ownership interest in Wugen, which was 2.2 million shares of Wugen common stock as of September 30, 2025 (the "Pledged Collateral"), to be held and released by Escrow Agent according to the terms of the Escrow Agreement, as security for the Secured Notes.

Upon a qualifying event involving a transaction such as an acquisition, merger or initial public offering in which the Pledged Collateral can be sold or liquidated prior to the Maturity Date, subject to certain limitations (such as a threshold price per share in the case of an initial public offering), the Company agreed to repay all indebtedness (including accrued interest) related to the Secured Notes plus a Bonus Payment (as defined in the Amended and Restated Note Purchase Agreement). If there is no such mandatory redemption prior to the Maturity Date, the Company agreed to pay the holders of Secured Notes a Bonus Payment under certain circumstances.

Upon an Event of Default (as defined in the Amended and Restated Note Purchase Agreement), the Company will have a thirty (30) day cure period (the "Cure Period"), and if the Event of Default is not so cured at the end of the Cure Period, the Company is required to distribute the Pledged Collateral to the Purchasers on a *pro rata* basis, determined based on the issuance of $10.0 million in Secured Notes, in full satisfaction of the indebtedness evidenced by the Secured Notes.

The foregoing descriptions of the Amended and Restated Note Purchase Agreement, Amended and Restated Senior Secured Notes, Escrow Agreement and Amended and Restated Pledge Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the Form of Amended and Restated Senior Secured Note Purchase Agreement, Form of Senior Secured Promissory Note, Form of the Amended and Restated Pledge Agreement and Form of Amended and Restated Escrow Agreement, copies of which are filed as Exhibit 10.21 (and Exhibit 10.25 for the first amendment thereto as amended on September 30, 2024), Exhibit 10.22, Exhibit 10.23 and Exhibit 10.24, respectively, to our Annual Report and on Form 10-K are incorporated herein by reference.

The issuance of the Additional Secured Notes was exempt from the registration requirements of the Securities Act of 1933, as amended, in accordance with Section 4(a)(2), as a transaction by an issuer not involving a public offering. In addition, our Board of Directors and the Audit Committee of our Board of Directors reviewed the transaction under our policy for Related Party Transactions (the "Policy") and determined that the issuance of the Additional Secured Notes was in compliance with the Policy.

On February 20, 2025, the Company and certain Noteholders agreed to Principal Terms for Conversion of their Secured Notes. Noteholders and the Company agreed that, subject to stockholder approval, at least $6.6 million principal amount of the Secured Notes will be converted into shares of our Common Stock at a conversion price of $0.65 per share ($26.00 per share, as adjusted for the Reverse Stock Split). As part of the conversion, the Company will issue warrants to purchase shares of our Common Stock to the converting Noteholders for up to an additional $3.3 million of shares of our Common Stock, at an exercise price of $0.65 per share ($26.00 per share, as adjusted for the Reverse Stock Split). Upon conversion, converting Noteholders would be subject to a lock-up period of 180 days from the date of conversion. Further, the Escrow Agreement will be amended such that the proceeds from the Pledged Collateral will be allocated among the Company and the converting Noteholders, as provided for in the Principal Terms. The conversion of principal amount of the Secured Notes will result in a dollar-for-dollar increase in stockholders' equity (partially offset by the carrying value of the portion of the Company's investment in the Pledged Collateral the proceeds of which will be paid to converting Noteholders), contributing to the Company's plan to gain compliance with the Nasdaq Minimum Shareholder Equity Rule and to maintaining listing of the our Common Stock on Nasdaq.

The Principal Terms of Conversion were approved at a Special Meeting of Stockholders held on March 31, 2025 and were effected pursuant to the terms of that certain Second Amendment to Amended and Restated Senior Secured Note Purchase Agreement and Related Agreements dated as of May 1, 2025 (the "Conversion Amendment"). On May 7, 2025, pursuant to the Conversion Amendment, the Secured Notes held by the participating noteholders were cancelled, and the Company issued unregistered shares of Common Stock and warrants to purchase an up to $3.3 million of Common Stock with terms as agreed in the Principal Terms for Conversion. The Company issued 253,083 unregistered shares of Common Stock and Common Stock Warrants to purchase up to 126,540 shares of Common Stock to the noteholders who converted. In addition, the Company transferred the right to receive the proceeds of the liquidation or sale of 1,067,796 of the Company's Wugen shares, if that occurs, which is recorded as a contingent liability of $692,531 as of September 30, 2025. If no such event occurs by August 2030, then the converting noteholders will receive the 1,067,796 shares of Wugen common stock. Shares of Common Stock, including those underlying the Common Stock Warrants, are subject to a 180-day lockup from date of issuance.

Sale of Unregistered Warrants

On November 20, 2024, the Company closed on a $6.9 million offering with a single institutional investor (the "Investor") for the issuance and sale of (i) 104,000 shares (the "Shares") of the Company's common stock, par value $0.0001 per share (the "Common Stock") and (ii) pre-funded warrants to purchase up to 63,925 shares of Common Stock (the "Pre-Funded Warrants") in a registered direct offering (the "Registered Offering"), pursuant to a shelf registration statement on Form S-3 (File No. 333-266991), which was declared effective by the SEC on August 26, 2022. The Registered Offering was made by means of a prospectus supplement filed with the SEC on November 20, 2024 that forms a part of such registration statement. All Pre-Funded Warrants issued in the Registered Offering were exercised on November 20, 2024. In a concurrent private placement (the "Private Placement" and together with the Registered Offering, the Company also issued unregistered warrants to purchase up to an aggregate of 167,925 shares of Common Stock ("Common Stock Warrants") for $41.20 per share. Share amounts and exercise price per share reflect the adjustment for the Reverse Stock Split that was effective on April 11, 2025.

On April 16, 2025, the SEC declared the registration statement effective which registered the 167,925 shares of Common Stock underlying the Common Stock Warrants. On May 15, 2025, the Company entered into a privately negotiated agreement with the holder of these Common Stock Warrants to reduce the exercise price of such warrants from $41.20 per share to $7.45 per share.

Issuance of Unregistered Shares of Common Stock for Commitment Shares

The Company issued 9,616 shares of the Company's Common Stock on March 12, 2025, reflecting the adjustment for the Reverse Stock Split that was effective on April 11, 2025. These shares were issued in connection with an Equity Purchase Agreement ("EPA") and a Registration Rights Agreement (the "RRA") the Company entered into with Square Gate Capital Master Fund, LLC – Series 4, a series limited liability company organized in the State of Delaware ("Square Gate"). Pursuant to Section 6.4(a) of the EPA, following expiration of Square Gates's Due Diligence Period (as defined in the EPA), the Company is obligated to pay to Square Gate a commitment fee of $150,000 (the "Commitment Fee"), which is required to be paid in the form of a number of shares of the Company's Common Stock, valued at the closing share price of the Common Stock on The Nasdaq Stock Market on February 19, 2025 ("Commitment Shares").

On April 16, 2025, the SEC declared the registration statement effective which registered the Commitment Shares, and the Commitment Shares were transferred to Square Gate, without restrictions.

Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not Applicable.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

Insider Adoption or Termination of Trading Arrangements

During the fiscal quarter ended September 30, 2025, none of our directors or officers informed us of the adoption, modification or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408.

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	File No.	Exhibit No.	Filing Date	
10.1	Equity Purchase Agreement, dated February 20, 2025, between the Company and Square Gate Master Fund - Series 4.	8-K	011-40591	10.1	02/21/2025	
10.2	Registration Rights Agreement, dated February 20, 2025, between the Company and Square Gate Master Fund - Series 4	8-K	011-40591	10.2	02/21/2025	
10.3	Definitive Proxy Statement dated February 21, 2025, on Form 14A, including Appendices	10-K	011-40591	10.35	03/28/2025	
10.4	Form of Promissory Note, dated May 8, 2025, between the Company and Holder	10-Q	011-40591	10.4	05/15/2025	
10.5	Form of Guaranty and Pledge Agreement, dated May 8, 2025, between the Dr. Hing C. Wong and Lender	10-Q	011-40591	10.5	05/15/2025	
10.6	Form of Unsecured Convertible Promissory Note, dated May 5, 2025, between the Company and Holder	10-Q	011-40591	10.6	05/15/2025	
10.7	Form of Placement Agency Agreement, dated May 13, 2025, between Company and Maxim Group LLC	8-K	011-40591	10.1	05/15/2025	
10.8	Form of Securities Purchase Agreement, dated May 13, 2025, between the Company and Purchaser	8-K	011-40591	10.2	05/15/2025	
10.9	Form of Pre-Funded Warrant Purchase Warrant	8-K	011-40591	4.2	05/15/2025	
10.10	Form of Common Stock Purchase Warrant	8-K	011-40591	4.1	05/15/2025	
10.11	Form of Common Stock Warrant, original issue date November 20, 2024, between Company and Holder, as amended	8-K	011-40591	4.3	05/15/2025	
10.12	Second Amendment to Amended and Restated Senior Secured Note Purchase Agreement and Related Agreements, dated May 1, 2025, between Company and Holder	10-Q	011-40591	10.12	08/18/2025	
10.13	Form of Common Stock Warrant, dated May 7, 2025, between Company and Holder	10-Q	011-40591	10.13	08/18/2025	
10.14	Letter Agreement to the License, Research and Co-Development Agreement, dated March 17, 2025, between Company and WY Biotech Co. Ltd.	10-Q	011-40591	10.14	08/18/2025	
10.15	Confirmation of Letter of Acceptance of Deliverable from Company by WY Biotech Co. Ltd., dated May 30, 2025	10-Q	011-40591	10.15	08/18/2025	
10.16	Second Letter Agreement to the License, Research and Co-Development Agreement, dated July 13, 2025, between Company and WY Biotech Co. Ltd.	10-Q	011-40591	10.16	08/18/2025	
10.17	Exclusive License Agreement 12-month Suspension, dated May 29, 2025, between the Company and Wugen, Inc.	10-Q	011-40591	10.17	08/18/2025	
10.18	First Amendment to the Equity Purchase Agreement, dated August 14, 2025, between the Company and Square Gate Master Fund – Series 4.	8-K	011-40591	10.1	08/15/2025	
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, 2025, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) the Condensed Balance Sheets as of December 31, 2024 and September 30, 2025 (unaudited); (ii) the Condensed Statements of Operations for the three and nine months ended September 30, 2024 (unaudited) and September 30, 2025 (unaudited); (iv) the Condensed Statements of Changes in Stockholders' Equity for the three and nine months ended September 30, 2024 (unaudited) and September 30, 2025 (unaudited); (v) the Condensed Statements of Cash Flows for the nine months ended September 30, 2024 (unaudited) and September 30, 2025 (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 14, 2025

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

Date: November 14, 2025

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

Exhibit 31.1

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

I, Hing C. Wong, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HCW Biologics Inc. for the quarter ended September 30, 2025;

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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) 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

   d) 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 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 the 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
Founder and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2025

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, 2025;

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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) 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

   d) 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 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 the 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 Officer)

Date: November 14, 2025

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, 2025 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 14, 2025

/s/ Hing C. Wong

By:

Hing C. Wong
Founder and Chief Executive Officer
(Principle 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, 2025 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 14, 2025

/s/ Rebecca Byam

By:

Rebecca Byam
Chief Financial Officer
(Principal Financial Officer)