As filed with the Securities and Exchange Commission on January 9, 2026

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

HCW BIOLOGICS INC.
(Exact name of Registrant as specified in its charter)

Delaware	2834	82-5024477
(State or Other Jurisdiction of Incorporation or Organization)	Primary Standard Industrial Classification Code Number	(I.R.S. Employer Identification Number)

2929 N Commerce Parkway
Miramar, FL 33025
(954) 842-2024
Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices

Hing C. Wong, Ph.D.
Chief Executive Officer
HCW Biologics Inc.
2929 N Commerce Parkway
Miramar, FL 33025
(954) 842-2024
Name, Address Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service

With a copy to:

James Groth
Clark Hill PLC
130 E. Randolph St., Ste. 3900
Chicago, IL 60601
(312) 985-5900

Yevgeniya (Jeny) Zarmon
Clark Hill PLC
210 Carnegie Center, Suite 102
Princeton, NJ 08540
(609) 785-2918

Approximate Date of Commencement of Proposed Sale to the Public: From time to time after the effective date of this registration statement, as determined by market conditions.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a) of the Securities Act, may determine.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED JANUARY 9, 2026

Resale of
up to 3,400,033 Shares of Common Stock

This prospectus relates to the proposed resale by the respective selling stockholders identified below of up to the following respective amounts of shares of our common stock, par value $0.0001 per share (our "Common Stock"):

(1) The proposed resale by certain investors who previously purchased senior secured promissory notes from us throughout 2024 of (a) 253,083 shares of our Common Stock issued to such investors upon the conversion of approximately $6.6 million aggregate principal amount of those notes on May 7, 2025 (the "Conversion Shares"), and (b) up to 126,540 shares of our Common Stock that may be issued upon exercise of the warrants issued to such investors in connection with that conversion (the "Conversion Warrants"). As of October 31, 2024, we issued an aggregate of approximately $6.9 million principal amount of senior secured promissory notes to a group of accredited investors (the "Secured Notes"). On May 7, 2025, pursuant to an amendment to the secured note purchase agreement approved by our stockholders, the holders of approximately $6.6 million of the Secured Notes elected to convert their notes into equity, and we issued to them the Conversion Shares and the Conversion Warrants. The Conversion Shares were originally subject to a 180-day lock-up, which has since expired. We are registering the resale of the Conversion Shares and the shares issuable upon exercise of the Conversion Warrants pursuant to the registration rights granted in the amendment effecting the conversion.

(2) The proposed resale of securities held by Armistice Capital Master Fund Ltd. ("Master Fund") and beneficially owned by Armistice Capital, LLC ("Armistice"), as the investment manager of the Master Fund, of 3,020,410 shares (the "Warrant Shares") that are issuable upon the exercise of certain new unregistered Common Stock Purchase Warrants issued by us on November 19, 2025 (the "New Warrants") in conjunction with the Inducement Agreement. Specifically, on November 19, 2025, we entered into a warrant inducement agreement (the "Inducement Agreement") with Armistice, pursuant to which the Armistice agreed to immediately exercise in full (i) 167,925 warrants originally issued on November 20, 2024 and amended on May 15, 2025, and (ii) 1,342,280 warrants originally issued on May 15, 2025, for an aggregate of 1,510,205 shares of our Common Stock at a reduced amended exercise price of $2.66 per share, generating gross proceeds of approximately $4.0 million (collectively, the "Existing Warrants"). Of these shares, approximately 299,000 were issued at closing, and the remaining 1,211,205 shares were held in abeyance, subject to issuance as and when permitted pursuant to the beneficial ownership limitations contained in the Existing Warrants. In consideration for the immediate exercise of all such warrants, and pursuant to the Inducement Agreement, we issued to the Investor the New Warrants to purchase an aggregate of 3,020,410 shares of our Common Stock, at an exercise price of $2.41 per share. The New Warrants are exercisable immediately and expire five and one-half years from their issuance.

We are registering the resale of the Warrant Shares pursuant to the registration rights set forth in the Inducement Agreement. The selling stockholders may offer, sell, or distribute all or a portion of the securities hereby registered publicly or through private transactions at prevailing market prices or at negotiated prices. We will not receive any of the proceeds from such sales of the shares of our Common Stock. We will bear all costs, expenses, and fees in connection with the registration of these securities, including with regard to compliance with state securities or "blue sky" laws. The selling stockholder of the Warrant Shares will bear all commissions and discounts, if any, attributable to its sale of shares of our Common Stock. See the section entitled "Plan of Distribution" of this prospectus for additional information.

As used in this prospectus, references to the "Company," "HCW Biologics," "HCWB," "we," "us" or "our" refer to HCW Biologics Inc., a Delaware corporation. As used in this prospectus, "selling stockholders" refers to Armistice and its permitted assigns.

Our Common Stock is listed on The Nasdaq Stock Market LLC ("Nasdaq") under the symbol "HCWB". On January 6, 2026, the last quoted sale price for our Common Stock as reported on Nasdaq was $1.20 per share.

We are an "emerging growth company," as defined under the federal securities laws, and, as such, may elect to comply with certain reduced public company reporting requirements for future filings.

Investing in our securities is speculative and involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 14 of this prospectus before investing in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2026

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The registration statement containing this prospectus, including the exhibits to the registration statement, provides additional information about us and the Common Stock offered under this prospectus. The registration statement, including the exhibits, can be read on our website and the website of the Securities and Exchange Commission. See "Where You Can Find More Information."

Information contained in, and that can be accessed through our web site, www.hcwbiologics.com, shall not be deemed to be part of this prospectus or incorporated herein by reference and should not be relied upon by any prospective investors for the purposes of determining whether to purchase the Common Stock offered hereunder.

Unless the context otherwise requires, the terms "we," "us," "our," the "Company," "HCW Biologics," "HCWB," and "our business" refer to HCW Biologics Inc. and "this offering" refers to the offering contemplated in this prospectus.

Neither we nor the selling stockholders authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under the circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our Common Stock. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the selling stockholders are not, making an offer of these securities in any jurisdiction where such offer is not permitted.

ABOUT THIS PROSPECTUS

This prospectus describes the general manner in which the selling stockholders identified in this prospectus may offer, from time to time, (1) shares of our Common Stock issued to certain secured noteholders who converted their notes into Conversion Shares (described below) and received certain Conversion Warrants (described below) that may be converted into shares of our Common Stock in the future, and (2) shares of our Common Stock that may be issued pursuant to Inducement Agreement (described below), as the case may be. We are not selling any securities under this prospectus and will not receive any proceeds from the sale of shares of our Common Stock by the selling stockholders.

This prospectus is part of a registration statement that we filed with the SEC. This prospectus provides you with general information regarding the securities being offered by the selling stockholders. You should read this prospectus as well as the additional information described under the headings "Information Incorporated by Reference" and "Where You Can Find More Information" before making an investment decision.

No person has been authorized to give any information or to make any representations other than those contained in this prospectus in connection with the offering made hereby, and if given or made, such information or representations must not be relied upon as having been authorized by us, the selling stockholders or by any other person. Neither the delivery of this prospectus nor any sale made hereunder shall, under any circumstances, create any implication that information herein is correct as of any time subsequent to the date hereof. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any security other than the securities covered by this prospectus, nor does it constitute an offer to or solicitation of any person in any jurisdiction in which such offer or solicitation may not lawfully be made.

This document may only be used where it is legal to sell these securities. The information contained in this prospectus (and in any supplement or amendment to this prospectus) is accurate only as of the date on the front of the document, and any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since those dates.

References to "selling stockholders" refers to the security holders identified herein in the section titled "Selling Stockholders" beginning on page 58 of this prospectus, who may sell securities from time to time as described in this prospectus.

Unless otherwise indicated, information contained in or incorporated by reference into this prospectus concerning our business and the industry and markets in which we operate, including with respect to our business prospects, our market position and opportunity, and the competitive landscape, is based on information from our management's estimates, as well as from industry publications, surveys, and studies conducted by third parties. Our management's estimates are derived from publicly available information, their knowledge of our business and industry, and assumptions based on such information and knowledge, which they believe to be reasonable. In addition, while we believe that information contained in the industry publications, surveys, and studies has been obtained from reliable sources, we have not independently verified any of the data contained in these third-party sources, and the accuracy and completeness of the information contained in these sources is not guaranteed.

Although we are not aware of any misstatements regarding the market and industry data presented in this prospectus and the documents incorporated herein by reference, these estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors" in this prospectus and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus, including 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. Accordingly, you should not place undue reliance on this information.

PROSPECTUS SUMMARY

The SEC allows us to "incorporate by reference" certain information that we file with the SEC, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will update automatically, supplement and/or supersede the information disclosed in this prospectus. Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other document that also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You should read the following summary together with the more detailed information regarding our company, our securities and our financial statements and notes to those statements included in this prospectus. This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus. This summary may not contain all the information that you should consider before determining whether to invest in our securities. You should read the entire prospectus carefully, including the information included in the "Risk Factors" section, as well as our financial statements, notes to the financial statements and the other information included or incorporated by reference in this prospectus, before making an investment decision.

Our Company

HCW Biologics 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 ß 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 or infected cells.

As of July 13, 2024, the Company, Dr. Hing C. Wong (the Company's CEO), 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 I, Item 3. – "Legal Proceedings" of our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 28, 2025. 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 product 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.

Reverse Stock Split of Our Common Stock

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-Stock-Split-adjusted basis when the markets opened on April 11, 2025, under the existing trading symbol "HCWB."

Our audited financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2024 that are incorporated by reference into this prospectus are presented without giving effect to the Reverse Stock Split. Except where the context otherwise requires, share numbers and price per share amounts in this prospectus reflect the Reverse Stock Split, including share numbers and price per share amounts with respect to prior transactions, which reflect the Reverse Stock Split retrospectively.

In addition to the Reverse Stock Split, the stockholders approved two other proposals at the Special Meeting: (1) use of our 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.

All authorized, issued, and outstanding shares of common stock, preferred stock, stock option awards, and per share data included in this prospectus 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.

Reverse Stock Split Presentation

The Company identified certain immaterial presentation errors in our previously issued interim financial information related to the Reverse Stock Split (the "Reverse Stock Split"). In the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025 (the "Q1 2025 10-Q"), we disclosed in Note 1, Organization and Summary of Significant Accounting Policies, that our board of directors had approved the Reverse Stock Split. However, the effects of the Reverse Stock Split were not reflected on the face of the financial statements or in certain share-based disclosures for periods presented as of March 31, 2025, as required for retrospective presentation.

The Company's Reverse Stock Split was retrospectively reflected in subsequent periodic reports. The correction related to the Reverse Stock Split affected only share-based information and amounts derived from share counts. Specifically, the correction impacted the presentation of common shares outstanding, weighted-average shares outstanding, and per-share amounts. The correction did not affect the Company's total stockholders' equity, cash balances, net cash used in operating activities, or the underlying economics of any transaction. Other than the share-based presentation and related measurement described below, the Company's consolidated financial position, results of operations, and cash flows were unchanged for all periods presented.

In evaluating whether the Company's previously issued interim financial information was materially misstated, the Company performed an analysis of quantitative and qualitative factors in accordance with Staff Accounting Bulletin No. 99 (Materiality) and Staff Accounting Bulletin No. 108 (Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements), as well as the guidance in ASC Topic 250, Accounting Changes and Error Corrections. We concluded that the presentation error and the related adjustments were immaterial to the previously issued financial statements, either individually or in the aggregate, for the applicable periods.

The following table presents the change in our Q1 2025 10-Q as a result of the Reverse Stock Split (i) as previously presented and (ii) as adjusted to give retrospective effect to the 1-for-40 Reverse Stock Split. This table is included solely to illustrate the impact of the Reverse Stock Split.

Financial Statement	Original Filing	As Adjusted
Condensed Balance Sheet		
As of December 31, 2024		
Shares outstanding	44,541,295	1,113,532
Common Stock (par value)	4,454	111
Additional paid-in capital	93,781,511	93,785,854
As of March 31, 2025		
Shares outstanding	44,934,120	1,123,353
Common Stock (par value)	4,493	112
Additional paid-in capital	94,186,471	94,190,852
Condensed Statements of Operation / Note 5: Net Loss Per Share		
Three Months Ended of March 31, 2024		
Net loss per share, basic and diluted	$ (0.20)	$ (8.03)
Weighted average shares outstanding, basic and diluted	37,223,588	930,590
Three Months Ended of March 31, 2025		
Net loss per share, basic and diluted	$ (0.05)	$ (1.97)
Weighted average shares outstanding, basic and diluted	44,675,656	1,116,891
Condensed Statements of Changes to Stockholders' Equity (Deficit)		
Balance March 31, 2024		
Shares	37,823,394	945,585
Amount	3,782	95
Additional paid-in capital	86,737,203	86,740,890
Balance March 31, 2025		
Shares	44,934,120	1,123,353
Amount	4,493	112
Additional paid-in capital	94,186,471	94,190,852
Note 1: Liquidity and Going Concern Footnote	The Company issued 384,615 shares	The Company issued 9,616 shares
	The holder has the right to exercise 6,717,000 at $1.03/share	The holder has the right to exercise 167,925 at $41.20/share

The Reverse Stock Split did not affect the stated par value of our common stock or the rights and privileges of holders of our common stock. Outstanding options, warrants and convertible securities were adjusted proportionately to reflect the Reverse Stock Split. Other than changes to the presentation above, the Reverse Stock Split did not affect our total stockholders' equity, cash flows or results of operations for any period presented.

Recent Developments

WY Biotech License Agreement

In November 2024, the Company and WY Biotech Co., Ltd. ("WY Biotech") entered into a License, Research and Co-Development Agreement ("WY Biotech License"), as amended. The WY Biotech License is a grant of an exclusive, worldwide license to use and apply HCW11-006, a preclinical molecule, for *in vivo* applications. The Company holds an Opt-In Right under the provisions of the WY Biotech License, which gives the Company the option to assume all control and responsibility for the development, manufacture and commercialization of HCW11-006 for *in vivo* applications in North America, South America, and Central America. The Company retains *ex vivo* rights. Under the amended terms, the parties agreed to extend the timing for the payment of the upfront license fee of $7.0 million and reduced the performance obligation for the Company to the delivery of a technical report that characterized the licensed molecule by May 13, 2025.

In the quarter ended June 30, 2025, the Company delivered the technical report and WY Biotech notified the Company that it completed its due diligence to study the technical report delivered by the Company and elected to continue with the exclusive worldwide WY Biotech License, as amended. As a result, WY Biotech is financially obligated to the Company, as detailed in the WY Biotech License, as amended, including the obligation to pay a $7.0 million upfront license fee. WY Biotech is in the process of finalizing agreements with its contract development and manufacturing organization ("CDMO") and investors. In order to accommodate WY Biotech's timing in finalizing agreements, the Company and WY Biotech agreed to extend the latest date for payment of the $7.0 million license fee to September 30, 2025. As reported on Form 8-K filed on September 2, 2025, WY Biotech informed the Company it has not yet finalized such agreements and will likely not meet the amended payment date. The Company and WY Biotech recently entered into term sheets providing principal terms to further amend the WY Biotech License, and the parties are currently negotiating the definitive agreements for further revisions of and additions to the Agreement.

On November 17, 2025, the Company and Beijing Trimmune Biotech Co., Ltd. ("Trimmune") entered into an Amended and Restated License, Research and Co-Development Agreement ("A&R License") following the assignment of the original WY Biotech License from WY Biotech Co., Ltd. to Trimmune. The parties restructured the terms of the original WY Biotech License to include the assignment of rights to Trimmune, payment of half of the $7.0 million upfront license fee (*i.e.*, $3.5 million) in cash at closing and the other half in transferable equity in Trimmune (valued based on its current round of equity financing), an option to license HCW9302 for *in vivo* applications in China or Asia, and a 90-day period to close the deal from execution of the A&R License. Pursuant to the terms of the A&R License, the Company will retain its payment-free, milestone-free, and royalty-free option to recapture all rights to the development and commercialization of the licensed molecule for *in vivo* applications in the United States, Canada, Central America, and South America (Opt-in Territory) after the conclusion of the Phase 1 clinical trial. Trimmume is financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the molecule in its territory. If the closing under the A&R License Agreement does not occur within 90 days of execution (*i.e.*, by January 16, 2026), all intellectual property and rights with respect to HCW11-006 will be returned to the Company. The Company has been informed that, as of the date of this prospectus, Trimmune and its investors are in the process of executing documents providing for financing of Trimmune, the proceeds of which will be used to fund the cash portion of the upfront license fee payable to the Company under the A&R License. As of the date of this prospectus, the closing under the A&R License has not occurred.

First-In-Human Clinical Trial to Evaluate HCW9302 in an Autoimmune Disease

On November 18, 2025, we issued a press release announcing that the first patient was dosed in a Company-sponsored, multi-center Phase 1 clinical trial to evaluate our lead product candidate, HCW9302, in patients with an autoimmune disorder. It is a subcutaneously injectable, first-in-kind interleukin-2 ("IL-2") fusion molecule constructed using the Company's legacy TOBI™ platform technology. IL-2, the active component of HCW9302, is the cytokine in humans and other vertebrates responsible for maintaining the proper numbers and functions of

regulatory T ("T_{reg}") cells in the body. T_{reg} cells control excessive inflammation caused by other immune cells, which is the etiology of autoimmune diseases. The Phase 1 multi-center dose-escalation study of HCW9302 is designed to treat up to 30 patients with alopecia areata. The primary objectives of the study are to evaluate the safety of HCW9302, injected under the skin (subcutaneously), and to determine the recommended dose level to advance to later phase clinical studies. Secondary objectives include assessment of disease responses and the effects of HCW9302 on proliferation and function of immune cells, particularly T_{reg} cells. Depending on the results of this study, multi-dose studies of HCW9302 in expanded cohorts of patients with alopecia areata and in patients with other inflammatory dermatological conditions are expected to be initiated.

Compliance with Nasdaq Listing Rules

On June 26, 2025, we announced that we received formal notice from Nasdaq that the Company is in compliance with Listing Rule 5550(b)(1) (the "Equity Rule"). On May 13, 2025, the Company received formal notice from Nasdaq that it regained compliance with the bid price requirement in Listing Rule 5550(a)(2), the public float requirement in Listing Rule 5550(a)(4), and the market value of publicly held shares requirement in Listing Rule 5550(a)(5). As a result, the Company believed that it was in compliance with all applicable criteria for continued listing on the Nasdaq Capital Market tier and that the previously disclosed listing compliance matters had been closed.

The Company was 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. If, during the term of the Panel Monitor, the Company does not continue to remain in compliance with the Equity Rule, the Company will not be provided with the opportunity to submit a compliance plan for review by the Listing Qualifications Staff and must instead request a hearing before the Panel to address the deficiency, with such request staying any further action with respect to the Company's listing on Nasdaq pending completion of the hearing process.

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, so its securities would be suspended from trading on Nasdaq on August 28, 2025 unless it requested a hearing by August 26, 2025. On August 26, 2025, we timely requested a hearing before the Panel, which stayed the suspension of trading of the Company's securities on Nasdaq pending completion of the hearing process.

On October 13, 2025, the Panel granted the Company an extension of time in which to regain compliance with all continued listing rules of the Exchange. The Panel's determination followed 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 Nasdaq, subject to, among other things, the Company demonstrating compliance with the Equity Rule by December 31, 2025, and with all other Nasdaq 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 was required to timely file Form 10-Q for the third quarter (which it did), and to 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.

Summary of Risk Factors

Investing in our securities involves a high degree of risk. You should review carefully all the information contained in this prospectus before making an investment in our securities. The following list summarizes some,

but not all, of these risks. Please read the information in the section titled "Risk Factors" for a more thorough description of these and other risks.

- The exercise, issuance and sale hereunder of Warrant Shares, Conversion Shares and shares of our Common Stock issuable upon exercise of the Conversion Warrants may cause substantial dilution and the price of our Common Stock to decline.
- The potential issuance and sale of shares of Common Stock under the Equity Purchase Agreement dated as of February 20, 2025 (the "ELOC Purchase Agreement") between the Company and Square Gate Capital Master Fund, LLC – Series 4 ("Square Gate") may cause substantial dilution and the price of our Common Stock to decline.
- Our need for future financing may result in the issuance of additional securities, which will cause investors to experience dilution.
- We have incurred significant financial losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability.
- There is substantial doubt regarding our ability to continue as a going concern based on our cash and cash equivalents as of September30, 2025. We will need to raise additional funding, which may not be available on acceptable terms, if at all, to continue as a going concern and advance our current and any potential future product candidates. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations. Raising additional capital may dilute our existing shareholders, restrict our operations or cause us to relinquish valuable rights.
- The Company implemented remediation of material weaknesses identified in previous reporting periods. If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our Common Stock.
- We and our Chief Executive Officer were involved in legal proceedings with Altor BioScience, LLC and NantCell (collectively, "Altor/NantCell"). In July 2024, the parties entered a Settlement Agreement which removed some of the uncertainties as to the outcome and cost of these proceedings. However, the Company has significant obligations that remain as a result of legal fees incurred but not paid for the defense of the Company, as well as our Chief Executive Officer. If we cannot negotiate acceptable payment plans to satisfy these obligations, an adverse result could have a negative material impact on our business and operations.
- As a result of the Settlement Agreement, the Company is unable to progress into Phase 2 clinical trials for HW9218, our lead product candidate for cancer indications. The Company is prepared to progress HCW9218 in Phase 2 clinical trials for nononcology indications; however, we must secure supply of clinical materials to do so. As a condition of the Settlement Agreement, the Company transferred the master cell line for HCW9218 to ImmunityBio, who in turn agreed to enter a supply agreement with the Company by January 2025. As of the date of this prospectus, there is no supply agreement in place. As a result of the delay in securing supply, there is no assurance that the Company will be able to continue the clinical development of HCW9218 in nononcology indications.
- On August 19, 2025, we received a written notice from the Nasdaq Listing Qualifications Staff that as of June 30, 2025, we were not in compliance with Listing Rule 5550(b)(1) and our securities would be suspended from trading unless we request a hearing by August 26, 2025. We timely requested a hearing on August 26, 2025, which took place before the Nasdaq Hearings Panel on September 25, 2025. The Company is in the process of implementing the compliance plan presented at the hearing, which includes the filing of the registration statement that includes this prospectus, and the Company is considering all other options available to it to regain compliance with the Equity Rule; however, there

can be no assurance that the Panel will grant the Company's request for continued listing or that the Company will be able to evidence compliance within the period of time that may be required by the Panel.

- Our ability to begin clinical trials may be delayed, or denied altogether, pending FDA authorization of our IND applications and our ability to negotiate appropriate agreements with clinical sites.
- Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates or any future product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization.
- Preliminary, topline or interim data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.
- The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis, if at all, our business will be substantially harmed.
- Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our product candidates are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and, therefore, be unable to commercialize our product candidates on a timely basis or at all.
- Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.
- We expect to rely on patents and other intellectual property rights to protect our technology, including product candidates and our immunotherapy platform technology, the prosecution, enforcement, defense, and maintenance of which may be challenging, time-consuming and costly. Failure to defend, protect or enforce these rights adequately, and costs and expenses associated with the same, could impact our financial condition and results of operations or otherwise harm our ability to compete and impair our business.
- We rely on third parties to manufacture our product candidates. Any failure by a third-party manufacturer to produce acceptable drug substance for us or to obtain authorization from the FDA or comparable regulatory authorities may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory approvals or commercialize approved products.
- Our information technology systems, or those used by our third-party contractors or consultants, may fail or suffer security breaches, which could adversely affect our business.

The Offering

As of October 31, 2024, we issued senior secured promissory notes to a group of accredited investors. On May 7, 2025, pursuant to an amendment to the secured note purchase agreement approved by our stockholders, the holders of approximately $6.6 million aggregate principal amount of these notes converted their notes into equity, and we issued to them 253,083 shares of our Common Stock (the "Conversion Shares") and warrants to purchase an additional 126,540 shares of our Common Stock at an exercise price of $26.00 per share (the "Conversion Warrants"). The Conversion Shares were previously subject to a 180-day lock-up, which has since expired. We are registering for resale the Conversion Shares and the shares of our Common Stock issuable upon exercise of the Conversion Warrants, and we have reserved 126,542 authorized and unissued shares of our Common Stock solely for issuance upon exercise of the Conversion Warrants.

In addition, pursuant to an inducement agreement dated November 19, 2025 (the "Inducement Agreement") between the Company and Armistice Capital Master Fund Ltd. ("Armistice"), Armistice exercised in full the Existing Warrants for an aggregate of 1,510,205 shares of our Common Stock at an amended exercise price of $2.66 per share. Of these shares, approximately 299,000 were issued at closing, and the remaining 1,211,205 shares were held in abeyance, subject to issuance as and when permitted pursuant to the beneficial ownership limitations contained in the Existing Warrants. In consideration for the immediate exercise, we issued the New Warrants to purchase an aggregate of 3,020,410 Warrant Shares at an exercise price of $2.41 per share. The New Warrants are exercisable immediately and expire five and one-half years from their issuance. We are registering for resale the 3,020,410 shares of our Common Stock for the Warrants Shares issuable upon exercise of the New Warrants. We have reserved 3,020,410 authorized and unissued shares of our Common Stock solely for issuance upon exercise of the New Warrants.

For more information, please see the sections entitled "The Secured Note Conversion" and "The Armistice Transaction."

Emerging Growth Company

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As such, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the prices of our securities may be more volatile.

We will remain an emerging growth company until the earliest of: (1) December 31, 2026 (the last day of the fiscal year following the fifth anniversary of the consummation of our initial public offering), (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (3) the last day of the fiscal year in which we are deemed to be a large accelerated filer, as defined in the Securities Exchange Act of 1934, as amended, (the "Exchange Act") or (4) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. References herein to "emerging growth company" shall have the meaning associated with that term in the JOBS Act.

Smaller Reporting Company

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our Common Stock held by non-affiliates exceeds $250 million as of the prior June 30, or (ii) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our Common Stock held by non-affiliates exceeds $700 million as of the prior June 30.

Corporate Information

Our principal executive office is located at 2929 N Commerce Parkway, Miramar, FL 33025, and our telephone number is (954) 842-2024. Our website address is www.hcwbiologics.com. Information on or accessed through our website is not incorporated into and not part of this prospectus.

OFFERING SUMMARY

This prospectus relates to the resale, from time to time, by the selling stockholders identified herein of up to 3,400,033 shares of our Common Stock, which are issuable upon exercise of the Conversion Shares, Conversion Warrants and New Warrants.

Issuer –Issuance of Common Stock	HCW Biologics Inc.
Shares of Common Stock to be Issued by Us	Up to 3,146,950 shares of our Common Stock, consisting of 3,020,410 shares issuable upon exercise of the New Warrants and 126,540 shares issuable upon exercise of the Conversion Warrants. The 253,083 Conversion Shares have already been issued, are outstanding and are being registered for resale in this registration statement as well. No shares are being issued by the Company in connection with this registration statement.
Shares of Common Stock outstanding as of the date of this prospectus	3,279,812, exclusive of 977,000 shares held in abeyance, subject to future issuance to Armistice in accordance with the beneficial ownership limitations contained in the Existing Warrants.
Resale of Common Stock	
Shares of Common Stock Offered by the Selling Stockholders	The selling stockholders are offering up to an aggregate of 3,400,033 shares of our Common Stock, consisting of: • 3,020,410 shares of our Common Stock issuable upon exercise of the New Warrants, • 253,083 Conversion Shares, and • 126,540 shares of Common Stock issuable upon exercise of the Conversion Warrants.
Terms of the Offering	The selling stockholders may sell the shares from time to time at prevailing market prices or at negotiated prices. See “Plan of Distribution.”
Use of Proceeds	We will not receive any proceeds from any sale of shares of our Common Stock by the selling stockholders. However, we may receive up to $7,279,188 in gross proceeds from the cash exercise of the New Warrants and up to $3,290,040 in gross proceeds from the cash exercise of the Conversion Warrants after the date of this prospectus. We intend to use any proceeds from the sales of shares to Armistice under the New Warrants and to the converting noteholders under the Conversion Warrants for general corporate purposes. General corporate purposes may include funding the continued progress of our preclinical and clinical development, research and development costs, manufacture and supply of product, potential strategic acquisitions or licensing of complementary businesses, services or technologies, working capital, capital expenditures and other general corporate purposes.

Risk Factors	Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading “Risk Factors” beginning on page 14 of this prospectus.
Nasdaq Symbols	Our Common Stock is listed on Nasdaq under the symbol “HCWB”.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the information incorporated herein by reference contain forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy, and other future conditions. This includes, without limitation, statements regarding the financial position and the plans and objectives of management for our future operations. Such statements can be identified by the fact that they do not relate strictly to historical or current facts. When used in this prospectus, words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "strive," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this prospectus and in any document incorporated by reference in this prospectus, including the Annual Report filed on Form 10-K on March 28, 2025 (the "Annual Report") and the Quarterly Report filed on Form 10-Q on November 14, 2025 (the "Quarterly Report"), may include, for example, statements about:

- management's going concern assessment;
- the occurrence of any event, change or other circumstances, including the outcome of any legal proceedings that may be instituted against us;
- financial performance and the ability to maintain the listing of our securities on Nasdaq, and the potential liquidity and trading of our securities;
- the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements and the risk of disruption to our current plans and operations;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize our drug candidates;
- timing, costs and outcome of regulatory review, and impact on our ability to receive FDA clearance for clinical trials;
- the ability to secure clinical sites, enroll patients, and initiate clinical trials;
- number of trials needed to obtain clinical approval;
- the ability of our clinical trials to demonstrate safety and efficacy of our drug candidates, and other positive results;
- the success, cost and timing of our development activities, preclinical studies and clinical trials;
- the timing and focus of our future clinical trials, and the reporting of data from those trials;
- our plans relating to commercializing our drug candidates, if approved;
- our plans and ability to establish sales, marketing and distribution infrastructure to commercialize any drug candidates for which we obtain approval;
- our ability to attract and retain key scientific and clinical personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our reliance on third parties to conduct clinical trials of our drug candidates, and for the manufacture of our drug candidates for preclinical studies and clinical trials;
- our ability to establish our own manufacturing facilities domestically;
- our ability to expand our drug candidates into additional indications and patient populations;
- the success of competing therapies that are or may become available;

- the beneficial characteristics, safety and efficacy of our drug candidates;
- political and regulatory developments in the United States and other jurisdictions;
- our ability to obtain and maintain regulatory approval of our drug candidates, and any related restrictions, limitations and/or warnings in the label of any approved drug candidate;
- our plans relating to the further development and manufacturing of our drug candidates, including additional indications for which we may pursue;
- cost of maintaining, expanding, and enforcing our intellectual property rights;
- our plans and ability to obtain or protect intellectual property rights;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technology;
- potential claims relating to our intellectual property;
- impact of litigation, regulatory inquiries, or investigations, as well as cost to indemnify our officers and directors against third-party claims related to our patents and other intellectual property;
- cost and timing of buildout of our new headquarters, including a biologics manufacturing facility, including risks of balances due to general contractor and subcontractors, cost overruns and delays, and ability to obtain additional funding required to complete the project;
- our ability to enter out-license agreements for the development and commercialization of the Company's non-core assets;
- cost 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; and
- other factors disclosed under the section entitled "Risk Factors" in this prospectus.

Forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management's beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control, including those described in the section titled "Risk Factors" and elsewhere in this prospectus and the documents incorporated by reference into this prospectus.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Accordingly, you should not place undue reliance on forward-looking statements as predictions of future events. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations, except as required by law.

You should read this prospectus, the documents incorporated by reference into this prospectus, any free writing prospectus and the documents that we reference in this prospectus and have filed with the SEC, as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below and incorporated by reference herein before making an investment decision. Our business, prospects, financial condition, or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. The trading price of our securities could decline due to any of these risks, and, as a result, you may lose all or part of your investment. Certain statements in "Risk Factors" are forward- looking statements. See "Cautionary Statement Regarding Forward-Looking Statements."

Risks Related to this Offering

Issuances of our Common Stock to the selling stockholders has caused and will continue to cause substantial dilution to our existing stockholders and could cause the price of our Common Stock to decline.

We are registering for resale (1) 3,020,410 shares of our Common Stock issuable upon exercise of the New Warrants to be issued as Warrant Shares, (2) 253,083 shares of our Common Stock issued as the Conversion Shares, and (3) up to 126,540 shares of our Common Stock issuable upon exercise of the Conversion Warrants.

The shares issuable upon exercise of the New Warrants and the Conversion Warrants may be sold into the public market at any time after the date of this prospectus. The number of shares ultimately sold by the selling stockholders under this prospectus is dependent upon the number of shares the selling stockholders elects to sell and the market conditions during the resale period. Depending on a variety of factors, including market liquidity of our Common Stock, the resale of a substantial number of Warrant Shares, Conversion Shares, or shares of our Common Stock issuable upon exercise of the Conversion Warrants may cause the trading price of our Common Stock to decline.

We may ultimately issue all, some, or none of the shares of Common Stock underlying the New Warrants and Conversion Warrants. The selling stockholders may sell all, some, or none of the shares of our Common Stock covered by this prospectus. Any issuance of shares upon exercise of the New Warrants or Conversion Warrants will result in dilution to the interests of our existing stockholders. The sale of a substantial number of shares of our Common Stock by the selling stockholders in this offering, or anticipation of such sales, could cause the trading price of our Common Stock to decline or make it more difficult for us to raise additional capital in the future at a time and at a price that we might otherwise desire.

The sale of a substantial number of shares of our Common Stock in the public market could adversely affect the prevailing market price of our shares.

We are registering for resale an aggregate of 3,020,410 shares of Common Stock issuable upon exercise of the New Warrants, 253,083 Conversion Shares, and 126,540 shares of our Common Stock issuable upon exercise of the Conversion Warrants. Sales of a substantial number of our shares in the public market, or the perception that such sales might occur, could adversely affect the market price of our shares. We cannot predict if and when the selling stockholders may sell such shares in the public markets. Furthermore, in the future, we may issue additional shares or other equity or debt securities convertible into shares. Any such issuance could result in substantial dilution to our existing stockholders and could cause our share price to decline.

Exercises of the New Warrants or Conversion Warrants may occur at times when our stock price is declining or volatile, which could further negatively impact the market price of our Common Stock. It is not possible to predict the actual number of shares that will be issued upon exercise of the New Warrants or the timing of such issuances and investors who purchase shares from the selling stockholders at different times may pay different prices.

Although the New Warrants and Conversion have a fixed exercise price, the selling stockholders may exercise such warrants at any time prior to their expiration. If exercises occur when the market price of our Common

Stock is below or near the exercise price, sales of the resulting shares by the selling stockholders could place downward pressure on our stock price.

The timing and number of shares issued upon exercise of the New Warrants and Conversion Warrants will depend on when and to what extent the selling stockholders elects to exercise the New Warrants. Because exercises may occur at any time during the term of the New Warrants and Conversion Warrants, it is not currently possible to predict the number of shares that will be issued or the gross proceeds, if any, that we may receive.

Further, because the selling stockholders may resell the warrants at varying prices and at different times, investors who purchase those shares may experience different levels of dilution and different investment outcomes. In addition, the expected or actual resale of a substantial number of shares by the selling stockholders may make it more difficult for us to raise additional capital in the future at a time and at a price we might otherwise desire.

Sales of shares issued upon exercise of the Conversion Warrants and New Warrants could cause the market price of our Common Stock to decline.

Although the selling stockholders must pay the fixed exercise price when exercising the New Warrants (unless utilizing a cashless exercise if permitted), the selling stockholders may resell the underlying shares at any price and at any time. Such resales, or the expectation that such resales may occur, could cause the market price of our Common Stock to decline.

Risks Related to HCWB's Business and Industry

There is substantial doubt about our ability to continue as a going concern. We will need to raise additional funding, even after this offering, whether or not the maximum offering amount is raised, which may not be available on acceptable terms, if at all to continue as a going concern and advance our product candidates. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations. Raising additional capital may dilute our existing shareholders, restrict our operations or cause us to relinquish valuable rights.

There is substantial doubt regarding our ability to continue as a going concern based only on the cash and cash equivalents as of September 30, 2025. We continuously evaluate whether there are conditions and events, considered in the aggregate, which raise substantial doubt about our ability to continue as a going concern within one year after the date that financial statements are issued. When substantial doubt exists based on this analysis, management evaluates whether the mitigating effect of our plans to raise capital or reduce costs sufficiently alleviates substantial doubt about our ability to continue as a going concern.

We are at the clinical development stage of our Company with no commercial revenues from the products we are developing, and it is possible we will never generate revenue or profit from product sales. As of September 30, 2025, we had cash and cash equivalents of $1.1 million and there was substantial doubt about our ability to continue as a going concern for at least 12 months from the issuance date of the financial statements appearing in the Quarterly Report, whether or not we curtail efforts with respect to certain of our current and future product candidates. We will require significant additional funding to advance any of our product candidates beyond the short term and to sustain our operations.

We may also seek to raise such capital through public or private equity, debt financing business development transactions, or other forms of financing. Raising funds in the current economic environment may be challenging, and such financing may not be available in sufficient amounts or on acceptable terms, if at all. The terms of any financing may harm existing stockholders. The issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or

convertible securities may dilute the ownership of existing stockholders. Incurring debt would result in increased fixed payment obligations, and we may agree to restrictive covenants, such as limitations on our ability to incur additional debt or limitations on our ability to acquire, sell or license intellectual property rights that could impede our ability to conduct our business.

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

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

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

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

Since we have already generated over 50 immunotherapeutic molecules, and plan to develop additional molecules, through our immunotherapy platform technology, our strategy includes funding operations in part through revenues derived from out-licensing molecules that are outside our oncological and anti-aging focus to third parties. Despite our efforts, we may be unable to enter into such licensing agreements. Supporting diligence activities conducted by potential licensors and negotiating the financial and other terms of a license agreement are long and complex processes with uncertain results, and we may fail to derive any revenues from these activities. If we fail to successfully out-license to third parties internally developed molecules that are not part of the Company's in-house clinical development programs, our revenues and return on our research and development activities would be negatively affected and we could be required to seek additional funding.

The success of our business development efforts, including license agreements, depends on our ability to realize the anticipate benefits of these transactions and is subject to numerous risks and uncertainties, many of which are outside of our control.

Our potential licensors intend to develop alternative products or pursue alternative technologies either on their own or in collaboration with others, potentially resulting in our receiving no future milestone or royalty payments under any such licenses. We enter exclusive worldwide license arrangements pursuant to which licensors will develop certain immunotherapy products under which we may earn upfront license fees, additional milestone or royalty payments, but there can be no assurance that licensors will perform as required under the terms of the license agreements or will be successful in commercializing any products related to this license or that any such payments will ever be earned.

We view our business development activities as an enabler of our strategy for clinical development activities and seek to generate growth by pursuing selected opportunities that have the potential to strengthen our clinical development program and provide a source of capital for our operations, including in-house development programs. The success of our business development activities is dependent on the availability of licensing partners, as well as being provided sufficient information that will enable us to accurately evaluate an opportunity.

The success of our business development transactions also depends on our ability to realize the anticipated benefits of these transactions and is subject to numerous risks and uncertainties, many of which are outside of our control. Unsuccessful clinical trials, regulatory hurdles, new information and commercialization challenges, inability to raise the capital necessary to execute the clinical development program, among other factors, may adversely impact revenue and income contribution from business development transactions and may lead to an adverse impact on our business. While we seek to mitigate risks and liabilities through, among other things, due diligence, we may be exposed to risks and liabilities as a result of business development transactions. There is no assurance that we will be able to enter into strategic business relationships on favorable terms with desired positive outcomes that are accretive to our business.

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

As of September 30, 2025, we had 36 full-time employees. We expect to experience continued growth in the number of our employees and the scope of our operations, particularly in the areas of drug development and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a public company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

Our business and operations are subject to risks related to climate change.

The long-term effects of global climate change present risks to our business. Extreme weather or other conditions caused by climate change could adversely impact our supply chain and the operation of our business, which is

geographically subject to higher incidents of climate events (such as hurricanes and other aggressive weather patterns). Such conditions could result in physical damage to our Miramar headquarters, clinical trial materials, clinical sites, or the facilities of our third-party manufacturing partners. These events could adversely affect our operations and our financial performance. The potential impacts of climate change may also include increased operating costs associated with additional regulatory requirements and investments in reducing energy, water use and greenhouse gas emissions.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability.

Since our inception, we have devoted most of our financial resources and all of our efforts to research and development, including preclinical studies and our clinical trials, and have incurred significant operating losses. In addition, the Company and Dr. Wong, our Founder and Chief Executive Officer, were parties in an extended arbitration, which was ongoing for over a year, during which time the Company recognized legal fees of nearly $22.0 million, net of $2.0 million insurance reimbursement, for its own defense and the defense of Dr. Wong. For the nine months ended September 30, 2024 and 2025, we reported a net loss of $26.7 million and $8.7 million, respectively. These losses are inclusive of reserve for credit losses and other expenses of $1.3 million and nil for the nine months ended September 30, 2024 and 2025, respectively. As of September 30, 2025, we had $1.1 million in cash and cash equivalents, in the balance sheet of our unaudited financial statements included in the Quarterly Report. From inception to September 30, 2025, we incurred cumulative net losses of $106.5 million. To date, we have financed our operations primarily through the sale of our redeemable preferred stock (all of which converted to Common Stock upon the effective date of our initial public offering, or IPO); payments received under our exclusive worldwide license (the “Wugen License”) with Wugen, Inc. (“Wugen”) for certain rights to two of our internally-developed molecules; proceeds from our IPO; a first lien mortgage of $6.5 million; proceeds from a Paycheck Protection Program (“PPP”) loan obtained through the Coronavirus Aid, Relief and Economic Security Act (which was forgiven); issuance of senior secured notes; and sale of Common Stock and warrants in private placements and direct registered offerings. Based on our current operating plans, we believe that our cash and cash equivalents as of September 30, 2025, will not be sufficient for the Company to continue as a going concern for at least one year from the issuance date of the financial statements appearing in the Quarterly Report.

Our losses have resulted principally from expenses incurred in the research and development of our product candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure, as well as from the significant expenses we have incurred defending ourselves in the prior dispute with Altor/NantCell and advancing legal expenses of Dr. Wong, each as described further below. We expect to continue to incur significant operating losses for the foreseeable future. The only revenue we have generated to date relates to the clinical material supply agreement and our Wugen License, which, upon a request from Wugen, we voluntarily suspended for a period of one year beginning on May 29, 2025 (during which time we have the right to terminate the license in order to enter other business development transactions related to the licensed molecules). We are currently in active discussions for a license agreement with major biologics manufacturing companies who are interested in licensing molecules to use as reagents in the manufacturing process for CAR-T therapies. We have not generated any revenues from product sales. We anticipate that our expenses will increase substantially as we initiate preclinical and clinical studies, scale up our manufacturing process and capabilities to support our clinical studies and grow to scale.

We have no products for which we have obtained marketing approval and have not generated any revenue from product sales. Even if we obtain marketing approval for, and are successful in commercializing, one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays, and other

unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

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

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

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

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

Our operations have consumed significant amounts of cash since inception. As of June 30, 2025, we held $2.4 million of cash and cash equivalents and there was substantial doubt about our ability to continue as a going concern for at least 12 months from the issuance date of the financial statements appearing in the Annual Report. We expect our expenses to increase in connections with our ongoing clinical development activities, particularly as we continue to initiate clinical trials of, and seek marketing approval for, our product candidates.

In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding for our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to:

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

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our technologies or product candidates, we will seek to finance our future

cash needs through equity offerings, royalty-based or debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of Common Stock, convertible securities or other equity securities, stockholders' interests may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect our stockholders' rights. In addition, new debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that further limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, which could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect their ability to oversee the development and potential future commercialization of our product candidates.

If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

On August 19, 2025, we received a written notice from the Nasdaq Listing Qualifications Staff that as of June 30, 2025, we were not in compliance with Listing Rule 5550(b)(1) and our securities would be suspended from trading unless we request a hearing by August 26, 2025. We timely requested a hearing on August 16, 2025 and took place before the Nasdaq Hearings Panel on September 25, 2025. The Company is in the process of implementing the compliance plan, including filing the registration statement that includes this prospectus, and the Company is considering all other options available to it to regain compliance with the Equity Rule; however, there can be no assurance that the Panel will grant the Company's request for continued listing or that the Company will be able to evidence compliance within the period of time that may be required by the Panel.

On June 26, 2025, we received formal notice from the Nasdaq Listing Qualifications Staff (the "Staff") that we were in compliance with the Equity Rule for continued listing of our securities on the Nasdaq Capital Market tier. We were also notified that we 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. If, during the term of the Panel Monitor, we do not continue to remain in compliance with the Equity Rule, we will not be provided with the opportunity to submit a compliance plan for review by the Staff and must instead request a hearing before the Nasdaq Hearing Panel (the "Panel") to address the deficiency, with such request staying any further action with respect to the listing of our securities on Nasdaq pending completion of the hearing process.

On August 19, 2025, we received written notice from the Staff that as of June 30, 2025, we were non-compliant with the Equity Rule, so our securities would be suspended from trading on Nasdaq on August 28, 2025 unless we request a hearing by August 26, 2025. On August 26, 2025, we timely requested a hearing before the Panel, which stayed the suspension of trading of our securities on Nasdaq pending completion of the hearing process, which included a hearing held before the Panel on September 25, 2025 at which the Company presented a detailed compliance plan, including the filing of the registration statement that includes this prospectus and the offering contemplated herein. On October 13, 2025, the Panel granted the Company an extension of time in which to regain compliance with all continued listing rules of the Exchange. The Panel granted the Company's request for continued listing on the Nasdaq, subject to, among other things, the Company demonstrating compliance with the Equity Rule by December 31, 2025, and with all other Nasdaq continued listing rules by February 16, 2026. The Company was advised that February 16, 2026 represents the outer limit of the Panel's discretionary authority to permit continued listing during the Company's period of non-compliance 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 was required to timely file Form 10-Q for the third quarter (which it did) and to 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.

The Company is in the process of implementing the compliance plan presented at the hearing and is considering all other options available to it to regain compliance with the Equity Rule; however, there can be no assurance that the Panel will grant our request for continued listing or that we will be able to evidence compliance within the period of time that may be required by the Panel.

The Company's balance sheet has liabilities that will require payment, and use of funds for this purpose will make less funding available for operations and clinical development.

Included in the Company's balance sheet as of September 30, 2025, are $19.4 million of obligations included in accounts payable that represent amounts past due. These include $12.3 million due for legal fees incurred as a result of mounting a defense for the Company and our Chief Executive Officer in a long-running arbitration proceeding that was settled on July 13, 2024. In January 2025, we received a $2.0 million insurance payment which was used to offset obligations for legal fees for the defense of our Chief Executive Officer incurred in connection with an arbitration related to claims made by ImmunityBio and its affiliates, which was settled in July 2024 and dismissed as of December 31, 2024. Also included in outstanding obligations is $2.7 million of obligations included in accounts payable for amounts owed for construction of a manufacturing facility that the Company is building at a property it owns in Miramar, Florida (the "Property"). As of September 30, 2025, certain subcontractors had filed mechanics liens related to unpaid invoices issued in connection with the facility. 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. To our knowledge as of the date hereof, 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 and filed a timely response to the B&I MSJ. The cases are being consolidated. A pretrial conference is set for November 20, 2026, and the case is set for a jury trial in the first two weeks of December 2026.

Risks Related to Ownership of Our Common Stock

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

The market price of our Common Stock may be highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. The market price of our Common Stock may

fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors described in this "Risk Factors" section included in the Annual Report.

Our principal stockholders and management own a meaningful percentage of our stock, which may allow them to influence matters subject to stockholder approval.

As of September 30, 2025, our executive officers, directors and their respective affiliates beneficially owned approximately 23.5% of our outstanding voting stock (excluding any warrants that may be exercised for shares of Common Stock or stock options exercisable within 60 days of such date held by such persons). Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to impact all matters requiring stockholder approval, in matters where they are eligible to vote. For example, these stockholders may be able to control or influence elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Common Stock that you may feel are in your best interest as one of our stockholders.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

To date, we have not completed any clinical trials required for the approval of our product candidates. We may experience delays in our clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time, or be completed on schedule, if at all. These clinical trials can be delayed, suspended, or terminated for a variety of reasons, including but not limited to delays in or failure to obtain regulatory authorization to commence a trial and IRB approval at each site, to reach agreement on acceptable terms with prospective clinical trial sites, or to recruit and enroll suitable patients to participate in a trial. In addition, the results of preclinical and early clinical trials of our product candidates may not be predictive of the results of our later-stage clinical trials. For example, while we may believe certain results in patients, such as stable disease, suggest encouraging clinical activity, stable disease is not considered a response for regulatory purposes in an endpoint assessing objective response rate. In addition, even if the regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or similar application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs.

Clinical trials must be conducted in accordance with the FDA's and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs or Ethics Committees at the medical institutions where the clinical trials are conducted. We could encounter delays if a clinical trial is put on hold by the FDA or other regulatory authorities, suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted or by the Data Review Committee or Data Safety Monitoring Board for such trial. For example, in November 2024, the FDA placed a full clinical hold on the Phase 1 study of HCW9302 due to insufficient information regarding chemistry, manufacturing and controls, which prevented us from initiating the study until the FDA lifted the clinical hold in January 2025 after finding our complete response to be satisfactory. If we experience further delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP requirements and other regulations. Furthermore, we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions to conduct

our clinical trials in compliance with GCP requirements. To the extent our collaborators fail to enroll participants for our clinical trials, fail to conduct the study in accordance with GCP, or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, and additional regulatory requirements, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening, and medical care.

Our lead product candidate, HCW9302, has been cleared by the FDA to initiate a first-in-human Phase 1 dose escalation clinical trial to evaluate HCW9302 in patients with moderate-to-severe alopecia areata, a common autoimmune disease in humans that currently has no curative FDA-approved treatments. On November 17, 2025, the first patient was dosed at The Ohio State University clinical sites. Our ability to advance development of HCW9302 depends on timely completion of current clinical studies, successfully meeting those studies' objectives, including dose finding and/or optimization for the Phase 2 evaluation, and obtaining FDA authorization to proceed to Phase 2 trials. If the FDA does not allow our Phase 2 clinical trials to proceed, we may be required to undertake additional IND-enabling activities or dose finding activities, which would result in further delay and additional costs. If we experience delays in the progression and completion of our clinical trials for HCW9302, or if we terminate a clinical trial prior to completion, the commercial prospects of such product candidate could be harmed, and our ability to generate revenues from the product candidate may be delayed. In addition, any delays in our clinical trials would require us to store material which could expose us to inventory risk, increased costs, slow down in development and approval process, as well as jeopardize our ability to commence product sales and generate revenues. Significant delays in the completion of the clinical trial could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates and may harm our business and results of operations.

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

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

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

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

or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any product candidate; and a decline in our share price.

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

Risks Related to Our Regulatory Environment

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

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

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

Our product candidates could fail to receive regulatory approval for many reasons including but not limited to flaws in trial design, dose selection, patient enrollment criteria and failure to demonstrate an acceptable risk: benefit profile. In addition, data obtained from clinical trials is susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. The FDA and other regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. As a result, we may be required to conduct additional preclinical studies, alter our proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which we hope to conduct clinical trials and develop and market our products, if approved. Further, even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

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

If we decide to pursue accelerated approval for any of our product candidates, it may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that it will receive marketing approval. If we are unable to obtain approval under an accelerated pathway, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and/or delay the timing of obtaining, necessary marketing approvals.

In the future, we may decide to pursue accelerated approval for one or more of our product candidates. Under the FDA's accelerated approval program, the FDA may approve a drug or biologic for a serious or life- threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Many cancer therapies rely on accelerated approval, and the treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials.

For drugs or biologics granted accelerated approval, post-marketing confirmatory trials are required to describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence, and, in some cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to approval.

Moreover, the FDA may withdraw approval of any product candidate approved under the accelerated approval pathway if, for example:

- the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with such product;
- other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use;
- we fail to conduct any required post-approval trial of our product candidate with due diligence; or
- we disseminate false or misleading promotional materials relating to the relevant product candidate.

In addition, the FDA may terminate the accelerated approval program or change the standards under which accelerated approvals are considered and granted in response to public pressure or other concerns regarding the accelerated approval program. Changes to or termination of the accelerated approval program could prevent or limit our ability to obtain accelerated approval of any of our clinical development programs. Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. In addition, the Oncology Center of Excellence has announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in

approval and post-marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies.

The recent enactment of FDORA included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post-approval study and requires sponsors to submit progress reports for required post-approval studies and any conditions required by the FDA. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post-approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports.

There is substantial uncertainty regarding the new Administration's initiatives and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. Similar initiatives may also be directed toward other government agencies. These initiatives could prevent, limit or delay development and regulatory approval, and/or impact commercialization, of our product candidates, which would impact our business.

FDA-regulated industries, such as ours, face substantial uncertainty regarding the regulatory environment we will face as we proceed with research and development, and possibly in future commercialization, efforts following the inauguration of President Trump in January 2025 (the "Administration"). Some of these efforts have manifested to date in the form of personnel measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays in or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. Moreover, the new Administration has proposed action to freeze or reduce the budget of the National Institutes of Health ("NIH") as related to its funding for medical research, which could decrease the ability of facilities that rely on NIH funding to enroll and conduct clinical trials or increase the costs to us of conducting clinical trials. There remains general uncertainty regarding future activities. The new Administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development and sale of new therapeutic products. For example, on January 20, 2025, President Trump announced an executive order establishing the Department of Government Efficiency to maximize government efficiency and productivity. Pressures on and uncertainty surrounding the U.S. federal government's budget and potential changes in budgetary priorities could adversely affect the funding for existing programs and grants and increase the costs to us of conducting clinical trials. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we or our collaborators become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the new Administration, there could be a material adverse effect on us and our business.

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

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

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

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

In addition, if we have any product candidate approved, our product labeling, advertising, and promotion will be subject to regulatory requirements and continuing regulatory review. In the United States, the FDA and the Federal Trade Commission ("FTC"), strictly regulate the promotional claims that may be made about pharmaceutical products to ensure that any claims about such products are consistent with regulatory approvals, not misleading or false in any particular way, and adequately substantiated by clinical data. The promotion of a drug product in a manner that is false, misleading, unsubstantiated, or for unapproved (or off-label) uses may result in enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or the FTC. In particular, a product may not be promoted for uses that are not consistent with the uses approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions and may result in false claims litigation under federal and state statutes, which can lead to consent decrees, civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid, and other federal and state healthcare programs. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

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

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. We may also encounter unexpected delays or

increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any. For example, the Oncology Center of Excellence within the FDA has advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate's dose-response relationship to facilitate optimum dose selection in a target population. Other recent Oncology Center of Excellence initiatives have included Project FrontRunner, a new initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options; Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post-marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies; and Project Equity, which is an initiative to ensure that the data submitted to the FDA for approval of oncology medical products adequately reflects the demographic representation of patients for whom the medical products are intended. More recently, as part of FDORA, sponsors will be required to submit Diversity Action Plans ("DAPs") for Phase 3 studies or other pivotal studies of new drugs. DAPs must include the sponsor's goals for enrollment for such studies, disaggregated by age group, sex, and racial and ethnic demographic characteristics of clinically relevant study populations; the sponsor's rationale for such goals; and an explanation of how the sponsor intends to meet such goals. Actions taken in the early days of the new presidential administration have created significant uncertainty as to whether Project Equity will continue and whether the statutory requirements related to DAPs will be implemented by FDA in the near future. We are considering these and other policy changes as they relate to our programs.

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

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

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of

operations, and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. Further, defending against any such actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Our current and future relationships with customers and third-party payors may be subject to applicable anti- kickback, fraud and abuse, transparency, health privacy, and other healthcare laws and regulations, which could expose us to significant penalties, including criminal, civil, and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as, market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations that may be applicable to our business include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal civil false claims laws, including the False Claims Act, which can be enforced by civil whistleblower or qui tam actions on behalf of the government, and criminal false claims laws and the civil monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government;
- HIPAA, as amended by HITECH, and their implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information;
- Analogous state laws and regulations such as state anti-kickback and false claims laws and analogous non-U.S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, including price increases. State and local laws require the registration of pharmaceutical sales representatives.

Efforts to ensure that our internal business processes and business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations

or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil and administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Furthermore, government shutdowns could also impact the ability of regulatory authorities and government agencies to function normally and support our operations. For example, the U.S. federal government has shut down repeatedly since 1980, including for a period of 35 days beginning on December 22, 2018. During a shutdown, certain regulatory authorities and agencies, such as the FDA, have had to furlough key personnel and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In addition, in the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. Previously, in March 2010, the ACA was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Healthcare reform initiatives culminated in the enactment of the IRA in August 2022, which, among other things, allows HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. The negotiated price may not exceed a statutory ceiling price. Only high-expenditure single-source drugs that have been approved for at least 11 years for single-source biologics (7 years for single-source drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, the first year in which negotiated prices become effective, CMS selected 10 high-cost Medicare Part D products in 2023, negotiations began in

2024, and the negotiated maximum fair price for each product has been announced. These negotiations resulted in significant price reductions for the products from their 2023 list prices, ranging from 38 to 79 percent, with an average price reduction of 59.4 percent. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, 20 Part B or Part D drugs will be selected. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The negotiated prices have represented, and will continue to represent, a significant discount from average prices to wholesalers and direct purchasers. The law also imposes rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation, and in November 2024, CMS finalized regulations for these inflation rebates. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high- expenditure single-source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry.

At the state level in the United States, legislatures are increasingly enacting laws and implementing regulations designed to control pharmaceutical and biologic product pricing, including price constraints, restrictions on certain product access, reporting on price increases and the introduction of high-cost drugs. In some states, laws have been enacted to encourage importation of lower cost drugs from other countries and bulk purchasing. For example, the FDA released a final rule in September 2020 providing guidance for states to build and submit plans for importing drugs from Canada, and FDA authorized the first such plan in Florida in January 2024. The authorization, which was originally set to expire in November 2025, has since been extended to November 2026. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drug products that we successfully commercialize or put pressure on our product pricing.

We expect that the ACA, the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

Risks Related to Commercialization of Our Product Candidates

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

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop, and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large

pharmaceutical and biotechnology companies, academic institutions, government agencies, and other public and private research organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and marketing of products that compete with our product candidates. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards relating to methods, facilities, and controls used in the manufacturing, processing, and packing of the product, which are intended to ensure that biological products are safe and that they consistently meet applicable requirements and specifications.

If the FDA or a comparable foreign regulatory authority does not approve the manufacture of our product candidates at any of our proposed contract manufacturer's facilities, or if any contract manufacturer fails to maintain a compliance status acceptable to the FDA or a comparable foreign authority, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. Any discovery of problems with a product, or a manufacturing facility used by us, may result in restrictions on the product or on the manufacturing facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. We may have little to no control regarding the occurrence of third-party manufacturer incidents.

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

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

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

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. The manufacturing capabilities of our suppliers have been impacted as a result of ongoing supply chain delays, and it may not be possible for us to timely manufacture our product candidates at desired levels. Reduced supply may also lead to increased costs for materials, which can adversely impact our business and results of operations There are a limited number of suppliers for raw materials that we use to manufacture our product candidates, and there may be a need to assess alternate suppliers to prevent a

possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. Reductions or interruptions in any of our third- party manufacturing processes as a result of supply chain delays caused global conflicts, public health emergencies (including a resurgence of a variant of the COVID-19 pandemic or future pandemic) or other reasons could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

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

We currently rely, and expect to continue to rely on, third parties, including independent clinical investigators, to conduct our preclinical studies and clinical trials and to monitor and manage data for our preclinical and clinical programs. We will rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, our reliance on these third parties will not relieve us of our regulatory responsibilities, and we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, including GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators, and trial sites. If we fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for technology related to our product candidates, including, but not limited to, our immunotherapy platform technology, product candidates, methods used to manufacture those product candidates, formulations thereof, and the methods for treating patients using those product candidates. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel platform technology and product candidates that are important to our business. The patent prosecution process is expensive and time-consuming, and we may not be able to prepare, file, and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, during the patent prosecution process, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections.

The issuance, scope, validity, enforceability, and commercial value of our current or future patent rights are highly uncertain. It is possible that we will fail to identify patentable aspects of inventions made in the course of

development and commercialization activities before it is too late to obtain patent protection on them. Our pending and future patent applications may not result in the issuance of patents that protect our technology or product candidates, in whole or in part, or that effectively prevent others from commercializing competitive technologies and product candidates. The patent examination process may require us to narrow the scope of the claims of our pending and future patent applications, which may limit the scope of patent protection that may be obtained. Further, even if we obtain patents with sufficient scope to protect our technology or product candidates in their present forms, future technical changes to our technology or product candidates may render the patent coverage inadequate.

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

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

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

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

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

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

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

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

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

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

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding

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

In addition, indemnity provisions in various agreements and our corporate documents potentially expose us to substantial liability for intellectual property infringement and other claims. In the ordinary course of business, we enter into agreements that may include indemnification provisions under which we agree to indemnify them for losses suffered or incurred as a result of claims of intellectual property infringement or other liabilities relating to or arising from our clinical trials, breach of warranties or other contractual obligations. In some cases, the indemnification will continue after the termination of the applicable agreement. In addition, in accordance with our bylaws and pursuant to indemnification agreements entered into with directors, officers and certain employees, we have indemnification obligations for claims brought against these persons arising out of certain events or occurrences while they are serving at our request in such capacities. For example, our founder and chief executive officer is subject to a claim from a former employer. We agreed to advance certain defense costs and other expenses, subject to an undertaking to repay us such amounts if, and to the extent that, it is ultimately determined that he is not entitled to indemnification, and his former employer is seeking reimbursement from us for advancements it has made on his behalf. The matter is ongoing. If these matters are resolved in favor of the former employer and if we are required to indemnify our founder and chief executive officer for a loss, we may be required to make an indemnity payment. While we maintain directors' and officers' liability insurance, such insurance may not be applicable, be adequate, or cover all liabilities that we may incur. Large indemnity payments, individually or in the aggregate, could have a material impact on our financial position.

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

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

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

Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use, or sell our product candidates or any products, if approved, the growth of our business will

likely depend in part on our ability to acquire, in-license, maintain, or use these proprietary rights. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

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

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. Disputes challenging our rights in or to patents or other intellectual property, such as the lawsuit as we faced in our legal proceedings with Altor/NantCell in 2024, have been and could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own. In addition, interferences, post-grant proceedings, opposition proceedings, derivation proceedings, or other intellectual property proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications.

The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

In addition to seeking patents for some of our technology and product candidates, we may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value, to maintain our competitive position with respect to our research programs and product candidates. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees or by other third parties of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus adversely

eroding our competitive position in our market. Further, monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our internally developed technology will be effective. Enforcing a claim that a third party illegally obtained and is using trade secrets and/or confidential know-how is also expensive, time-consuming, and unpredictable.

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

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

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

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

Many of our employees, including our senior management, were previously employed at universities or at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure, and non-competition agreements in connection with such previous employment. Similarly, we work with consultants, contractors, collaborators, advisors, or other third parties who have worked with, and do currently work with, other companies, including our competitors or potential competitors, and have executed proprietary rights, non-disclosure, and non-competition agreements in connection with such other companies. Although we try to ensure that our employees, consultants, contractors, collaborators, advisors, or other third parties do not use or disclose the proprietary information or know-how of others in their work for us, we are and may become subject to claims that we or these employees or individuals that we work with have used or disclosed confidential information or intellectual property of others, including trade secrets or other proprietary information, or that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement with a current or former employer or competitor.

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

Risks Related to Data Privacy and Cybersecurity

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

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

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

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

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

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

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

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

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

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

Other Risks Related to an Investment in our Company

We are an emerging growth company, and the reduced reporting requirements applicable to emerging growth companies may make our Common Stock less attractive to investors.

We are an emerging growth company and are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies,

including, but not limited to, only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 reduced disclosure obligations regarding executive compensation in this Prospectus and our periodic reports and proxy statements, exemptions from the requirements of holding non-binding advisory votes on executive compensation and seeking stockholder approval of any golden parachute payments not previously approved and not being required to adopt certain accounting standards until those standards would otherwise apply to private companies. We could be an emerging growth company until the last day of the fiscal year following the fifth anniversary of this offering, although circumstances could cause us to lose that status earlier, including if we become a large accelerated filer (in which case we will cease to be an emerging company as of the date we become a large accelerated filer, which, generally, would occur if, at the end of a fiscal year, among other things, the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter), if we have total annual gross revenue of $1.235 billion or more during any fiscal year (in which cases we would no longer be an emerging growth company as of March 31 of such fiscal year), or if we issue more than $1.0 billion in non-convertible debt during any three year period before that time (in which case we would cease to be an emerging growth company immediately). Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

Our Common Stock price may be volatile and as a result you could lose all or part of your investment.

In addition to volatility associated with equity securities in general, the value of your investment could decline due to the impact of any of the following factors upon the market price of our shares of Common Stock:

- disappointing results from our development efforts;
- decline in demand for our shares of Common Stock;
- downward revisions in securities analysts' estimates or changes in general market conditions;
- technological innovations by competitors or in competing products;
- investor perception of our industry or our prospects; and
- general economic trends.

Stock markets in general have experienced extreme price and volume fluctuations, and the market prices of securities have been highly volatile. These fluctuations are often unrelated to operating performance and may adversely affect the market price of our shares of Common Stock.

Potential future sales pursuant to registration rights granted by the Company and under Rule 144 may depress the market price for our shares of Common Stock.

The Company has granted a number of its stockholders' registration rights with respect to their shares of Common Stock. Such future sales of our shares of Common Stock by our existing stockholders, pursuant to and in accordance with the provisions of any registration statement, may have a depressive effect on the market price of our shares of Common Stock. Further, in general, under Rule 144 under the Securities Act, a person who has satisfied a minimum holding period of between six months and one-year and any other applicable requirements of Rule 144, may thereafter sell such shares publicly. A significant number of our currently issued and

outstanding shares of Common Stock held by existing stockholders, including officers and directors and other principal stockholders are currently eligible for resale pursuant to and in accordance with the provisions of Rule 144. The possible future sale of our shares by our existing stockholders, pursuant to and in accordance with the provisions of Rule 144, may have a depressive effect on the price of our Shares of Common Stock in the applicable trading marketplace.

Financial Industry Regulatory Authority, Inc. ("FINRA") has adopted sales practice requirements that may also limit a stockholder's ability to buy and sell our Common Stock.

FINRA has adopted rules that require that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative, low-priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our shares of Common Stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares of Common Stock.

We face risks related to compliance with corporate governance laws and financial reporting standards.

The Sarbanes-Oxley Act, as well as related rules and regulations implemented by the SEC and the Public Company Accounting Oversight Board ("PCAOB"), require changes in the corporate governance practices and financial reporting standards for public companies. These laws, rules and regulations, including compliance with Section 404 of the Sarbanes-Oxley Act relating to internal control over financial reporting, referred to as Section 404, materially increased our legal and financial compliance costs and made some activities more time- consuming and more burdensome.

Risks Related to Securities Markets and Investment in Our Stock

Nasdaq may delist our securities from trading on its exchange.

Our Common Stock is listed on Nasdaq. We cannot assure you that our securities will continue to be listed on Nasdaq in the future. The inability to comply with Nasdaq's continued requirements or standards could result in the delisting of our Common Stock, which could have a material adverse effect on our financial condition and could cause the value of the Common Stock to decline.

If our Common Stock were to be delisted from trading on Nasdaq and the trading price of our Common Stock were below $5.00 per share on the date the Common Stock is delisted, trading in our Common Stock would also be subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a "penny stock" and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

Volatility in the Company's share price could subject the Company to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. If the Company faces such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm its business.

A "short squeeze" due to a sudden increase in demand for shares of our Common Stock that largely exceeds supply and/or focused investor trading in anticipation of a potential short squeeze have led to, may be currently leading to, and could again lead to, extreme price volatility in shares of our Common Stock.

Investors may purchase shares of our Common Stock to hedge existing exposure or to speculate on the price of our Common Stock. Speculation on the price of our Common Stock may involve long and short exposures. To the extent aggregate short exposure exceeds the number of shares of our Common Stock available for purchase on the open market, investors with short exposure may have to pay a premium to repurchase shares of our Common Stock for delivery to lenders of our Common Stock. Those repurchases may, in turn, dramatically increase the price of shares of our Common Stock until additional shares of our Common Stock are available for trading or borrowing. This is often referred to as a "short squeeze." With the recent substantial increase in volume of our shares being traded and trading price, the proportion of our Common Stock that may be traded in the future by short sellers may increase the likelihood that our Common Stock will be the target of a short squeeze. A short squeeze and/or focused investor trading in anticipation of a short squeeze have led to, may be currently leading to, and could again lead to volatile price movements in shares of our Common Stock that may be unrelated or disproportionate to our financial performance or prospects and, once investors purchase the shares of our Common Stock necessary to cover their short positions, or if investors no longer believe a short squeeze is viable, the price of our Common Stock may rapidly decline. Investors that purchase shares of our Common Stock during a short squeeze may lose a significant portion of their investment. Under the circumstances, we caution you against investing in our Common Stock, unless you are prepared to incur the risk of losing all or a substantial portion of your investment.

Increases in market interest rates may cause potential investors to seek higher returns and therefore reduce demand for our Common Stock, which could result in a decline in our stock price.

One of the factors that may influence the price of our Common Stock is the return on our Common Stock (i.e., the amount of distributions as a percentage of the price of our Common Stock) relative to market interest rates. An increase in market interest rates, which are currently at low levels relative to historical rates, may lead prospective purchasers of our Common Stock to expect a return, which we may be unable or choose not to provide as we have never paid a dividend and have no current intention to pay any dividends. Further, higher interest rates would likely increase our borrowing costs and potentially decrease the cash available. Thus, higher market interest rates could cause the market price of our Common Stock to decline.

If securities or industry analysts do not publish research or reports about the Company, or publish negative reports, the Company's share price and trading volume could decline.

The trading market for the Company's shares of Common Stock will depend, in part, on the research and reports that securities or industry analysts publish about the Company. The Company does not have any control over these analysts. If the Company's financial performance fails to meet analyst estimates or one or more of the analysts who cover the Company downgrade its shares of Common Stock or change their opinion, the Company's share price would likely decline. If one or more of these analysts cease coverage of the Company or fail to regularly publish reports on the Company, it could lose visibility in the financial markets, which could cause the Company's share price or trading volume to decline.

Volatility in the price of our Common Stock may subject us to securities litigation.

As discussed above, the market for our Common Stock has been characterized recently by significant price volatility when compared to seasoned issuers, and we expect that our share price will continue to be more volatile than a seasoned issuer for the indefinite future. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

Because the Company does not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

The Company currently anticipates that it will retain future earnings for the development, operation and expansion of its business and does not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of the Company's shares of Common Stock would be your sole source of gain on an investment in such shares for the foreseeable future.

The Company's share price has fluctuated historically and may continue to fluctuate.

The Company's share price can be volatile. Among the factors that may affect the volatility of the Company's stock price are the following:

- Speculation in the investment community or the press about, or actual changes in, the Company's competitive position, organizational structure, executive team, operations, financial condition, financial reporting and results, expense discipline, strategic transactions, or progress on achieving expected benefits;
- The announcement of new products, services, acquisitions, or dispositions by the Company or its competitors;
- Increases or decreases in revenue or earnings, changes in earnings estimates by the investment community, and variations between estimated financial results and actual financial results; and
- Sales of a substantial number of shares of the Company's shares of Common Stock by large shareholders.

Future offerings of debt, which would be senior to our Common Stock upon liquidation, and/or preferred equity securities, which may be senior to our Common Stock for purposes of distributions or upon liquidation, could adversely affect the market price of our Common Stock.

In the future, we may attempt to increase our capital resources by making additional offerings of debt or preferred equity securities, including convertible or non-convertible senior or subordinated notes, convertible or non-convertible preferred stock, medium-term notes and trust preferred securities. Upon liquidation, holders of our debt securities and shares of preferred stock and lenders with respect to other borrowings will receive distributions of our available assets prior to the holders of our Common Stock. In addition, any preferred stock we may issue could have a preference on liquidating distributions or a preference on distribution payments that could limit our ability to make a distribution to the holders of our Common Stock. Since our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings. Thus, our stockholders bear the risk of our future offerings reducing the market price of our Common Stock.

Anti-takeover provisions contained in our charter and bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our charter contains provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. We are also subject to anti-takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions will include:

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the right of our Board to elect a director to fill a vacancy created by the expansion of our Board or the resignation, death, or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on our Board; and

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders.

Our charter provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our charter provides that, subject to limited exceptions, any (i) derivative action or proceeding brought on our behalf of under Delaware law, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee of HCWB's stockholders, (iii) any action asserting a claim against HCWB or any of its directors, officers or other employees arising pursuant to any provision of the DGCL, the charter or the bylaws of HCWB (in each case, as may be amended from time to time), (iv) any action asserting a claim against HCWB or any of its directors, officers or other employees governed by the internal affairs doctrine of the State of Delaware or (v) any other action asserting an "internal corporate claim," as defined in Section 115 of the DGCL, in all cases subject to the court's having personal jurisdiction over all indispensable parties named as defendants shall, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have subject matter jurisdiction thereof, another state or federal court located within the State of Delaware. The charter also provides that unless a majority of the Board of HCWB, acting on behalf of HCWB, consents in writing to the selection of an alternative forum (which consent may be given at any time, including during the pendency of litigation), the federal district courts of the United States of America, to the fullest extent permitted by law, will be the sole and exclusive forum for the resolution of any action asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of HCWB's capital stock shall be deemed to have notice of and to have consented to the provisions of HCWB's certificate of incorporation described above. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with HCWB or its directors, officers, or other employees, which, along with potential increased costs of litigating the courts provided by the choice of forum provision, may discourage such lawsuits against HCWB and its directors, officers, and employees. Alternatively, if a court were to find these provisions of HCWB's amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, HCWB may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect HCWB's business and financial condition.

THE SECURED NOTE FINANCING AND NOTEHOLDER TRANSACTION

General

As of October 31, 2024, we issued an aggregate of approximately $6.9 million in principal amount of senior secured promissory notes to a group of accredited investors (the "Secured Notes"). Of this amount, approximately $2.9 million of Secured Notes were purchased by members of our board of directors and executive officers. The Secured Notes bear interest at a rate of 9% per annum, payable quarterly in arrears, and mature on March 27, 2026, at which time all outstanding principal and accrued but unpaid interest becomes due. The Secured Notes may be prepaid in whole or in part at any time prior to maturity, subject to a 5% prepayment premium. The Secured Notes are secured by a pledge of our equity interest in Wugen, Inc. (the "Pledged Collateral").

Terms of the Secured Notes

The Secured Notes were issued pursuant to a note purchase agreement that, among other things, provides the holders with rights to receive repayment upon certain corporate transactions in which the Pledged Collateral may be sold or otherwise liquidated, subject to specified conditions, and provides customary notice and cure periods following an event of default. Upon an uncured event of default, we would be required to distribute the Pledged Collateral to the noteholders on a pro rata basis, in full satisfaction of the indebtedness under the Secured Notes.

Conversion of Secured Notes and Issuance of Conversion Shares and Conversion Warrants

On May 1, 2025, we entered into a Second Amendment to the Secured Note purchase agreement (the "Conversion Amendment"), which was approved by our stockholders at a special meeting held on March 31, 2025. Pursuant to the Conversion Amendment, the holders of approximately $6.6 million in aggregate principal amount of the Secured Notes agreed to convert their Secured Notes into equity. On May 7, 2025, we cancelled the outstanding Secured Notes held by the participating noteholders and issued to them (i) an aggregate of 253,083 unregistered Conversion Shares and (ii) Conversion Warrants to purchase an aggregate of 126,540 additional shares of our Common Stock at an exercise price of $26.00 per share. The Conversion Shares were subject to a 180-day lock-up period, which has since expired.

The Conversion Shares and the shares issuable upon exercise of the Conversion Warrants are being registered for resale by the noteholders pursuant to the registration rights granted in the Conversion Amendment.

Selling Stockholders Associated with the Secured Note Financing

The selling stockholders who were parties to the Secured Note Financing include certain holders of the Secured Notes who received Conversion Shares and Conversion Warrants upon the conversion of their Secured Notes. These selling stockholders may, from time to time, resell the Conversion Shares and the shares issuable upon exercise of the Conversion Warrants in accordance with this prospectus.

THE ARMISTICE TRANSACTION

General

On November 18, 2024, we entered into a securities purchase agreement with Armistice pursuant to which HCWB agreed to offer and sell (i) in a registered direct offering (x) 104,000 shares of our Common Stock and (y) pre-funded warrants to purchase up to 63,925 shares of Common Stock and (ii) in a concurrent private placement, an unregistered warrant to purchase up to an aggregate of 167,925 shares of our Common Stock (the "Purchase Warrant") with an exercise price of $41.20 per share. The combined purchase price for each share of Common Stock and accompanying Purchase Warrant to purchase one share of Common Stock was $41.20 per share and the combined purchase price for each Pre-Funded Warrant and accompanying Purchase Warrant to purchase one share of Common Stock was $41.1999. On the closing date of November 20, 2024, Armistice exercised all the Pre-Funded Warrants at an exercise price of $0.0001 per share of Common Stock.

The Common Stock and Pre-Funded Warrants were each sold with an accompanying Purchase Warrant to purchase one share of Common Stock, and the Common Stock and pre-funded warrants were immediately separated from the Purchase Warrant and were issued separately. The Purchase Warrant has an exercise price of $41.20 per share, were exercisable immediately, and expire on the five-year anniversary of the date of issuance.

The shares of Common Stock and pre-funded warrants in the registered offering were offered and sold to Armistice pursuant to a shelf registration statement on Form S-3 (File No. 333-266991), which was declared effective by the U.S. Securities and Exchange Commission (the "SEC") on August 26, 2022. That registered offering was made by means of a prospectus supplement filed with the SEC on November 20, 2024, that formed a part of such registration statement. 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 payable by HCWB. That offering closed on November 20, 2024.

The Purchase Warrant described above was offered and sold by HCWB to Armistice in a transaction not involving a public offering exclusively to Armistice, an accredited investor, under Section 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D promulgated thereunder and, along with the shares of our Common Stock underlying such Purchase Warrant ("Warrant Shares"), were not previously registered under the Securities Act or applicable state securities law. We agreed to register the Warrant Shares for resale by Armistice in the event of such exercise. Armistice controlled the timing and amount of any exercise of the Purchase Warrant, and HCWB had no right under the Purchase Warrant to require Armistice to exercise any portion of the Purchase Warrant. The Warrant Shares were registered for resale on April 16, 2025.

On May 15, 2025, we completed a follow-on public offering of an aggregate of 671,140 units at a purchase price of $7.45 per unit priced at-the-market under Nasdaq rules. Each unit consists of one share of Common Stock (or pre-funded warrant in lieu thereof) and two warrants, each to purchase one share of common stock. The warrants had an exercise price of $7.45 per share, are exercisable immediately upon issuance, and expire on the five-year anniversary of the original issuance date. The shares of Common Stock (or pre-funded warrants) and the warrants comprising the units are immediately separable and will be issued separately in the follow-on public offering.

The shares of Common Stock, pre-funded warrants and common stock warrants in the registered offering were offered and sold to Armistice pursuant to a registration statement on Form S-1, as amended (File No. 333-287136), which was declared effective by the SEC on May 13, 2025. The gross proceeds to the Company from the offering were approximately $4.0 million before deducting the placement agent's fees and other offering expenses payable by HCWB. The offering closed on May 15, 2025.In addition, on May 15, 2025, the Company entered into a privately negotiated agreement with the Armistice for the Purchase Warrant to purchase up to 167,925 shares of common stock to reduce the exercise price of the Purchase Warrants from $41.20 per share to $7.45 per share.

Upon completion of these transactions, Armistice held 1,510,205 common stock warrants, which could be exercised for shares of the Company's Common Stock for $7.45 per share.

November 2025 Warrant Inducement and New Warrant Issuance

On November 19, 2025, we entered into a warrant inducement agreement with Armistice (the "Inducement Agreement"), pursuant to which Armistice agreed to immediately exercise in full (i) 167,925 warrants originally issued on November 20, 2024 which were adjusted for the Reverse Stock Split and further amended on May 15, 2025, and (ii) 1,342,280 warrants originally issued on May 15, 2025 (collectively, the "Existing Warrants"). Armistice exercised the Existing Warrants for an aggregate of 1,510,205 shares of our Common Stock at an amended exercise price of $2.66 per share, resulting in gross proceeds to the Company of approximately $4.0 million before fees and expenses. Of these shares, approximately 299,000 were issued at closing, and the remaining 1,211,205 shares were held in abeyance, subject to issuance as and when permitted pursuant to the beneficial ownership limitations contained in the Existing Warrants.

In consideration for the immediate exercise of the Existing Warrants, we issued to Armistice new unregistered Common Stock Purchase Warrants (the "New Warrants") to purchase up to 3,020,410 shares of our Common Stock (the "New Warrant Shares"). The New Warrants have an exercise price of $2.41 per share, are exercisable immediately, and expire five and one-half years after their issuance.

The New Warrants were issued in a private placement pursuant to Section 4(a)(2) of the Securities Act. The New Warrants and the New Warrant Shares have not been registered under the Securities Act, are subject to restrictions in the Inducement Agreement and may not be offered or sold absent an effective registration statement or an applicable exemption from registration.

Pursuant to the Inducement Agreement, we agreed to file a registration statement to register the resale of the New Warrant Shares. Armistice retains sole discretion regarding whether, when, and to what extent it will exercise the New Warrants, and we have no ability to require Armistice to exercise any portion of the New Warrants.

USE OF PROCEEDS

All of the securities offered by this prospectus are being registered for the account of the selling stockholders. We will not receive any proceeds from the sale of these securities by the selling stockholders. We have agreed to pay all costs, expenses, and fees relating to the registration of the securities covered by this prospectus. The selling stockholders will bear all commissions and discounts, if any, attributable to its sale of shares of our Common Stock. We may receive proceeds from any cash exercise of the Conversion Warrants or New Warrants to the extent they are not exercised on a cashless basis. *See the section entitled "Plan of Distribution" of this prospectus for additional information*. The prices at which the shares of Common Stock covered by this prospectus may actually be sold will be determined by the prevailing public market price for shares of our Common Stock, by negotiations between the selling stockholders and buyers of our Common Stock in private transactions or as otherwise described in "Plan of Distribution."

MARKET PRICE OF OUR COMMON STOCK AND DIVIDEND INFORMATION

Market Price of Our Common Stock

Our Common Stock is currently listed on Nasdaq, under the symbol “HCWB”.

On January 6, 2026, the closing sale price of our Common Stock was $1.20 per share.

As of March 25, 2025, there were approximately 3,300 holders of record of our Common Stock. Such numbers do not include beneficial owners holding our securities through nominee names.

Dividend Policy

HCWB does not anticipate paying any cash dividends in the foreseeable future. If HCWB incurs indebtedness in the future to fund its future growth, its ability to pay dividends may be further restricted by the terms of such indebtedness.

BENEFICIAL OWNERSHIP OF SECURITIES

The following table sets forth certain information with respect to the beneficial ownership of our Common Stock as of January 6, 2026, by:

- each stockholder, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of our Common Stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned by them, subject to community property laws where applicable. Shares of our Common Stock subject to stock options that are currently exercisable or exercisable within 60 days of September 30, 2025 are deemed to be outstanding and to be beneficially owned by the person holding the stock options for the purpose of computing the percentage ownership of that person, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Percentage ownership of our Common Stock is based on 3,279,812 shares of our Common Stock outstanding on January 6, 2026. Unless otherwise indicated, the address of each of the individuals and entities named below is c/o HCW Biologics Inc., 2929 N. Commerce Parkway, Miramar, Florida 33025.

Name of Beneficial Owner	Common Stock	Options Exercisable within 60 days	Aggregate Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Directors and Executive Officers				
Hing C. Wong, Ph.D.[1]	501,911	20,000	521,911	15.9%
Peter Rhode, Ph.D.[2]	1,939	1,233	3,172	*
Rebecca Byam[3]	43,010	5,375	48,385	1.5%
Scott T. Garrett[4]	25,505	2,198	27,703	*
Rick S. Greene[5]	2,006	2,198	4,264	*
Lisa M. Giles[6]	896	2,599	3,495	*
All executive officers and directors as a group (7 persons)	581,047	34,853	615,900	18.8%

* Represents beneficial ownership of less than one percent of the outstanding shares of our Common Stock.
(1) Consists of (a) 398,719 shares held directly by Dr. Hing C. Wong and (b) 103,192 shares held by Dr. Hing C. Wong and Ms. Bee Yau Huang.
(2) Consists of 1,939 shares held directly by Peter Rhode.
(3) Consists of 43,010 shares held directly by Rebecca Byam.
(4) Consists of (a) 6,697 shares held by Garrett Capital Partners, LLC. Mr. Garrett is deemed to beneficially own the shares held by Garrett Capital Partners, LLC and (b) 18,808 shares held directly by Mr. Garrett.
(5) Consists of 2,066 shares held directly by Rick S. Greene.
(6) Consists of 896 shares held by Lisa M. Giles Living Trust.

SELLING STOCKHOLDERS

The securities offered under this prospectus may be offered from time to time by the selling stockholders named below or by any of its respective pledgees, donees, transferees or other successors-in-interest. As used in this prospectus, the term "selling stockholder" includes the selling stockholders identified below and any donees, pledgees, transferees or other successors-in-interest selling shares received after the date of this prospectus from the selling stockholders as a gift, pledge or other non-sale related transfer. The selling stockholders named below will acquire the shares of our Common Stock being offered under this prospectus directly from us. We will issue the securities to the selling stockholders in reliance on an exemption from the registration requirements of the Securities Act pursuant to Section 4(a)(2) of the Securities Act and Rule 506 promulgated thereunder.

The following table sets forth as of January 6, 2026: (1) the name of the selling stockholders for whom we are registering shares of our Common Stock under the registration statement of which this prospectus is a part, (2) the number of shares of our Common Stock beneficially owned by the selling stockholder prior to the offering, determined in accordance with Rule 13d-3 under the Exchange Act, (3) the number of shares of our Common Stock that may be offered by the selling stockholders under this prospectus and (4) the number of shares of our Common Stock to be owned by the selling stockholders after completion of this offering. We will not receive any of the proceeds from the sale of the shares of our Common Stock offered under this prospectus. The amounts and information set forth below are based upon information provided to us by the selling stockholders or its representatives, or on our records, as of January 6, 2026.

	Shares of Common Stock Beneficially Owned Prior to the Offering (1)			Shares of Common Stock Beneficially Owned After the Completion of the Offering (2)	
Name of Selling stockholders	Number	Percentage	Number of Shares Being Offered	Number	Percentage
Armistice Capital, LLC (3)	4,530,615 (3A)	61.2% (3B)	3,020,410	1,510,205 (3C)	20.4% (3D)
Dr. Hing C. Wong (4)	548,161	7.4%	138,750	409,411	5.5%
Chris Cheung and Ling Cheung (5)	12,981	*	12,981	—	*
Michael Poon and Manwah Wong (6)	5,770	*	5,770	—	*
Ho Cheung Wong (7)	3,462	*	3,462	—	*
Ho Sang Yeung (8)	14,424	*	14,424	—	*
R. Kemp Riechmann, Trustee of Revocable Trust of Roland Kemp Riechmann (9)	14,424	*	14,424	—	*
Benjamin J. Patz (10)	17,308	*	17,308	—	*
Rebecca Byam (11)	47,241	*	12,693	34,548	*
Scott T. Garrett (12)	28,197	*	8,077	20,120	*
Gary M. Winer (13)	3,462	*	3,462	—	*
Lee Flowers (14)	7,163	*	1,443	4,758	*
Rick S. Greene (15)	2,547	*	1,443	1,104	*
O'Neill AAF LLC (16)	144,231	2.0%	144,231	—	*
Kathy Chiu (17)	1,115	*	1,115	—	*

* Represents beneficial ownership of less than one percent based on 3,279,812 shares issued and outstanding on January 6, 2026, plus 977,000 shares held in abeyance and not considered issued and outstanding, 126,540 shares issuable upon the exercise of Conversion Warrants plus 3,020,410 Warrant Shares, or 7,403,762 shares of Common Stock.

(1) Beneficial ownership prior to the offering assumes selling stockholders hold all of the shares of Common Stock being registered for resale by this prospectus. For officers and directors of the Company, beneficial

ownership reports all shares which would be held in the event Conversion Warrants were exercised. The percentages shown are based on 7,403,762 shares of Common Stock outstanding, based on the shares of Common Stock issued and outstanding as of January 6, 2026 (which includes 253,083 Conversion Shares that were not registered at the time of issuance) plus 977,000 shares of Common Stock held in abeyance plus 126,540 shares issuable upon exercise of the Conversion Warrants plus 3,020,410 Warrant Shares issuable upon the exercise of New Warrants.

(2) Beneficial ownership after the completion of the offering assumes the sale of all shares of Common Stock being registered for resale by this prospectus, including Warrant Shares issuable upon the exercise of the New Warrants purchased under the Inducement Agreement, as well as all Conversion Shares and shares issuable upon the exercise of the Conversion Warrants purchased under the Conversion Amendment. The selling stockholders may sell all, some, or none of the shares offered under this prospectus, subject to ownership restrictions for Armistice described below. The percentages shown are based on 7,403,762 shares of Common Stock outstanding, based on the shares of Common Stock issued and outstanding as of January 6, 2026 (which includes 253,083 Conversion Shares that were not registered at the time of issuance) plus 977,000 shares of Common Stock held in abeyance plus 126,540 shares issuable upon exercise of the Conversion Warrants plus 3,020,410 Warrant Shares issuable upon the exercise of New Warrants.

(3) The securities are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company (the "Master Fund") and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC ("Armistice"), as the investment manager of the Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice. The securities are subject to a beneficial ownership limitation of 4.99%, and such limitation restricts the selling stockholder from holding all shares purchase under the Inducement Agreement or exercising that portion of the New Warrants that would result in the selling stockholder and its affiliates owning, after exercise, a number of shares of Common Stock in excess of the beneficial ownership limitation. See also footnote (3A) for a description of Armistice's beneficial ownership blocker and the treatment of abeyance shares and warrant shares for purposes of this table. The address of Armistice Capital Master Fund Ltd. is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

(3A) The numbers of shares held and ownership percentages shown for Armistice before the offering assume (i) the issuance of 1,510,205 shares of Common Stock that may become issuable upon settlement of shares currently held in abeyance pursuant to the 4.99% beneficial ownership blocker in the applicable agreements, and (ii) the issuance of 3,020,410 Warrant Shares underlying the New Warrants held by Armistice, in each case solely for purposes of presentation in this table. The number of shares shown as beneficially owned after completion of the offering may differ from the actual number of shares the selling stockholder could own from time to time and are subject to an ownership blocker, as discussed below. Notwithstanding these amounts, Armistice is subject to a 4.99% (or, at the selling stockholder's election, 9.99%) beneficial ownership limitation that contractually prohibits Armistice from acquiring or holding shares of our Common Stock in excess of such limitation at any time. As a result, Armistice does not beneficially own more than 4.99% of our Common Stock prior to this offering and will not beneficially own more than 4.99% (or 9.99%, as applicable) after this offering, regardless of the number of shares registered for resale.

(3B) The percentage beneficial ownership amounts shown for Armistice do not reflect the contractual beneficial ownership blocker and therefore overstate Armistice's actual beneficial ownership. Armistice's actual beneficial ownership before and after the offering will remain at or below 4.99% (or, at the selling stockholder's election, 9.99%), because Armistice may not exercise, convert or settle any securities to the extent such action would result in ownership above the applicable limitation. Thus, the number of shares shown as beneficially owned after completion of the offering may differ from the actual number of shares the selling stockholder may own from time to time.

3(C) The number of shares held and ownership percentages shown for Armistice after the offering assume that the selling stockholder has sold all shares registered in this registration statement for the New Warrants. The number of shares shown as beneficially owned after completion of the offering may differ from the actual number of shares the selling stockholder could own from time to time and are subject to an ownership blocker, as discussed in note 3(D).

3(D) For purposes of this table, we assume Armistice sells all shares registered in this offering for the New Warrants and therefore holds only shares of Common Stock issued on November 20, 2025 after the offering. Because the New Warrants are subject to a beneficial ownership blocker (generally 4.99% or, at the selling stockholder's election, 9.99%), the number of shares shown as beneficially owned after completion of the offering may differ from the actual number of shares the selling stockholder could own from time to time.

(4) Consists of (a) 306,219 shares held directly by Dr. Hing C. Wong, (b) 103,192 shares held by Dr. Wong and Ms. Bee Yau Huang, (c) 92,500 Conversion Shares held directly by Dr. Wong, and (d) 46,250 shares issuable upon the exercise of Conversion Warrants held directly by Dr. Wong.

(5) Consists of (a) 8,654 Conversion Shares and (b) 4,327 shares issuable upon the exercise of Conversion Warrants held directly by Mr. Chris Cheung and Ms. Ling Cheung.

(6) Consists of (a) 3,847 Conversion Shares and (b) 1,923 shares issuable upon the exercise of Conversion Warrants held directly by Michael Poon and Manway Wong.

(7) Consists of (a) 2,308 Conversion Shares and (b) 1,154 shares issuable upon the exercise of Conversion Warrants held directly by Ho Cheung Wong.

(8) Consists of (a) 9,616 Conversion Shares and (b) 4,808 shares issuable upon the exercise of Conversion Warrants held directly by Hoi Sang Yeung.

(9) Consists of (a) 9,616 Conversion Shares and (b) 4,808 shares issuable upon the exercise of Conversion Warrants held directly by the Revocable Trust of Roland Kemp Riechmann.

(10) Consists of (a) 11,539 Conversion Shares and (b) 5,769 shares issuable upon the exercise of Conversion Warrants held directly by Benjamin J. Patz.

(11) Consists of (a) 34,548 shares, (b) 8,462 Conversion Shares and (c) 4,231 shares issuable upon the exercise of Conversion Warrants held directly by Rebecca Byam,

(12) Consists of (a) 6,697 shares held by Garrett Capital Partners, LLC. Mr. Garrett is deemed to beneficially own the shares held by Garrett Capital Partners, LLC, (b) 13,423 shares held directly by Mr. Garrett, who is the sole member of Garrett Capital Partners, (c) 5,385 Conversion Shares, and (d) 2,692 shares issuable upon the exercise of Conversion Warrants held directly by Mr. Garrett. The address for Garrett Capital Partners, LLC is 51 Pembroke Dr., Lake Forest, IL 60045.

(13) Consists of (a) 2,308 Conversion Shares and (b) 1,154 shares issuable upon the exercise of Conversion Warrants held directly by Gary M. Winer.

(14) Consists of (a) 4,758 shares held directly by Wendy and Lee Flower, (b) 962 Conversion Shares held directly by Lee Flowers, and (c) 481 shares issuable upon the exercise of Conversion Warrants held directly by Lee Flowers.

(15) Consists of (a) 1,104 shares, (b) 962 Conversion Shares, and (c) 481 shares issuable upon the exercise of Conversion Warrants held directly by Rick S. Greene.

(16) Consists of (a) 96,154 Conversion Shares and (b) 48,077 shares issuable upon the exercise of Conversion Warrants held directly by O'Neill AAF LLC, and may be deemed to be beneficially owned by George D. O'Neill, Jr., Manager, who controls the right to vote and dispose of the securities. The address for O'Neill AAF LLC is P.O. Box 112, Lake Wales, FL 33859.

(17) Consists of (a) 770 Conversion Shares and (b) 385 shares issuable upon the exercise of Conversion Warrants held directly by Kathy Chiu.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the executive officer and director compensation arrangements discussed under "Executive Compensation" and "Director Compensation," respectively, since January 1, 2022, the following are the only transactions or series of similar transactions to which we were or will be a party in which the amount involved exceeds the lesser of (i) $120,000 or (ii) 1% of the Company's average total assets at year-end for the last two completed fiscal years and in which any director, nominee for director, executive officer, beneficial holder of more than 5% of our capital stock or any member of their immediate family or any entity affiliated with any of the foregoing persons had or will have a direct or indirect material interest.

Private Placement

On February 20, 2024, we entered into subscription agreements with certain of our officers and directors, pursuant to which we sold an aggregate of 44,643 shares of our Common Stock, $0.0001 par value per share, at a purchase price of $56.00 per share for an aggregate purchase price of $2.5 million. (The foregoing number of shares sold and purchase price are as adjusted for the Reverse Stock Split.)

The following table summarizes the Common Stock purchased by our directors, executive officers, and beneficial owners of more than 5% of Common Stock (after adjustment for the Reverse Stock Split).

Name and Title	Shares of Common Stock	Total Purchase Price
Rebecca Byam, Chief Financial Officer	19,018	$1,064,999.60
Dr. Hing C. Wong, Chief Executive Officer*	18,483	$1,035,003.20
Scott Garrett, Chairman of the Board	3,572	$ 200,001.20

* Beneficial owner of more than 5% of the Common Stock

The shares have not been registered and will not be sold or transferred except as permitted under law and pursuant to registration or exemption therefrom. The Board of Directors and Audit Committee of the Board of Directors reviewed the transaction under the policy for Related Party Transactions and determined that the transaction was in compliance with such policy.

Secured Note Financing

As of October 31, 2024, we received approximately $6.9 million from the issuance of the Secured Notes. Of the total issuance of Secured Notes, the Company issued $2.9 million to members of the Company's board of directors and officers, including $2.4 million purchased by Dr. Hing C. Wong, Founder and CEO, $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, former member of the board of directors, $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 following table summarizes the aggregate principal amounts of Secured Notes purchased by our directors, executive officers, and beneficial owner of more than 5% of Common Stock at par.

Name and Title	Aggregate Principal Amount of Secured Notes
Dr. Hing C. Wong, Chief Executive Officer*	$ 2,405,000
Rebecca Byam, Chief Financial Officer	$ 220,000
Scott T. Garrett, Chairman of the board of directors	$ 140,000
Gary M. Winer,	$ 60,000
Lee Flowers, Senior Vice President for Business Development	$ 25,000
Rick S. Greene, Director	$ 25,000

* Beneficial owner of more than 5% of our Common Stock

The Senior Notes bear interest at a rate of 9% per annum, payable quarterly in arrears, and mature on March 27, 2026 (the "Maturity Date"), on which date the principal balance and accrued but unpaid interest under the Secured Notes shall be due and payable. The Secured Notes may be prepaid in whole or in part at any time prior to the Maturity Date and are subject to a 5% prepayment penalty ("Premium Amount"). The Secured Notes are secured by the Pledged Collateral. 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), we have agreed to repay all indebtedness (including accrued interest) related to the Secured Notes plus a Premium Amount. Upon an Event of Default (as defined in the Note Purchase Agreement), we 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, we are required to distribute the Pledged Collateral to the Purchasers on a pro rata basis, in full satisfaction of the indebtedness evidenced by the Secured Notes.

The Pledged Collateral has not been registered and will not be sold or transferred except as permitted under law and pursuant to registration or exemption therefrom. The Board of Directors and Audit Committee of the Board of Directors reviewed the transaction under the policy for Related Party Transactions and determined that the transaction was in compliance with such policy.

The holders of $6.6 million of the outstanding principal of the Secured Notes have agreed to and effected the conversion of the Secured Notes held by them into shares of the Company's Common Stock at a conversion price of $26.00 per share, warrants to purchase approximately $3.3 million of the Company's Common Stock at an exercise price of $26.00 per share, and the right to their pro rata share of 49.11% of the proceeds of the Company's shares of Wugen common stock ("Wugen Shares"), if and when such shares are ever sold (the "Wugen Proceeds"). The conversion was approved at a Special Meeting of Stockholders held on March 31, 2025 and was effected pursuant to the terms of 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 a total of 253,083 unregistered shares of Common Stock (which are subject to a 180-day lock-up) and warrants to purchase an additional 126,540 shares of Common Stock at an exercise price of $26.00 per share.

Convertible Bridge Notes

As of May 7, 2025, we 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 this offering the Convertible Bridge Notes will be converted into shares of our Common Stock at the final offering

price in this offering. In addition, holders of the Convertible Bridge Notes have the right to receive a portion of Wugen Proceeds with respect to a 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, a former member of the Company's Board of Directors.

Stock Option Grants to Executive Officers

We have granted stock options to our named executive officers as more fully described in the section entitled "Executive Compensation."

Indemnification Agreements

We have entered into indemnification agreements with each of our directors and officers. The indemnification agreements and our amended and restated certificate of incorporation and amended and restated bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Review, Approval or Ratification of Transactions with Related Parties

Our written related party transactions policy states that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our Common Stock and any members of the immediate family of and any entity affiliated with any of the foregoing persons are not permitted to enter into a material related party transaction with us without the review and approval of our audit committee. The policy provides that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our Common Stock or with any of their immediate family members or affiliates in which the amount involved exceeds $120,000 must be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee considers the relevant facts and circumstances available and deemed relevant to the committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related party's interest in the transaction.

DESCRIPTION OF OUR SECURITIES

The following is a description of our securities of as set forth in certain provisions of our Second Amended and Restated Certificate of Incorporation (the "Charter") and our Amended and Restated Bylaws (the "Bylaws"), and applicable forms of warrant, each previously filed with the SEC and incorporated by reference as an exhibit to this registration statement of which this prospectus forms a part. This summary does not purport to be complete and is qualified in its entirety by the full text of the Charter, Bylaws, applicable forms of warrant, and the applicable provisions of the Delaware General Corporation Law (the "DGCL"). We encourage you to read our Charter, Bylaws, applicable forms of warrant, and the applicable portions of the DGCL carefully.

Authorized and Outstanding Stock

The Charter authorizes the issuance of an aggregate of 250 million shares of Common Stock, $0.0001 par value per share and 10 million shares of preferred stock, $0.0001 par value per share. Our purpose is to engage in any lawful act or activity for which corporations may be organized under the DGCL. Unless our board of directors determines otherwise, we will issue all shares of our capital stock in uncertificated form.

As of December 8, 2025, HCWB had 3,045,607 shares of its Common Stock issued and outstanding and 0 shares of preferred stock issued and outstanding.

Common Stock

Voting Rights

Each holder of Common Stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our certificate of incorporation and bylaws do not provide for cumulative voting rights. Because of this, the holders of a plurality of the shares of Common Stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. With respect to matters other than the election of directors, at any meeting of the stockholders at which a quorum is present or represented, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at such meeting and entitled to vote on the subject matter shall be the act of the stockholders, except as otherwise required by law. The holders of a majority of the stock issued and outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders.

Dividend Right

Subject to preferences that may be applicable to any then outstanding redeemable preferred stock, holders of Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

We have never declared or paid any cash dividends on our Common Stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, future debt instruments may materially restrict our ability to pay dividends on our Common Stock. Payment of future cash dividends, if any, will be at the discretion of the Board after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of current or then- existing debt instruments and other factors the Board deems relevant.

Rights upon Liquidation, Dissolution and Winding-Up

In the event of our liquidation, dissolution or winding up, holders of Common Stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of redeemable preferred stock.

Preemptive or Other Rights

Holders of Common Stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to the Common Stock. The rights, preferences and privileges of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of redeemable preferred stock that we may designate in the future.

Reverse Stock Split

As reported on the Form 8-K we filed with the SEC on April 1, 2025, as approved by our stockholders and board of directors on that date as part of our plan to regain compliance with applicable continued listing rules of The Nasdaq Stock Market, we filed a Certificate of Amendment to our Certificate of Incorporation, as corrected, to effect a reverse stock split at a ratio of 40-to-1 with respect to shares of our Common Stock, which amendment became effective as of 12:01 a.m. Eastern time on April 11, 2025.

Our Transfer Agent

The transfer agent will continue to be Equiniti Trust Company, LLC.

Authorized but Unissued Capital Stock

Delaware law does not require stockholder approval for any issuance of shares that are authorized and available for issuance. However, the listing requirements of Nasdaq require stockholder approval of certain issuances equal to or exceeding 20% of the then-outstanding voting power or the then-outstanding number of shares of Common Stock. These additional shares may be used for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions. Additionally, the number of authorized shares of any series of Common Stock or preferred stock may be increased or decreased (but not below the number of shares thereof outstanding) by the affirmative vote of the holders of a majority in voting power, irrespective of the provisions of Section 242(b)(2) of the DGCL.

The HCWB Board may generally issue shares of one or more series of preferred stock on terms designed to discourage, delay or prevent a change of control of HCWB or the removal of our management. Moreover, our authorized but unissued shares of preferred stock will be available for future issuances in one or more series without stockholder approval and could be utilized for a variety of corporate purposes, including future offerings to raise additional capital, to facilitate acquisitions and employee benefit plans.

One of the effects of the existence of authorized and unissued and unreserved shares of Common Stock or preferred stock may be to enable HCWB's board of directors to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of HCWB by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of our management and possibly deprive our stockholders of opportunities to sell their shares of Common Stock at prices higher than prevailing market prices.

Vacancies and Newly Created Directorships

The Charter provides that, subject to the rights granted to one or more series of preferred stock then outstanding, any newly-created directorship on the board of directors that results from an increase in the number of directors and any vacancies on our board of directors will be filled solely only by the affirmative vote of a majority of the remaining directors, even if less than a quorum, by a sole remaining director or by the stockholders.

Special Stockholder Meetings

The Charter provides that special meetings of our stockholders may be called at any time only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, subject to the rights of holders of any series of preferred stock then outstanding.

Stockholder Action by Written Consent

Pursuant to Section 228 of the DGCL, any action required to be taken at any annual or special meeting of the stockholders of a Delaware corporation may be taken without a meeting, without prior notice, and without a vote if a consent or consents in writing, setting forth the action so taken, is or are signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares of our stock entitled to vote thereon were present and voted, unless our amended and restated certificate of incorporation provides otherwise. Subject to applicable law and the rights, if any, of the holders of any outstanding series of preferred stock or any other outstanding class or series of stock of HCWB, the Charter does not permit our holders of Common Stock to act by consent in writing.

Section 203 of the DGCL

HCWB will be subject to the provisions of Section 203 of the DGCL, which we refer to as "Section 203" regulating corporate takeovers. In general, Section 203 prohibits a publicly held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, HCWB's board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by HCWB's board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock.

The provisions of Delaware law and the provisions of the Charter and HCWB's Bylaws could have the effect of discouraging others from attempting hostile takeovers and as a consequence, they might also inhibit temporary fluctuations in the market price of Common Stock that often result from actual or rumored hostile takeover attempts. These provisions might also have the effect of preventing changes in HCWB's management. It is also possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, our stockholders will have appraisal rights in connection with a merger or consolidation in which we are a constituent entity. Pursuant to the DGCL, stockholders who properly demand and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Court of Chancery of the State of Delaware, plus interest, if any, on the amount determined to be the fair value, from the effective time of the merger or consolidation through the date of payment of the judgment.

Stockholders' Derivative Actions

Under the DGCL, any of our stockholders may bring an action in our name to procure a judgment in our favor, also known as a derivative action, provided that the stockholder bringing the action is a holder of our shares at the time of the transaction to which the action relates or such stockholder's stock thereafter devolved by operation of law. To bring such an action, the stockholder must otherwise comply with Delaware law regarding derivative actions.

Exclusive Forum for Certain Lawsuits

Our Charter requires, unless we consent in writing to the selection of an alternative forum, that (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim against us, our directors, officers or employees arising pursuant to any provision of the DGCL or our Charter or bylaws, or (iv) any action asserting a claim against us, our directors, officers or employees governed by the internal affairs doctrine may be brought only in the Court of Chancery in the State of Delaware, except any claim (A) as to which the Court of Chancery of the State of Delaware determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), (B) which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or (C) for which the Court of Chancery does not have subject matter jurisdiction, as to which the Court of Chancery and the federal district court for the District of Delaware shall have concurrent jurisdiction. If an action is brought outside of Delaware, the stockholder bringing the suit will be deemed to have consented to service of process on such stockholder's counsel. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, a court may determine that this provision is unenforceable, and to the extent it is enforceable, the provision may have the effect of discouraging lawsuits against HCWB's directors and officers, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder.

Notwithstanding the foregoing, our Charter provides that the exclusive forum provision will not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Additionally, unless we consent in writing to the selection of an alternative forum, the federal courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act against us or any of our directors, officers, other employees, or agents. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these provisions. We note, however, that there is uncertainty as to whether a court would enforce this provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

Limitations on Liability and Indemnification of Officers and Directors

The DGCL authorizes corporations to limit or eliminate the personal liability of directors to corporations and their stockholders for monetary damages for breaches of directors' fiduciary duties, subject to certain exceptions. The Charter includes a provision that eliminates the personal liability of directors for monetary damages to the corporation or its stockholders for any breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL. The effect of these provisions is to eliminate the rights of us and our stockholders, through stockholders' derivative suits on our behalf, to recover monetary damages from a director for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior. However, exculpation does not apply to any director if the director has breached such

director's duty of loyalty, acted in bad faith, knowingly or intentionally violated the law, authorized illegal dividends, redemptions or repurchases or derived an improper benefit from his or her actions as a director.

The limitation of liability provision in the Charter may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

There is currently no pending material litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought.

Listing

The Common Stock of HCWB is listed on Nasdaq under the symbol "HCWB".

SECURITIES ACT RESTRICTIONS ON RESALE OF COMMON STOCK

Rule 144

Pursuant to Rule 144 under the Securities Act ("Rule 144"), a person who has beneficially owned restricted shares of Common Stock of HCWB for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been an affiliate of HCWB at the time of, or at any time during the three months preceding, a sale and (ii) HCWB is subject to the Exchange Act periodic reporting requirements for at least three months before the sale and has filed all required reports under Section 13 or 15(d) of the Exchange Act during the 12 months (or such shorter period as it was required to file reports) preceding the sale.

Persons who have beneficially owned restricted shares of Common Stock of HCWB for at least six months but who are affiliates of HCWB at the time of, or at any time during the three months preceding, a sale would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the average weekly reported trading volume of Common Stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales by affiliates of HCWB under Rule 144 are also limited by manner of sale provisions and notice requirements and by the availability of current public information about HCWB.

PLAN OF DISTRIBUTION

The shares of Common Stock listed in the table appearing under "Selling Stockholders" are being registered to permit the resale of Common Stock by the selling stockholders from time to time after the date of this prospectus. There can be no assurance that the selling stockholders will sell any or all of the Common Stock offered hereby. We will not receive any of the proceeds from the sale of the Common Stock by the selling stockholders.

The selling stockholders may sell all or a portion of the Common Stock offered hereby from time to time directly to purchasers or through one or more underwriters, broker-dealers or agents, at either market prices prevailing at the time of sale or at privately negotiated prices (but not at a fixed price), by a variety of methods including the following:

- on any national securities exchange or over-the-counter market on which the Common Stock may be listed or quoted at the time of sale;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which a broker-dealer may attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer, as principal, and a subsequent resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- private negotiation transactions;
- in transactions otherwise than on such exchanges or in the over-the-counter market;
- through a combination of any such methods; or
- through any other method permitted under applicable law.

We will pay the reasonable expenses incident to the registration of the Common Stock offered hereby. We have agreed to indemnify the selling stockholders and certain other persons against certain liabilities in connection with the offering of shares offered hereby, including liabilities arising under the Securities Act or if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

The selling stockholders and any broker-dealers or agents that are involved in selling the securities registered hereunder may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling stockholders has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

We have advised the selling stockholders that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes a selling stockholders, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase, any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

TAXATION

United States Federal Income Tax Considerations

The following discussion is a summary of the U.S. federal income tax considerations generally applicable to the ownership and disposition of our Common Stock, which we refer to collectively as our securities. This summary is based upon U.S. federal income tax law as of the date of this prospectus, which is subject to change or differing interpretations, possibly with retroactive effect. This summary does not discuss all aspects of U.S. federal income taxation that may be important to particular investors in light of their individual circumstances, including investors subject to special tax rules (e.g., financial institutions, insurance companies, broker-dealers, tax-exempt organizations (including private foundations), taxpayers that have elected mark-to-market accounting, S corporations, regulated investment companies, real estate investment trusts, passive foreign investment companies, controlled foreign corporations, investors that will hold our securities as part of a straddle, hedge, conversion, or other integrated transaction for U.S. federal income tax purposes or investors that have a functional currency other than the U.S. dollar), all of whom may be subject to tax rules that differ materially from those summarized below. In addition, this summary does not discuss other U.S. federal tax consequences (e.g., estate or gift tax), any state, local, or non-U.S. tax considerations, the Medicare tax or any alternative minimum tax consideration. In addition, this summary is limited to investors that will hold our securities as a "capital asset," as defined under the U.S. Tax Code (generally, property held for investment). No ruling from the Internal Revenue Service, (the "*IRS*") has been or will be sought regarding any matter discussed herein. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax aspects set forth below.

A "*non-U.S. Holder*" is a beneficial holder of securities who or that is neither a U.S. Holder nor a partnership for U.S. federal income tax purposes.

If a partnership (including an entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our securities, the tax treatment of a partner, member or other beneficial owner of such partnership will generally depend upon the status of the partner, member or other beneficial owner, the activities of the partnership, and certain determinations made at the partner, member or other beneficial owner level. If you are a partner, member, or other beneficial owner of a partnership holding our securities, you are urged to consult your tax advisor regarding the tax consequences of the ownership and disposition of our securities.

THIS DISCUSSION OF U.S. FEDERAL INCOME TAX CONSIDERATIONS IS FOR GENERAL INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE HOLDERS SHOULD CONSULT THEIR TAX ADVISORS CONCERNING THE U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF OWNING AND DISPOSING OF OUR SECURITIES, AS WELL AS THE APPLICATION OF ANY, STATE, LOCAL, AND NON-U.S. INCOME, ESTATE AND OTHER TAX CONSIDERATIONS.

U.S. Holders

Taxation of Distributions

We do not intend to pay cash dividends for the foreseeable future. If we pay distributions to U.S. Holders of shares of our Common Stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. Holder's adjusted tax basis in our Common Stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the Common Stock and will be treated as described under "*U.S. Holders-Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock*" below.

Dividends we pay to a U.S. Holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. Holder will generally constitute "qualified dividends" that will be subject to tax at the maximum tax rate accorded to long-term capital gains.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of Common Stock

A U.S. Holder will recognize gain or loss on the sale, taxable exchange or other taxable disposition of our Common Stock. Any such gain or loss will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder's holding period for such Common Stock exceeds one year. The amount of gain or loss recognized will generally be equal to the difference between (1) the sum of the amount of cash and the fair market value of any property received in such disposition and (2) the U.S. Holder's adjusted tax basis in such Common Stock. A U.S. Holder's adjusted tax basis in its Common Stock will generally equal the U.S. Holder's acquisition cost (i.e., the amount paid for the Common Stock or as discussed below, an amount equal to the sum of the U.S. Holder's initial investment in a Warrant and the exercise price of such Warrant) less any prior distributions treated as a return of capital. The deductibility of capital losses is subject to limitations.

Non-U.S. Holders

Taxation of Distributions

As discussed above, we do not intend to pay cash dividends for the foreseeable future. In general, any distributions (including constructive distributions) we make to a non-U.S. Holder of shares of our Common Stock, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the non-U.S. Holder's conduct of a trade or business within the United States, we will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such non-U.S. Holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (generally on an IRS Form W-8BEN or W-8BEN-E, as applicable). In the case of any constructive dividend, it is possible that this tax would be withheld from any amount owed to a non-U.S. Holder by the applicable withholding agent, including cash distributions on other property subsequently paid or credited to such non-U.S. Holder. Any distribution not constituting a dividend will be treated first as reducing (but not below zero) the non-U.S. Holder's adjusted tax basis in its shares of our Common Stock and, to the extent such distribution exceeds the non-U.S. Holder's adjusted tax basis, as gain realized from the sale or other disposition of the Common Stock, which will be treated as described under "*Non-U.S. Holders-Gain on Sale, Exchange, Redemption, Expiration or Other Taxable Disposition of Common Stock*" below. In addition, if we determine that we are classified as a "United States real property holding corporation" (see "*Non-U.S. Holders-Gain on Sale, Exchange, Redemption, Expiration or Other Taxable Disposition of Common Stock*" below), we will withhold 15% of the fair market value of any property distributed that exceeds our current and accumulated earnings and profits.

Dividends we pay to a non-U.S. Holder that are effectively connected with such non-U.S. Holder's conduct of a trade or business within the United States (or, if an applicable tax treaty so requires, are attributable to a U.S. permanent establishment or fixed base maintained by the non-U.S. Holder) will generally not be subject to U.S. withholding tax, provided such non-U.S. Holder complies with certain certification and disclosure requirements (generally by providing an IRS Form W-8ECI). Instead, such dividends will generally be subject to U.S. federal income tax, net of certain deductions, at the same graduated individual rates or corporate rates applicable to U.S. Holders. If the non-U.S. Holder is a corporation, dividends that are effectively connected income may also be subject to a "branch profits tax" at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty).

Gain on Sale, Exchange, Redemption, Expiration or Other Taxable Disposition of Common Stock

A non-U.S. Holder will generally not be subject to U.S. federal income or withholding tax in respect of gain recognized on a sale, taxable exchange or other taxable disposition of our Common Stock unless:

- the gain is effectively connected with the conduct of a trade or business by the non-U.S. Holder within the United States (or, if an applicable tax treaty so requires, is attributable to a U.S. permanent establishment or fixed base maintained by the non-U.S. Holder);
- the non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are met; or
- (i) we are or have been a "United States real property holding corporation" for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the non-U.S. Holder held our Common Stock, and (ii) shares of our Common Stock (A) are not regularly traded on an established securities market or (B) are regularly traded on an established securities market, but the non-U.S. Holder has owned, directly or constructively (including through ownership of warrants), more than 5% of our Common Stock at any time within the shorter of the five-year period preceding the disposition or such non-U.S. Holder's holding period for the shares of our Common Stock. There can be no assurance that our Common Stock will be treated as regularly traded on an established securities market for this purpose.

Gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates. Any gains described in the first bullet point above of a non-U.S. Holder that is a foreign corporation may also be subject to an additional "branch profits tax" at a 30% rate (or lower applicable treaty rate). Gain described in the second bullet point above will generally be subject to a 30% U.S. federal income tax. Non-U.S. Holders are urged to consult their tax advisors regarding possible eligibility for benefits under income tax treaties.

If the third bullet point above applies to a non-U.S. Holder, gain recognized by such non-U.S. holder on the sale, exchange or other disposition of our Common Stock will be subject to tax at generally applicable U.S. federal income tax rates. In addition, if our stock is not regularly traded on an established securities market for this purpose, a buyer of our Common Stock from such non-U.S. Holder may be required to withhold U.S. income tax at a rate of 15% of the amount realized upon such disposition. We will be classified as a United States real property holding corporation if the fair market value of our "United States real property interests" equals or exceeds 50% of the sum of the fair market value of our worldwide real property interests plus our other assets used or held for use in a trade or business, as determined for U.S. federal income tax purposes. We believe that we currently are, and expect to remain for the foreseeable future, a United States real property holding corporation. Non-U.S. Holders are urged to consult their tax advisors regarding the application of these rules.

Additional U.S. Federal Tax Considerations

Additional Tax on Net Investment Income

In addition to regular U.S. federal income tax, certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their net gain from the sale, exchange or other disposition of Common Stock, or dividends with respect to Common Stock. Each U.S. Holder is urged to consult its own tax advisor regarding the application of this tax.

Backup Withholding and Additional Information Reporting

In general, information returns may be filed with the IRS in connection with actual or constructive dividends paid to a U.S. Holder in respect of our securities, and the proceeds received by a U.S. Holder from the sale, exchange or other disposition of our securities within the United States or through certain U.S.-related financial intermediaries will be subject to U.S. information reporting rules, unless a U.S. Holder is a corporation or other exempt recipient and properly establishes its rights to an exemption. Backup withholding at a rate of

24% may apply to such payments if a U.S. Holder does not establish an exemption from backup withholding or fails to provide a correct taxpayer identification number and make any other required certifications.

In general, information returns may be filed with the IRS in connection with dividends paid to non-U.S. Holders, and the proceeds received by a non-U.S. Holder from the sale, exchange or other disposition of our securities within the United States or through certain U.S.-related financial intermediaries. Copies of the information returns reporting dividends, and any withholding may also be made available to the tax authorities in the country in which the non-U.S. Holder resides under the provisions of a treaty or agreement. A non-U.S. Holder may be subject to backup withholding (currently at a rate of 24%) in connection with actual or constructive dividends with respect to our securities and the proceeds from the sales, exchange or other disposition of our securities unless the non-U.S. Holder provides to the applicable withholding agent a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable form) certifying under penalties of perjury that the non-U.S. Holder is not a United States person, or otherwise qualifies for an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will be allowed as a refund or credit against U.S. federal income tax liability, provided that the required information is timely furnished to the IRS. Holders are urged to consult their own tax advisor regarding the information reporting and backup withholding rules.

Foreign Account Tax Compliance Act

Sections 1471 through 1474 of the U.S. Tax Code and the Treasury Regulations and administrative guidance promulgated thereunder (commonly referred as the "*Foreign Account Tax Compliance Act*" or "*FATCA*") generally impose withholding at a rate of 30% in certain circumstances on actual or constructive dividends in respect of our securities which are held by or through certain foreign financial institutions (including investment funds), unless any such institution (1) enters into, and complies with, an agreement with the IRS to report, on an annual basis, information with respect to interests in, and accounts maintained by, the institution that are owned by certain U.S. persons and by certain non-U.S. entities that are wholly or partially owned by U.S. persons and to withhold on certain payments, or (2) if required under an intergovernmental agreement between the United States and an applicable foreign country, reports such information to its local tax authority, which will exchange such information with the U.S. Department of Treasury. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Accordingly, the entity through which our securities are held will affect the determination of whether such withholding is required. Similarly, dividends in respect of our securities held by an investor that is a non-financial non-U.S. entity that does not qualify under certain exceptions will generally be subject to withholding at a rate of 30%, unless such entity either (1) certifies to us or the applicable withholding agent that such entity does not have any "substantial United States owners" or (2) provides certain information regarding the entity's "substantial United States owners," which will in turn be provided to the U.S. Department of Treasury. Prospective investors should consult their tax advisors regarding the possible implications of FATCA on their investment in our securities.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon by Clark Hill PLC, Chicago, Illinois and Los Angeles, California.

EXPERTS

The financial statements of HCWB as of December 31, 2024 and for the year ended December 31, 2024 incorporated in this prospectus and elsewhere in the registration statement of which it forms a part by reference to the Annual Report on Form 10-K filed on March 28, 2025 have been so incorporated by reference in reliance on the report of Crowe LLP ("Crowe"), independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

The financial statements of HCWB as of December 31, 2023 and for the year ended December 31, 2023 incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of Grant Thornton LLP ("Grant Thornton"), independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

Change in Auditor

On September 19, 2024, HCWB dismissed its previous independent accounting firm, Grant Thornton and engaged Crowe as its independent auditor.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act. In accordance with the Exchange Act, we file periodic reports, proxy and information statements and other information with the SEC. Our filings with the SEC are available to the public over the Internet at the SEC's website at www.sec.gov. You may also find documents we filed on our website at www.hcwbiologics.com. Information contained in or accessible through our website does not constitute a part of this prospectus and is not incorporated by reference herein.

This prospectus is part of a registration statement we filed with the SEC. This prospectus omits some information contained in the registration statement in accordance with SEC rules and regulations. You should review the information and exhibits in the registration statement for further information about us and the securities we are offering. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference in this prospectus is considered to be part of this prospectus. Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated, and those future filings may modify or supersede some of the information included or incorporated in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents listed below (File No. 001-40591) and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (in each case, other than those documents or the portions of those documents not deemed to be filed) between the date of the initial registration statement and the effectiveness of the registration statement and following the effectiveness of the registration statement until the offering of the securities under the registration statement is terminated or completed:

(i) our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as filed with the SEC on March 28, 2025;

(ii) our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2025, as filed with the SEC on May 15, 2025, June 30, 2025, as filed with the SEC on August 18, 2025, and September 30, 2025, as filed with the SEC on November 14, 2025; and

(iii) Current Reports on Form 8-K filed after December 31, 2024.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address or telephone number:

HCW Biologics Inc.
2929 N Commerce Parkway
Miramar, FL 33025
(954) 842-2024

HCW BIOLOGICS INC.

Up to 3,400,033 Shares of Common Stock

PROSPECTUS

[●], 2026

PART II

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the fees and expenses payable by the registrant in connection with the issuance and distribution of the securities being registered. All of the amounts shown are estimates, except for the SEC registration fee:

Legal fees and expenses	$ 50,000
Accounting fees and expenses	$ 35,000
SEC registration fee	$ 1,500
Miscellaneous fees and expenses	$
Total	$ 86,500

Item 14. Indemnification of Directors and Officers.

Section 145 of the DGCL concerning indemnification of officers, directors, employees and agents is set forth below.

Section 145. Indemnification of officers, directors, employees and agents; insurance.

(a) A corporation shall have power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe the person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that the person's conduct was unlawful.

(b) A corporation shall have power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by the person in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

(c) (1) To the extent that a present or former director or officer of a corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (a) and (b)

of this section, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith. For indemnification with respect to any act or omission occurring after December 31, 2020, references to "officer" for purposes of these paragraphs (c)(1) and (2) of this section shall mean only a person who at the time of such act or omission is deemed to have consented to service by the delivery of process to the registered agent of the corporation pursuant to § 3114(b) of Title 10 (for purposes of this sentence only, treating residents of this State as if they were nonresidents to apply § 3114(b) of Title 10 to this sentence).

(2) The corporation may indemnify any other person who is not a present or former director or officer of the corporation against expenses (including attorneys' fees) actually and reasonably incurred by such person to the extent he or she has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in subsections (a) and (b) of this section, or in defense of any claim, issue or matter therein.

(d) Any indemnification under subsections (a) and (b) of this section (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of the present or former director, officer, employee or agent is proper in the circumstances because the person has met the applicable standard of conduct set forth in subsections (a) and (b) of this section. Such determination shall be made, with respect to a person who is a director or officer of the corporation at the time of such determination, (1) By a majority vote of the directors who are not parties to such action, suit or proceeding, even though less than a quorum, or (2) By a committee of such directors designated by majority vote of such directors, even though less than a quorum, or (3) If there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion, or (4) By the stockholders.

(e) Expenses (including attorneys' fees) incurred by an officer or director of the corporation in defending any civil, criminal, administrative or investigative action, suit or proceeding may be paid by the corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that such person is not entitled to be indemnified by the corporation as authorized in this section. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents of the corporation or by persons serving at the request of the corporation as directors, officers, employees or agents of another corporation, partnership, joint venture, trust or other enterprise may be so paid upon such terms and conditions, if any, as the corporation deems appropriate.

(f) The indemnification and advancement of expenses provided by, or granted pursuant to, the other subsections of this section shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. A right to indemnification or to advancement of expenses arising under a provision of the certificate of incorporation or a bylaw shall not be eliminated or impaired by an amendment to or repeal or elimination of the certificate of incorporation or the bylaws after the occurrence of the act or omission that is the subject of the civil, criminal, administrative or investigative action, suit or proceeding for which indemnification or advancement of expenses is sought, unless the provision in effect at the time of such act or omission explicitly authorizes such elimination or impairment after such action or omission has occurred.

(g) A corporation shall have power to purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under this section. For purposes of this subsection, insurance shall include any insurance provided directly or indirectly (including pursuant to any fronting or reinsurance

arrangement) by or through a captive insurance company organized and licensed in compliance with the laws of any jurisdiction, including any captive insurance company licensed under Chapter 69 of Title 18, provided that the terms of any such captive insurance shall:

(1) Exclude from coverage thereunder, and provide that the insurer shall not make any payment for, loss in connection with any claim made against any person arising out of, based upon or attributable to any (i) personal profit or other financial advantage to which such person was not legally entitled or

(ii) deliberate criminal or deliberate fraudulent act of such person, or a knowing violation of law by such person, if (in the case of the foregoing paragraph (g)(1)(i) or (ii) of this section) established by a final, nonappealable adjudication in the underlying proceeding in respect of such claim (which shall not include an action or proceeding initiated by the insurer or the insured to determine coverage under the policy), unless and only to the extent such person is entitled to be indemnified therefor under this section;

(2) Require that any determination to make a payment under such insurance in respect of a claim against a current director or officer (as defined in paragraph (c)(1) of this section) of the corporation shall be made by an independent claims administrator or in accordance with the provisions of paragraphs (d)(1) through (4) of this section; and

(3) Require that, prior to any payment under such insurance in connection with any dismissal or compromise of any action, suit or proceeding brought by or in the right of a corporation as to which notice is required to be given to stockholders, such corporation shall include in such notice that a payment is proposed to be made under such insurance in connection with such dismissal or compromise.

For purposes of paragraph (g)(1) of this section, the conduct of an insured person shall not be imputed to any other insured person. A corporation that establishes or maintains a captive insurance company that provides insurance pursuant to this section shall not, solely by virtue thereof, be subject to the provisions of Title 18.

(h) For purposes of this section, references to "the corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under this section with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued.

(i) For purposes of this section, references to "other enterprises" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a person with respect to any employee benefit plan; and references to "serving at the request of the corporation" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the corporation" as referred to in this section.

(j) The indemnification and advancement of expenses provided by, or granted pursuant to, this section shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

(k) The Court of Chancery is hereby vested with exclusive jurisdiction to hear and determine all actions for advancement of expenses or indemnification brought under this section or under any bylaw, agreement, vote

of stockholders or disinterested directors, or otherwise. The Court of Chancery may summarily determine a corporation's obligation to advance expenses (including attorneys' fees).

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment of expenses incurred or paid by a director, officer or controlling person in a successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to the court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

Article IV of the Company's By-laws provides:

Each person who was or is made a party to, or is threatened to be made a party to, or is involved in any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative, legislative or any other type whatsoever (a "Proceeding"), by reason of the fact that such person (or a person of whom such person is the legal representative), is or was a director or officer of the Corporation or, while serving as a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans (for purposes of this Article VI, an "Indemnitee"), shall be indemnified and held harmless by the Corporation to the fullest extent permitted by the DGCL as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), against all expenses, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes and penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such Indemnitee in connection therewith, provided such Indemnitee acted in good faith and in a manner that the Indemnitee reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or Proceeding, had no reasonable cause to believe the Indemnitee's conduct was unlawful. Such indemnification shall continue as to an Indemnitee who has ceased to be a director or officer of the Corporation and shall inure to the benefit of such Indemnitees' heirs, executors and administrators. Notwithstanding the foregoing, subject to Section 6.5 of these Bylaws, the Corporation shall indemnify any such Indemnitee seeking indemnity in connection with a Proceeding (or part thereof) initiated by such Indemnitee only if such Proceeding (or part thereof) was authorized by the Board or such indemnification is authorized by an agreement approved by the Board.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is theretofore unenforceable.

Item 15. Recent Sales of Unregistered Securities.

During the past three years, we sold the following securities without registration under the Securities Act:

Sale of Common Stock and Warrants

On November 18, 2024, the Company entered into a securities purchase agreement ("SPA") with Armistice Capital Master Fund Ltd. ("Armistice") pursuant to which the Company agreed to offer and sell (i) in a registered direct offering (the "Registered Offering") (x) 104,000 shares (the "Shares") of the Company's Common Stock,

par value $0.0001 per share (the "Common Stock"), and (y) pre-funded warrants to purchase up to 63,925 shares of Common Stock (the "Pre-Funded Warrants") and (ii) in a concurrent private placement (the "Private Placement" and together with the Registered Offering, the "Offering"), unregistered warrants to purchase up to an aggregate of 167,925 shares of Common Stock ("Armistice Warrants"). The combined purchase price for each Share and accompanying Armistice Warrant to purchase one share of Common Stock was $41.20 per Share and the combined purchase price for each Pre-Funded Warrant and accompany Common Stock Warrant to purchase one share of Common Stock is $41.1999.

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

The shares of Common Stock and Pre-Funded Warrants in the Registered Offering were offered pursuant to a shelf registration statement on Form S-3 (File No. 333-266991), which was declared effective by the U.S. Securities and Exchange Commission (the "SEC") on August 26, 2022. The Registered Offering has been made by means of a prospectus supplement filed with the SEC on November 20, 2024 that forms a part of such registration statement.

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

On November 18, 2024, the Company entered into a placement agency agreement (the "Placement Agency Agreement") with Maxim Group LLC ("Maxim" or the "Placement Agent") pursuant to which the Company engaged the Placement Agent as the exclusive placement agent in connection with the Offering. The Company agreed to pay the Placement Agent a cash fee equal to 7.0% of gross proceeds from the sale of Shares, Pre-Funded Warrants and Common Stock Warrants to the Purchaser. The Company also agreed to reimburse the Placement Agent for out-of-pocket expenses, including the reasonable legal fees of its counsel not to exceed $50,000. The Placement Agent Agreement also contains representations, warranties, indemnification and other provisions customary for transactions of this nature.

On February 20, 2024, the Company completed a $2.5 million private placement of shares of Common Stock with certain of its officers and directors at a price of $56.00 per share. The Company issued 44,643 shares of Common Stock in connection with the offering. The shares have not been registered and will not be sold or transferred except as permitted under law and pursuant to registration or exemption therefrom. The Board of Directors and Audit Committee of the Board of Directors reviewed the transaction under the Company's policy for Related Party Transactions (the "Policy") and determined that the transaction was in compliance with the Policy.

On February 20, 2025, the Company entered into an equity purchase agreement (the "ELOC Purchase Agreement") with Square Gate Capital Master Fund, LLC – Series 4 ("Square Gate") pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right to direct Square Gate to purchase up to an aggregate of $20,000,000 of shares of our Common Stock, plus, at the Company's option upon utilizing the initial $20,000,000, an additional amount equal to the lesser of 100% of the Company's market capitalization at the time of exercise of such option or $20,000,000, over the 36-month term of the ELOC Purchase Agreement. The Company issued 9,616 shares of our Common Stock to Square Gate on March 12, 2025, as its Commitment Fee under the ELOC Purchase Agreement (the "Commitment Shares").

The Company filed a Registration Statement on Form S-1 with respect to the potential resale (1) by Armistice of shares of our Common Stock that may be issued to Armistice upon exercise of the Armistice Warrants, and

(2) by Square Gate of the Commitment Shares and shares of our Common Stock that may be issued to Square Gate pursuant to the ELOC Purchase Agreement, which Registration Statement became effective on April 16, 2025.

On November 19, 2025, the Company entered into a warrant inducement agreement with Armistice Capital Master Fund Ltd. (the "Inducement Agreement"), pursuant to which Armistice agreed to immediately exercise in full all of its outstanding warrants originally issued on November 20, 2024 (as amended on May 15, 2025) and on May 15, 2025 (the "Existing Warrants") to purchase an aggregate of 1,510,205 shares of Common Stock at an amended exercise price of $2.66 per share, resulting in aggregate gross proceeds to the Company of approximately $4.0 million before fees and expenses. In consideration for the immediate exercise of the Existing Warrants, the Company issued to Armistice, in a private placement pursuant to Section 4(a)(2) of the Securities Act, new unregistered Common Stock Purchase Warrants (the "New Warrants") to purchase up to 3,020,410 shares of Common Stock at an exercise price of $2.41 per share. The New Warrants are exercisable immediately and expire five and one-half years from their issuance. The New Warrants and the shares of Common Stock issuable upon their exercise have not been registered under the Securities Act. The Company agreed, pursuant to the Inducement Agreement, to file a registration statement covering the resale of the shares issuable upon exercise of the New Warrants.

Item 16. Exhibits.

The exhibits to this registration statement are listed in the Exhibit Index to this registration statement, which immediately precedes the Signature Page, and which Exhibit Index is hereby incorporated by reference.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the "Securities Act");

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (i), (ii) and (iii) do not apply if the registration statement is on Form S-1 and the information required to be included in a post- effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) that, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein,

and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof;

(3) to remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) that, for the purpose of determining liability under the Securities Act to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness.

Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use; and

(5) that, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities:

the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of an undersigned registrant; and

(iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

EXHIBIT INDEX

Exhibit No.	Exhibit title	Incorporated by reference				Filed or furnished herewith
		Form	File No.	Exhibit No.	Filing date	
3.1	Amended and Restated Certificate of Incorporation	8-K	001-40591	3.1	07/26/2021	
3.1a	Certificate of Amendment of Certificate of Incorporation, filed March 31, 2025.	8-K	001-40591	3.1a	04/01/2025	
3.1b	Certificate of Correction of the Certificate of Amendment of Certificate of Incorporation, filed April 1, 2025.	8-K	001-40591	3.1b	04/01/2025	
3.2	Amended and Restated Bylaws	8-K	001-40591	3.2	07/26/2021	
4.1	Specimen Stock Certificate	S-1/A	333-256510	4.1	07/09/2021	
4.2	Description of Securities	10-K	001-40591	4.2	03/29/2022	
4.3	Form of Common Stock Purchase Warrant between the Company and Holder	8-K	001-40591	4.1	11/20/2024	
4.4	Form of Pre-Funded Common Stock Purchase Warrant between the Company and Holder	8-K	001-40591	4.2	11/20/2024	
4.5	Form of New Warrant	8-K	001-40591	4.1	11/20/2025	
5.1	Opinion of Clark Hill PLC					X
10.1	Form of Indemnification Agreement between HCW Biologics Inc. and each of its officers and directors.	S-1/A	333-256510	10.1	07/09/2021	
10.2+	2019 Equity Incentive Plan, as amended, and forms of agreement thereunder.	S-1	333-256510	10.2	07/09/2021	
10.3+	First Amendment to 2019 Equity Incentive Plan.	S-1	333-256510	10.3	07/09/2021	
10.4+	2021 Equity Incentive Plan and forms of agreement thereunder	S-1	333-256510	10.4	07/09/2021	
10.5+	Employment Agreement, dated July 6, 2021, between Peter Rhode and HCW Biologics Inc.	S-1	333-256510	10.6	07/09/2021	
10.6+	Employment Agreement, dated October 9, 2019, between Rebecca Byam and HCW Biologics Inc.	S-1	333-256510	10.7	07/09/2021	
10.7+	Non-Employee Director Compensation Policy.	S-1	333-256510	10.8	07/09/2021	
10.8+	Employment Agreement, dated June 18, 2021, between Dr. Hing C. Wong and HCW Biologics Inc.	S-1	333-256510	10.13	07/09/2021	

Exhibit No.	Exhibit title	Incorporated by reference				Filed or furnished herewith
		Form	File No.	Exhibit No.	Filing date	
10.9+	Executive Incentive Bonus Plan	S-1	333-256510	10.11	07/09/2021	
10.10†	Exclusive License Agreement, dated December 24, 2020, between HCW Biologics Inc. and Wugen, Inc.	S-1	333-256510	10.10	07/09/2021	
10.11†	Master Services Agreement, dated March 14, 2019, between HCW Biologics Inc. and EirGenix, Inc.	S-1	333-256510	10.12	07/09/2021	
10.12†#	Purchase and Sale Agreement, by and between HCW Biologics Inc. and Wai 3300 Corporate Way, LLC, dated May 27, 2022	10-Q	001-40591	10.1	08/12/2022	
10.13	Capital on Demand Sales Agreement, dated August 19, 2022, by and between HCW Biologics Inc. and Jones Trading Institutional Services LLC	S-3	333-266991	1.2	08/19/2022	
10.14	Loan Agreement by and between HCW Biologics Inc. and Cogent Bank, dated August 15, 2022	10-Q	001-40591	10.1	11/07/2022	
10.15	Mortgage and Security Agreement by and between HCW Biologics Inc. and Cogent Bank, dated August 15, 2022	10-Q	001-40591	10.2	11/07/2022	
10.16	Form of Subscription Agreement, dated February 20, 2024, by and between the Company and the Subscribers party thereto	8-K	001-40591	10.1	02/22/2024	
10.17†#	Form of Senior Secured Note Purchase Agreement, dated March 28, 2024, by and between the Company and the Purchaser party thereto	10-K	001-40591	10.17	04/01/2024	
10.18†#	Form of Senior Secured Promissory Note, dated March 28, 2024, by and between the Company and the Holder party thereof	10-K	001-40591	10.18	04/01/2024	
10.19†#	Form of Pledge Agreement, dated March 28, 2024, by and between the Company, Escrow Agent and Noteholder party thereto	10-K	001-40591	10.19	04/01/2024	
10.20†#	Form of Escrow Agreement, dated March 28, 2024, by and between the Company, Escrow Agent and Noteholder party thereto	10-K	001-40591	10.20	04/01/2024	
10.21	Senior Secured Note Purchase Agreement, dated March 28, 2024, by and between the Company and the Purchaser party thereto	10-Q	001-40591	10.1	05/15/2024	

Exhibit No.	Exhibit title	Incorporated by reference				Filed or furnished herewith
		Form	File No.	Exhibit No.	Filing date	
10.22	Form of Subscription Agreement, dated February 20, 2024, by and between the Company and the Subscribers party thereto	10-Q	001-40591	10.5	05/15/2024	
10.23	Form of Amended and Restated Senior Secured Note Purchase Agreement, dated July 2, 2024, by and between the Company and the Purchaser party thereto	10-Q	001-40591	10.1	08/14/2024	
10.24	Form of Senior Secured Promissory Note by and between the Company and the Holder party thereof	10-Q	001-40591	10.2	08/14/2024	
10.25	Form of Amended and Restated Pledge Agreement, dated July 2, 2024, by and among the Company, Escrow Agent and Noteholder parties thereto	10-Q	001-40591	10.3	08/14/2024	
10.26	Form of Escrow Agreement, dated July 2, 2024, by and among the Company, Escrow Agent and Noteholder parties thereto	10-Q	001-40591	10.4	08/14/2024	
10.27	Form of First Amendment to the Amended and Restated Senior Secured Note Purchase Agreement, dated September 30, 2024, by and between the Company and Purchaser parties thereto	10-Q	001-40591	10.5	11/14/2024	
10.28	Settlement Agreement and Release, dated July 13, 2024, by and between the Company and Altor BioScience, LLC, NantCell, Inc., and ImmunityBio, Inc.	10-Q	001-40591	10.6	11/14/2024	
10.29	Placement Agency Agreement, dated November 18, 2024, between the Company and Maxim Group LLC.	8-K	001-40591	10.1	11/20/2024	
10.30	Securities Purchase Agreement, dated November 19, 2024, between the Company and Purchaser	8-K	001-40591	10.2	11/20/2024	
10.31	Equity Purchase Agreement, dated February 20, 2025, between the Company and Square Gate Master Fund—Series 4.	8-K	001-40591	10.1	02/21/2025	
10.32	Registration Rights Agreement, dated February 20, 2025, between the Company and Square Gate Master Fund— Series 4.	8-K	001-40591	10.2	02/21/2025	

Exhibit No.	Exhibit title	Incorporated by reference				Filed or furnished herewith
		Form	File No.	Exhibit No.	Filing date	
10.33	Letter Agreement to the License, Research and Co-Development Agreement, dated March 17, 2025, between Company and WY Biotech Co. Ltd.	10-Q	001-40591	10.14	08/18/2025	
10.34	Confirmation of Letter of Acceptance of Deliverable from Company by WY Biotech Co. Ltd., dated May 30, 2025	10-Q	001-40591	10.15	08/18/2025	
10.35	Second Letter Agreement to the License, Research and Co-Development Agreement, dated July 13, 2025, between Company and WY Biotech Co. Ltd.	10-Q	001-40591	10.16	08/18/2025	
10.36	Exclusive License Agreement 12-month Suspension, dated May 29, 2025, between the Company and Wugen, Inc.	10-Q	001-40591	10.17	08/18/2025	
10.37	First Amendment to the Equity Purchase Agreement, dated August 14, 2025, between the Company and Square Gate Master Fund – Series 4.	8-K	001-40591	10.1	08/15/2025	
10.38	Form of Inducement Agreement between the Company and Armistice Capital Management, LLC	8-K	001-40591	10.1	11/20/2025	
23.1a	Consent of Independent Registered Public Accounting Firm (Grant Thornton, Predecessor)					X
23.1b	Consent of Independent Registered Public Accounting Firm (Crowe LLP, Successor)					X
23.2	Opinion of Clark Hill PLC (included in Exhibit 5.1)					
97.1	HCW Biologics Inc. Compensation Recovery Policy	10-K	001-40591	97.1	04/01/2024	
99.1	Audit Committee Charter of the Registrant					X
99.2	Compensation Committee Charter of the Registrant					X
99.3	HCW Biologics Inc. Related Party Transaction Policy					X
107	Filing Fee Table					X

† *Certain portions of this document that constitute confidential information have been redacted in accordance with Regulation S-K, Item 601(b)(10).*

+ *Indicates management contract or compensatory plan.*
# *Certain information in this document has been excluded pursuant to Item 601(a)(5) or (a)(6) of Regulation S-K. The Registrant agrees to furnish supplementally such information to the SEC upon request.*

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, in the city of Miramar, State of Florida, on January 9, 2026.

HCW BIOLOGICS INC.

By: /s/ Hing C. Wong
Name: Hing C. Wong
Title: *Founder & Chief Executive Officer*

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Hing C. Wong, acting alone or together with another attorney-in-fact, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and re-substitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any or all further amendments (including post-effective amendments) to this registration statement (and any additional registration statement related hereto permitted by Rule 462(b) promulgated under the Securities Act (and all further amendments, including post-effective amendments, thereto)), and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized.

Signature	Title	Date
/s/ Scott T. Garrett Scott T. Garrett	Chairman of the Board of Directors	January 9, 2026
/s/ Rebecca Byam Rebecca Byam	Chief Financial Officer	January 9, 2026
/s/ Hing C. Wong Hing C. Wong	Chief Executive Officer	January 9, 2026
/s/ Rick S. Greene Rick S. Greene	Director	January 9, 2026
/s/ Lisa M. Giles Lisa M. Giles	Director	January 9, 2026

Clark Hill

Jim Groth
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F312-985-5999
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Clark Hill
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T (312) 985-5900
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January 8, 2026

HCW Biologics Inc.
2929 N Commerce Parkway
Miramar, Florida 33025

Re: HCW Biologics Inc.
Resale Registration Statement Under Form S-1 (File No. 333-287136)

Ladies and Gentlemen:

We have acted as counsel to HCW Biologics Inc., a Delaware corporation (the "**Company**"), in connection with the filing of a Registration Statement on Form S-1 (as it may be amended or supplemented, the "**Registration Statement**") with the U.S. Securities and Exchange Commission (the "**SEC**") under the Securities Act of 1933, as amended (the "**Securities Act**"), relating to the resale by the selling stockholders identified in the Registration Statement (the "**Selling Stockholders**") of shares of the Company's common stock, $0.0001 par value per share (the "**Common Stock**").

The Registration Statement relates to the resale of: (i) 253,083 shares of Common Stock issued to certain investors upon the conversion on May 7, 2025 of approximately $6.6 million aggregate principal amount of senior secured promissory notes previously issued by the Company (the "**Conversion Shares**"); (ii) up to 126,540 shares of Common Stock issuable upon the exercise of warrants issued in connection with such conversion, at an exercise price of $26.00 per share (the "**Conversion Warrants**"); and (iii) up to 3,020,410 shares of Common Stock issuable upon the exercise of certain common stock purchase warrants issued on November 19, 2025 to Armistice Capital Master Fund Ltd. pursuant to a warrant inducement agreement, at an exercise price of $2.41 per share (the "**New Warrants**," and such shares, the "**Warrant Shares**").

In connection with this opinion, we have examined and relied upon: (i) the Registration Statement; (ii) the prospectus included therein (the "**Prospectus**"); (iii) the Company's certificate of incorporation and bylaws, each as amended and in effect on the date hereof; (iv) certain resolutions of the Company's board of directors authorizing the conversion of the secured promissory notes, the issuance of the Conversion Shares, the Conversion Warrants, the New Warrants and the shares issuable upon exercise thereof, and the filing of the Registration Statement; and (v) the originals or copies, certified or otherwise, identified to our satisfaction, of such records of the Company, certificates of public officials regarding the Company, officers of the Company, and such matters of law and regulation and such other documents as we have deemed relevant and necessary for the basis of our opinions hereinafter expressed.

In such examination, we have assumed the following: (i) the authenticity of documents submitted to us as originals and the conformity to authentic original documents, agreements and instruments of all documents, agreements and instruments submitted to us as facsimiles or PDFs, or as certified, conformed or reproduced copies, and the genuineness of all signatures; (ii) the legal capacity and competency of all signatories and the genuineness and validity of all signatures on all documents, (iii) the conformity to the originals of all documents submitted to us as copies and the authenticity of the originals of such copies; (iv) all documents filed as exhibits to the Registration Statement that have not been executed will conform to the forms thereof; and (v) the truth, accuracy and completeness of the information, factual matters, representations, warranties and covenants contained in the records, agreements (including the Transaction Agreements), documents, instruments and certificates we have reviewed. In making our examination of documents executed or to be executed, we have assumed that the parties thereto, other than the Company, had or will have the power, corporate or other, to enter into and perform all obligations thereunder and have also assumed the due authorization by all requisite action, corporate or other, and the execution and delivery by such parties of such documents and the validity and binding effect thereof on such parties. As to any facts material to the opinions expressed herein that we did not independently establish or verify, we have relied upon statements and representations of officers and other representatives of the Company and others and of public officials.

We have further assumed that at the time of issuance and to the extent any such issuance would exceed the maximum share capital of the Company currently authorized, the number of shares of Common Stock that the Company is authorized to issue shall have been increased in accordance with the bylaws such that a sufficient number of shares of Common Stock are authorized and available for issuance under the bylaws.

Based upon the foregoing, and subject to the assumptions, qualifications and limitations set forth herein, we are of the opinion that:

1. The Conversion Shares have been duly authorized and are validly issued, fully paid and nonassessable.

2. The shares of Common Stock issuable upon the exercise of the Conversion Warrants have been duly authorized and, when issued upon proper exercise of the Conversion Warrants in accordance with their terms (including payment of the applicable exercise price), will be validly issued, fully paid and nonassessable.

3. The shares of Common Stock issuable upon the exercise of the New Warrants have been duly authorized and, when issued upon proper exercise of the New Warrants in accordance with their terms (including payment of the applicable exercise price), will be validly issued, fully paid and nonassessable.

We hereby consent to the filing of this opinion as Exhibit 5.1 to the Registration Statement and to the reference to our firm under the heading "Legal Matters" in the Registration Statement. In giving such consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the SEC promulgated thereunder.

Our opinion is limited to the General Corporation Law of the State of Delaware and the federal laws of the United States of America. We express no opinion as to the laws of any other jurisdiction. This opinion is rendered as of the date hereof, and we undertake no obligation to update or supplement this opinion to reflect any facts or circumstances that may arise after the date hereof or any changes in applicable law.

Very truly yours,

/s/ Clark Hill PLC
CLARK HILL PLC

Exhibit 23.1a

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated May 15, 2024 (except for Note 16, as to which the date is March 28, 2025), with respect to the financial statements of HCW Biologics Inc. included in the Annual Report on Form 10-K for the year ended December 31, 2024, which are incorporated by reference in this Registration Statement. We consent to the incorporation by reference of the aforementioned report in this Registration Statement, and to the use of our name as it appears under the caption "Experts."

/s/ Grant Thornton LLP

Fort Lauderdale, Florida
January 9, 2026

Exhibit 23.1b

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement of HCW Biologics Inc. on Form S-1 of our report dated March 28, 2025 on the balance sheet of HCW Biologics Inc. as of December 31, 2024 and the statements of operations, changes in stockholders' equity (deficit) and cash flows for the year ended December 31, 2024, and to the reference to us under the heading "Experts" in the prospectus.

/s/ Crowe LLP
Crowe LLP

Indianapolis, Indiana
January 9, 2026

CHARTER OF THE AUDIT COMMITTEE
OF THE BOARD OF DIRECTORS OF HCW BIOLOGICS INC.
(Adopted and approved on June 10, 2021
and effective as of the Company's initial public offering)

1. Purpose

1.1 The purpose of the Audit Committee (the "***Committee***") of the Board of Directors (the "***Board***") of HCW Biologics Inc. (the "***Company***") shall be to:

1.1.1 Oversee the accounting and financial reporting processes of the Company and audits of the financial statements of the Company;

1.1.2 Assist the Board in oversight and monitoring of (i) the integrity of the Company's financial statements, (ii) review financial statement presentation and disclosure for required regulatory filings, (iii) the Company's compliance with legal and regulatory requirements, (iv) the independent auditor's qualifications, independence and performance, and (v) the Company's internal accounting and financial controls;

1.1.3 Provide the Board with the results of its monitoring and recommendations derived therefrom; and

1.1.4 Provide to the Board such additional information and materials as it may deem necessary to make the Board aware of significant financial matters that require the attention of the Board.

1.2 In addition, the Committee will undertake those specific duties and responsibilities listed below and such other duties as the Board may from time to time prescribe, or as may be required by law from time to time.

1.3 The Board and management shall ensure that the Committee has adequate funding and other resources and authority to discharge its responsibilities as determined by the Committee.

1.4 While the Committee has the responsibilities and authority set forth in this Charter, it is not the duty of the Committee to plan or conduct audits of the Company's financial statements or its internal control over financial reporting or to determine that that the Company's financial statements are complete and are in accordance with generally accepted auditing principles ("***GAAP***"). This is the responsibility of management and the independent auditor. Nor is it the duty of the Committee to assure compliance with laws or regulations or the Company's code of business conduct and ethics.

2. Membership & Organization

2.1 The Committee will consist of at least three (3) members of the Board, all of whom in the judgment of the Board shall be independent in accordance with the listing standards of the Nasdaq Stock Market, (except as otherwise permitted by the rules of the Nasdaq Stock Market and the rules of the U.S. Securities and Exchange Commission ("***SEC***") as may be

in effect from time to time). Each member shall in the judgment of the Board have the ability to read and understand the Company's financial statements. At least one (1) member of the Committee shall in the judgment of the Board be an audit committee financial expert in accordance with the rules and regulations of the SEC and at least one (1) member (who may also serve as the Committee's financial expert) shall in the judgment of the Board have accounting or related financial management expertise in accordance with the listing standards of the Nasdaq Stock Market. In addition, Committee members will satisfy any additional requirements mandated by the rules and regulations of the SEC or the listing standards of the Nasdaq Stock Market. The Committee will review its membership annually for compliance with the above requirements.

2.2 The members of the Committee will be appointed by the Board, on the recommendation of the Nominating and Corporate Governance Committee when applicable, and will serve at the discretion of the Board and may be replaced by the Board at any time or for any reason. Unless a chair is designated by the Board, the members of the Committee may appoint a chair of the Committee (the "***Chair***").

3. Responsibilities

In addition to such other responsibilities as may be delegated to the Committee from time-to-time by the Board, the Committee shall:

3.1 Review on a continuing basis the adequacy of the Company's system of internal controls, including meeting periodically with the Company's management and the independent auditors to review the adequacy of such controls and to review before release the disclosure regarding such system of internal controls required under SEC rules to be contained in the Company's periodic filings and, if applicable, the attestations or reports by the independent auditors relating to such disclosure;

3.2 Pre-approve all audit and permissible non-audit services and related engagement fees and terms for services provided to the Company by the independent auditors (or subsequently approving non-audit services in those circumstances where a subsequent approval is necessary and permissible);

3.3 Review and provide guidance with respect to the external audit and the Company's relationship with its independent auditors by: (i) reviewing the independent auditors' proposed audit scope, approach and independence; (ii) obtaining on a periodic basis in accordance with applicable requirements of the Public Company Accounting Oversight Board ("***PCAOB***") a written statement from the independent auditors regarding relationships and services with the Company which may impact independence or objectivity, and to the extent there are relationships, monitoring and investigating such relationships, including actively engaging in a dialogue with the independent auditors with respect to any disclosed relationships or services that may impact the objectivity and independence of the independent auditors, and presenting such information to the Board; (iii) receiving and reviewing a report by the independent auditors describing any material issues raised by the most recent internal quality control review, or peer review, of the independent auditing firm, or by any inquiry or investigation by governmental or

professional authorities and any steps taken to deal with any such issues; (iv) discussing with the Company's independent auditors the financial statements and audit findings, including any significant adjustments, management judgments and accounting estimates, critical audit matters addressed during the audit, significant new accounting policies, any alternative treatments of financial information within GAAP that the independent auditor has discussed with management, ramifications of the use of these alternative disclosures and the treatment preferred by the independent auditor and disagreements with management and any other matters required to be discussed by applicable accounting standards; and (v) reviewing reports submitted to the Committee by the independent auditors in accordance with the applicable SEC requirements and other legal or regulatory requirements;

3.4 Recommend to the Board as to whether the Company's audited financial statements should be included in the Company's Annual Report on Form 10-K based on the Committee's review and discussions (1) with management of the audited financial statements, (2) with the independent auditor of the matters required to be discussed by the PCAOB and the SEC, and (3) with the independent auditor concerning the independent auditor's independence;

3.5 Review and discuss with management and the independent auditors the annual audited financial statements and quarterly unaudited financial statements, including the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations," prior to filing the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, respectively, with the SEC;

3.6 Direct the Company's independent auditors to review before filing with the SEC the Company's interim financial statements included in Quarterly Reports on Form 10Q, using professional standards and procedures for conducting such reviews;

3.7 Conduct a post-audit review of the financial statements and audit findings, including any significant suggestions for improvements provided to management by the independent auditors;

3.8 Review before release the unaudited quarterly or annual operating results (or financial outlook or guidance) to be stated in the Company's quarterly earnings release with particular attention to any use of "pro forma" or "adjusted" non-GAAP information;

3.9 Review the contents of the officer certifications to be filed with the SEC pursuant to Sections 302 and 906 of the Sarbanes-Oxley Act and the process conducted to support the certifications;

3.10 Consider the establishment, and oversee the activities, of any internal audit function within the Company;

3.11 Review any reports by management or internal auditors, if any, regarding the effectiveness of, or any deficiencies in, the design or operation of internal controls and any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls and review before release the disclosure regarding the Company's system of internal controls required under SEC rules to be contained in the Company's periodic filings and, if applicable, the attestations or reports by the independent auditors relating to such disclosure;

3.12 Oversee compliance with legal requirements for disclosure of the Company's independent auditor's services and Committee members, member qualifications and activities;

3.13 Periodically review the Company's code of business conduct and ethics and approve any amendments thereto or waivers thereof, and perform the functions delegated to the Committee set forth in the Company's code of business conduct and ethics;

3.14 Review, in conjunction with counsel, any legal matters that could have a significant impact on the Company's financial statements;

3.15 Provide oversight and review at least annually of the Company's financial risk management policies, including its investment policies;

3.16 If necessary, institute special investigations with full access to all books, records, facilities and personnel of the Company;

3.17 As appropriate, engage and obtain advice and assistance from outside legal, accounting or other advisors with funding to be provided by the Company;

3.18 Conduct appropriate review and oversight of related party transactions, as defined by applicable rules of the SEC and Nasdaq Stock Market;

3.19 Review and assess the adequacy of this Charter and recommending any proposed changes to the Board for approval, on an annual basis;

3.20 Review annually its own performance against the responsibilities outlined in this Charter and as otherwise established by the Board;

3.21 Provide a report in the Company's proxy statement in accordance with the rules and regulations of the SEC;

3.22 Establish procedures for receiving, retaining and treating complaints received by the Company regarding accounting, internal accounting controls or auditing matters and procedures for the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters;

3.23 Review and discuss with management, the independent auditor and the internal auditor, if any, the Company's major financial risk exposures and the steps management has taken to monitor and control such exposures;

3.24 Review the adequacy and effectiveness of the Company's information and cyber security policies and the internal controls regarding information and cyber security; and

3.25 Review with management and members of internal audit, if any, the Company's business continuity and disaster preparedness planning.

4. Authority

The Committee shall:

4.1 Have the sole authority to appoint, compensate, retain, oversee the work of and to terminate the engagement of the independent auditors (including resolving disagreements between management and the independent auditors regarding financial reporting) for the purpose of preparing or issuing an audit report or related work;

4.2 Have the sole authority to approve the engagement of the Company's independent auditors to perform permissible non-audit services (or subsequently approving non-audit services in those circumstances where a subsequent approval is necessary and permissible) and, in the exercise of such authority, the Committee (or a subcommittee comprised solely of Committee members) shall consider whether the provision of such services is compatible with maintaining the independence of the Company's independent auditors;

4.3 Have the authority to form, and delegate authority to, one (1) or more subcommittees, comprised of one (1) or more Committee members, which subcommittee(s) shall have the responsibilities and authority delegated to them, including, if so designated, the full responsibility and authority of the Committee with respect to delegated matters including, without limitation, authority to delegate to one (1) or more designated members of the Committee the authority to pre-approve audit and permissible non-audit services, provided such pre-approval decision is presented to the full Committee at its scheduled meetings;

4.4 Have the authority to establish pre-approval policies that are detailed as to the particular services to which such policies would apply and include a requirement that the Committee be promptly informed of each service approved in accordance with such policies; provided, however, that nothing in this paragraph provides the Committee with authority to delegate its responsibilities under the Securities Exchange Act of 1934, as amended, to management

4.5 Have authority to set policies regarding the hiring by the Company of current or former employees of the Company's independent auditors; and

4.6 Have the authority to obtain advice, reports or opinions from internal or external counsel and other expert advisors at the Company's expense.

5. Meetings & Minutes

The Committee will meet at least four (4) times each year, either in person, by teleconference or video conference. The Chair, in consultation with the other members of the Committee, will set the dates, times and places of such meetings. The Chair or any other member of the Committee may call meetings of the Committee by notice in accordance with the Bylaws. A majority of the total number of then-serving members of the Committee shall constitute a quorum for the transaction of business at Committee meetings. The approval of a majority of such quorum shall constitute a valid act of the Committee at a duly held Committee meeting. The Committee may also act by unanimous written consent of the then-serving members of the Committee.

The Committee will meet separately with the Chief Executive Officer and separately with the Chief Financial Officer of the Company at such times as are appropriate to review the financial affairs of the Company. The Committee will also meet separately with the Internal Audit Executive, if any, at such times as are appropriate to review matters the Committee or the Internal Audit Executive believes should be discussed privately. The Committee will meet separately with the independent auditors of the Company, at such times as it deems appropriate, but not less than quarterly, to fulfill the responsibilities of the Committee under this charter.

The Committee will maintain written minutes of its meetings, which minutes will be filed with the minutes of the meetings of the Board.

6. Reports

In addition to preparing the report for inclusion in the Company's proxy statement in accordance with the rules and regulations of the SEC, the Committee will make regular reports to the Board regarding its activities.

7. Compensation

Members of the Committee shall receive such compensation, if any, for their service as Committee members in accordance with the Company's standard compensation arrangements for non-employee directors. Such compensation may include retainers or per meeting fees as well as equity awards. Fees may be paid in such form of consideration as is determined by the Board.

CHARTER OF THE COMPENSATION COMMITTEE
OF THE BOARD OF DIRECTORS OF HCW BIOLOGICS INC.

(Adopted and approved on June 10, 2021
and effective as of the Company's initial public offering)

1. Purpose

1.1 The purpose of the Compensation Committee (the "***Committee***") of the Board of Directors (the "***Board***") of HCW Biologics Inc. (the "***Company***") shall be to assist the Board in discharging its responsibilities relating to the review, determination and execution of the Company's compensation philosophy, and the compensation of the Company's Chief Executive Officer ("***CEO***"), other executive officers, and other personnel as may be determined by the Board, and fulfilling the Board's oversight responsibilities with respect to the Company's overall compensation policies, plans and programs and human capital management function.

1.2 The compensation programs for the Company's executive officers shall (i) be designed to attract, motivate and retain talented executives responsible for the success of the Company, (ii) be determined within a competitive framework, (iii) factor in the achievement of the Company's overall financial results, individual contributions and compensation philosophy of "pay for performance"; and (iv) align the interests of the executive officers with the long-term interests of the Company's stockholders, thereby incentivizing management to increase stockholder value.

1.3 The Board and management shall ensure that the Committee has adequate funding and other resources and authority to discharge its responsibilities as determined by the Committee.

2. Committee Membership & Organization

2.1 The Committee shall consist of at least two (2) members. The members of the Committee shall meet the (i) independence requirements of the Nasdaq Stock Market and (ii) non- employee director definition of Rule 16b-3 promulgated under Section 16 ("***Section 16***") of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***").

2.2 The members of the Committee will be appointed by the Board on the recommendation of the Nominating and Corporate Governance Committee or in the absence of a nominating and corporate governance committee, the members of the Committee will be appointed by the Board and will serve at the discretion of the Board and may be replaced by the Board at any time or for any reason. Unless a chair is designated by the Board, the members of the Committee may appoint a chair of the Committee (the "***Chair***").

3. Committee Responsibilities

In addition to such other responsibilities as may be delegated to the Committee from time-to-time by the Board, the Committee shall:

3.1 Set the compensation of the CEO and, in consultation with the CEO, review and approve the compensation of the other executive officers, in each case based on an evaluation of their performance and expected future contributions;

3.2 Establish annual and long-term performance goals and objectives for the CEO and, in consultation with the CEO, review and establish the goals and objectives for the other executive officers;

3.3 Evaluate the performance of the CEO and, in consultation with the CEO, review and evaluate the performance of the other executive officers in light of the goals and objectives established for them;

3.4 Approve employment agreements, offers of employment and other elements of compensation and benefits (other than ordinary health, welfare and retirement benefits provided broadly to employees) provided to the CEO and other executive officers;

3.5 Approve severance or termination arrangements or plans for the CEO and other executive officers, including in the event of a change-in-control;

3.6 Administer the Company's cash and equity-based incentive plans that are stockholder- approved and/or where participants include executive officers and directors, in each case, to the extent provided under those plans; and make recommendations to the Board with respect to improvements or changes to such plans or the adoption of new plans when appropriate;

3.7 Review and certify achievement with respect to cash or equity awards under corporate performance-based plans;

3.8 Review and discuss with management the Company's overall aggregate equity usage/budget relative to market;

3.9 Provide oversight of the Company's overall compensation and incentive plans and benefits programs, and recommend or approve improvements or changes to such plans and programs or recommend or adopt new plans and programs when appropriate;

3.10 Review on a periodic basis, and make recommendations to the Board as to, the compensation payable by the Company to non-employee directors in connection with their service on the Board and/or any committees of the Board;

3.11 Review and approve the selection of the Company's peer companies for purposes of evaluating the Company's compensation competitiveness and establishing the appropriate positioning of the levels and mix of compensation elements;

3.12 For so long as the Company is subject to the periodic reporting requirements of the Exchange Act, when applicable, review and discuss with management the Company's "Compensation Discussion and Analysis" (the "***CD&A***") to be included in the Company's annual report or annual proxy statement; based on the review and discussion, recommend to the Board that the CD&A be included in the Company's annual report or annual proxy statement, and produce a report of the Committee for inclusion in the Company's annual proxy statement that complies with the rules and regulations of the Securities and Exchange Commission ("***SEC***") and any other applicable rules and regulations;

3.13 Review with management the Company's major compensation-related risk exposures and the steps management has taken to monitor and control such exposures, and assess whether the Company's compensation policies and practices create risks that are reasonably likely to have a material adverse effect on the Company;

3.14 When applicable, review and recommend to the Board for approval the frequency with which the Company will conduct stockholder advisory "say-on-pay" votes (the "***Say-on- Pay Vote***") required by Section 14A of the Exchange Act, and assess the results of the Company's most recent Say-on-Pay Vote and take such assessment into consideration when establishing the compensation of the Company's executive officers;

3.15 Periodically review and discuss with the CEO and the Board, the development and succession plans for senior management positions;

3.16 Recommend or determine stock ownership guidelines for executive officers and non- employee directors and monitor compliance with such guidelines;

3.17 Annually review and assess the adequacy of this Charter and recommend any proposed changes to the Board for approval; and

3.18 Review annually its own performance against the responsibilities outlined in this Charter and as otherwise established by the Board.

The CEO will not be present for the voting or deliberations by the Committee on the CEO's compensation.

4. AUTHORITY

The Committee shall have:

4.1 The authority to form, and delegate authority to, one (1) or more subcommittees, comprised of one (1) for more Committee members, which subcommittee(s) shall have the responsibilities and authority delegated to them, including, if so designated, the full responsibility and authority of the Committee with respect to delegated matters, unless otherwise prohibited by applicable laws or listing standards;

4.2 The authority to delegate to one or more officers of the Company, any of its responsibilities and authority that do not relate to the amount or form of compensation of "officers" as defined in Section 16, including its responsibilities and authority related to the administration of compensation and incentive plans and benefits programs;

4.3 The authority to obtain advice, reports or opinions from internal or external counsel and other expert advisors at the Company's expense;

4.4 The sole authority to retain and terminate any compensation consultant, legal counsel or other advisor to assist in the evaluation of CEO or executive officer compensation, in each case at the Company's expense; and

4.5 The sole authority to approve the fees and other retention terms of consultants, legal counsel or other advisors engaged by the Committee.

In selecting advisors, the Committee shall take into account the independence requirements established by law, rule, regulation or order, including, without limitation, Rule 5605(d)(3) of the Nasdaq Stock Market.

5. Meetings & Minutes

The Committee shall meet at least four (4) times annually in person, by teleconference or by video conference. In addition, the Committee will also meet, as required, in response to the needs of the Board and as necessary to fulfil its responsibilities. The Chair, in consultation with the other members of the Committee, will set the dates, times and places of such meetings. The Chair or any other member of the Committee may call meetings of the Committee by notice in accordance with the Bylaws. A majority of the total number of then-serving members of the Committee shall constitute a quorum for the transaction of business at Committee meetings. The approval of a majority of such quorum shall constitute a valid act of the Committee at a duly held Committee meeting. The Committee may also act by unanimous written consent of the then-serving members of the Committee.

The Committee will maintain written minutes of its meetings, which minutes will be filed with the minutes of the meetings of the Board.

6. Reports

The Committee will make regular reports to the Board related to its activities. The Committee will prepare a report for inclusion in the Company's proxy statement in accordance with the rules and regulations of the SEC.

7. Compensation

Members of the Committee shall receive such compensation, if any, for their service as Committee members in accordance with the Company's standard compensation arrangements for non-employee directors. Such compensation may include retainers or per meeting fees as well as equity awards. Fees may be paid in such form of consideration as is determined by the Board.

HCW BIOLOGICS INC.

RELATED PARTY TRANSACTIONS POLICY

(Adopted and approved on June 10, 2021
and effective as of the Company's initial public offering)

1. Purpose

HCW Biologics Inc. (collectively with its subsidiaries, the "***Company***") is committed to promoting high standards of ethical business conduct and compliance with applicable laws, rules and regulations. As part of this commitment, the Company has adopted this Related Party Transactions Policy (this "***Policy***").

The Company expects its directors, officers and employees to avoid conflicts of interests that interfere with the performance of their duties to the Company or that might deprive the Company of that person's undivided loyalty in business dealings. Transactions to which the Company is a party and in which a Related Party (as defined below) has a material interest may present an actual or potential conflict of interest or create the appearance of a conflict. Whether a conflict exists is often unclear and, in many circumstances, transactions with Related Parties may, on balance, be beneficial to the Company and its stockholders and stakeholders. While the Company's code of business conduct and ethics addresses these matters generally, the Company has adopted this Policy to set forth the procedures for the identification, review, consideration and approval or ratification of transactions involving the Company and Related Parties by the Audit Committee (the "***Audit Committee***") of the Board of Directors (the "***Board***").

2. Approval of Related Party Transactions

2.1 Policy

All transactions with Related Parties, other than transactions for which Audit Committee approval is not required by this Policy, may be consummated or shall continue only if the Audit Committee shall have approved or ratified such transaction in accordance with the guidelines set forth in this Policy. A listing of and supplementary information on all such transactions shall be provided to the Audit Committee on a periodic basis.

Prior to entering into a transaction which may involve a conflict of interest, directors, executive officers and employees must comply with existing conflict of interest policies. For any transaction with a Related Party which meets the threshold for Audit Committee review, the Compliance Officer must be informed of the facts and circumstances of the proposed transaction. The Compliance Officer will report the transaction, together with a summary of the material facts, to the Audit Committee for their review at the next regularly scheduled Audit Committee meeting.

The Audit Committee shall approve or ratify only those transactions with Related Parties that, in light of known circumstances, are in or are not inconsistent with, the best interests of the Company, its stockholders and its stakeholders. No director shall participate in any approval or ratification of any transactions with Related Parties for which they are a Related Party. The Audit Committee, in the Audit Committee's sole discretion, may impose such conditions as it deems

appropriate on the Company or the Related Party in connection with the approval or ratification of the proposed transaction. The Audit Committee shall convey the decision, including any conditions imposed on the transaction, to the Compliance Officer, who shall convey the decision to the appropriate persons within the Company.

2.2 Factors

The Audit Committee, in approving, ratifying or rejecting the proposed transaction with a Related Party, shall consider the relevant and available facts and circumstances, including such facts as: (i) whether the transaction with the Related Party is fair to the Company on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the Related Party's interest in the transaction; (ii) the impact on a director's independence in the event the Related Party is a director, immediate family member of a director or an entity with which a director is affiliated; and (iii) any other relevant information and considerations with respect to the proposed transaction.

2.3 Ongoing Transactions

If a transaction with a Related Party is of the type that will be ongoing, the Audit Committee may establish guidelines for the Company to follow in its ongoing dealings with the Related Party. Thereafter, the Audit Committee, from time to time as the Audit Committee deems appropriate, shall review and assess such ongoing relationships with the Related Party to confirm that such relationships remain in compliance with the Audit Committee's guidelines, if any, and that the transaction with the Related Party remains appropriate, in which case the Audit Committee will ratify any transactions with Related Party that result from such ongoing relationships.

3. Disclosure

All transactions with Related Parties that are required to be disclosed in the Company's filings with the U.S. Securities and Exchange Commission ("SEC"), as required by the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, and related rules and regulations, or the Company's financial statements pursuant to Accounting Standards Codification Topic 850, *Related Party Disclosures* ("***ASC 850***"), shall be so disclosed in accordance with such laws, rules and regulations.

The material features of this Policy shall be disclosed in the Company's annual report on Form 10-K or in the Company's proxy statement, as required by applicable laws, rules and regulations.

4. Board Notice

The Audit Committee shall update the Board with respect to any transactions with Related Parties as part of its regular updates to the Board regarding Audit Committee activities.

5. Standing Pre-Approval for Certain Related Party Transactions

The Audit Committee has determined that for the purposes of this Policy, in the absence of facts or circumstances indicating special or unusual benefits to the Related Party, the following transactions, arrangements or relationships need not be approved by the Audit Committee under this Policy:

- any employment by the Company of an executive officer of the Company if:
  - the related compensation is required to be reported in the Company's proxy statement under the SEC's compensation disclosure requirements (generally applicable to "named executive officers") under Item 402 of Regulation S-K; or
  - the executive officer is not an immediate family member of another executive officer or director of the Company, the related compensation would be reported in the Company's proxy statement under Item 402 of Regulation S-K if the executive officer were a "named executive officer," and the Compensation Committee of the Board approved (or recommended that the Board approve) such compensation;
- any compensation paid to a director (in such capacity) if the compensation is required to be reported in the Company's proxy statement under Item 402 of Regulation S-K (or is excluded from disclosure pursuant thereto);
- any transaction where the Related Party's interest arises solely from the ownership of the Company's capital stock and all holders of the Company's capital stock received the same benefit on a *pro rata* basis (e.g. dividends);
- any transaction with a Related Party (a) where the rates or charges involved are determined by competitive bids; (b) involving the rendering of services as a common or contract carrier or public utility, at rates or charges fixed in conformity with law or governmental authority; or (c) involving services as a bank depositary of funds, transfer agent, registrar, trustee under a trust indenture or similar services;
- any transaction, if the aggregate amount involved in a fiscal year of the Company does not exceeds $120,000;
- any transaction with another company at which a Related Party's only relationship is as (a) an employee (other than an executive officer) or director, (b) a beneficial owner of less than 5%, together with such Related Party's immediate family members, of that company's outstanding equity, or (c) in the case of partnerships, a limited partner, if the limited partner, together with such Related Party's immediate family members, has an interest of less than 5% and the limited partner does not hold another position in the partnership, if the aggregate amount involved does not exceed $120,000;
- transactions available to all employees;
- ordinary course business travel and expenses, advances and reimbursements; and
- any indemnification payments and other payments made pursuant to (a) directors and officers insurance policies, (b) the Company's Certificate of Incorporation or Bylaws then in effect and/or (c) any policy, agreement or instrument approved by the Board.

6. Definitions

As used in this Policy, the following terms have the meanings set forth in this section.

"***Compliance Officer***" means the Company's Director, Legal Affairs; *provided that*, in the event that the Director, Legal Affairs is otherwise unavailable, the Company's Chief Financial Officer shall be authorized to serve as the Compliance Officer in the interim or to designate another person as the Compliance Officer.

"***Related Party***" means any:

- person who is, or at any time since the beginning of the Company's last fiscal year, was, a director or executive officer of the Company or, a nominee to become a director of the Company or a candidate to be employed by the Company; such other member of the Company's senior management as jointly determined by the Chief Financial Officer and Compliance Officer;
- security holder known by the Company to be the beneficial owner of more than 5% of any class of the Company's voting securities (a "***significant stockholder***"); or
- "***immediate family member***" of any of the foregoing, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law of such person, and any person (other than a tenant or employee) sharing the household of such person.

For purposes of this Policy, a "***transaction with a Related Party***" means any transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships), involving the Company (including any of its subsidiaries) in which any Related Person has, had or will have a direct or indirect material interest and the aggregate amount involved exceeds $120,000.

7. Amendments

This Policy has been approved by the Board, and the Audit Committee may from time to time recommend amendments to this Policy for consideration by the Board.

Calculation of Filing Fee Tables

S-1

HCW Biologics Inc.

Table 1: Newly Registered and Carry Forward Securities ☐Not Applicable

		Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial Effective Date	Filing Fee Previously Paid in Connection with Unsold Securities to be Carried Forward
Newly Registered Securities													
Fees to be Paid	1	Equity	Common stock, par value $0.0001 per share	457(a)	253,083	$ 1.80	$ 455,549.40	0.0001381	$ 62.91				
Fees to be Paid	2	Equity	Common stock, par value $0.0001 per share, issuable upon the exercise of warrants	Other	3,146,950	$ 3.36	$ 10,573,752.00	0.0001381	$ 1,460.24				
Fees Previously Paid													
Carry Forward Securities													
Carry Forward Securities													
				Total Offering Amounts:			$ 11,029,301.40		$ 1,523.15				
				Total Fees Previously Paid:					$ 0.00				
				Total Fee Offsets:					$ 0.00				
				Net Fee Due:					$ 1,523.15				

Offering Note

[1] The shares of common stock, par value $0.0001 per share (the "Common Stock"), of HCW Biologics Inc. (the "Company") being registered hereunder are being registered for sale by the selling stockholders named in the prospectus to which this Registration Statement on Form S-1 relates. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), the shares of Common Stock being registered hereunder include such indeterminate number of shares of Common Stock as may be issuable with respect to the shares of Common Stock being registered hereunder as a result of stock splits, stock dividends or similar transactions. The proposed maximum offering price per unit is estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act and based upon the average of the high and low sale prices of the Common Stock on the Nasdaq Capital Market on December 16, 2025.

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[2] The shares of the Company's Common Stock being registered hereunder are being registered for sale by the selling stockholders named in the prospectus to which this Registration Statement on Form S-1 relates. Pursuant to Rule 416 under the Securities Act, the shares of Common Stock being registered hereunder include such indeterminate number of shares of Common Stock as may be issuable with respect to the shares of Common Stock being registered hereunder as a result of stock splits, stock dividends or similar transactions. The amount registered consists of up to 3,146,950 shares of Common Stock issuable upon the exercise of warrants. All 3,146,950 shares of Common Stock are to be offered for resale by the selling stockholders named in the prospectus contained in this Registration Statement on Form S-1. The Registrant will not receive any proceeds from the sale of its Common Stock by the selling stockholders. Pursuant to Rule 457(g) of the Securities Act, the proposed maximum offering price per share for the shares of common stock issuable upon exercise of the warrants is based on the exercise price of such warrants. The warrants have exercise prices ranging from $2.41 to $26.00, and the proposed maximum offering price per share represents a weighted average exercise price.

Table 2: Fee Offset Claims and Sources ☑Not Applicable

		Registrant or Filer Name	Form or Filing Type	File Number	Initial Filing Date	Filing Date	Fee Offset Claimed	Security Type Associated with Fee Offset Claimed	Security Title Associated with Fee Offset Claimed	Unsold Securities Associated with Fee Offset Claimed	Unsold Aggregate Offering Amount Associated with Fee Offset Claimed	Fee Paid with Fee Offset Source

Rules 457(b) and 0-11(a)(2)												
Fee Offset Claims	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Fee Offset Sources	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Rule 457(p)												
Fee Offset Claims	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Fee Offset Sources	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 3: Combined Prospectuses ☑Not Applicable

	Security Type	Security Class Title	Amount of Securities Previously Registered	Maximum Aggregate Offering Price of Securities Previously Registered	Form Type	File Number	Initial Effective Date
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A