Filed pursuant to Rule 424(b)(4)
Registration Statement No. 333-293396

2,477,292 Units, each consisting of:

One Share of Common Stock or One Pre-Funded Warrant to Purchase One Share of Common Stock and One Common Stock Warrant to Purchase One Share of Common Stock Up to 2,477,292 Shares of Common Stock or Shares of Common Stock Underlying Pre-Funded Warrants
2,477,292 Shares of Common Stock Underlying Common Stock Warrants

---

We are offering on a reasonable best efforts basis 2,477,292 units ("Units") each consisting of one share of our common stock, par value $0.0001 per share (our "Common Stock"), and one warrant (each a "Common Stock Warrant" or "warrant"), each warrant to purchase one shares of our Common Stock at an offering price of $0.6055 per Unit, for gross proceeds of approximately $1.5 million. The public offering price per Unit has been determined between us and the placement agent based upon a number of factors, including market conditions at the time of pricing, our history and our prospects, the industry in which er operate, our past and present operation results and the general condition of the securities market at the time of this offering. The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The Common Stock or Pre-Funded Warrants (as defined below) and Common Stock Warrants are immediately separable and will be issued separately in this offering. Each Common Stock Warrant will be exercisable beginning on the effective date of such shareholder approval as may be required by the applicable rules and regulations of the Nasdaq Capital Market (or any successor entity) to permit the exercise of the Common Stock Warrants ("Shareholder Approval") for one share of Common Stock at an exercise price of $0.6055 per share (100% of the public offering price per Unit) and will expire on the fifth anniversary of the date of Shareholder Approval. If we are unable to obtain any required Shareholder Approval, the common warrants will not be exercisable and therefore have no value.

Our Common Stock is listed on The Nasdaq Stock Market LLC ("Nasdaq") under the symbol "HCWB". On February 17, 2026, the last quoted sale price for our Common Stock as reported on Nasdaq was $0.6011 per share.

We are also offering to investors in our Common Stock that would otherwise result in the investor's beneficial ownership exceeding 4.99% of our outstanding Common Stock immediately following the consummation of this offering the opportunity to invest in pre-funded warrants, each to purchase one share of our Common Stock ("Pre-Funded Warrant") (in lieu of shares of our Common Stock). Subject to limited exceptions, a holder of Pre-Funded Warrants will not have the right to exercise any portion of its Pre-Funded Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, such limit may be increased to up to 9.99%) of our Common Stock outstanding immediately after giving effect to such exercise. Each Pre-Funded Warrant will be exercisable for one share of our Common Stock. The purchase price of each Pre-Funded Warrant will be equal to the price per share of one share of our Common Stock, minus $0.0001, and the exercise price of each Pre-Funded Warrant will equal $0.0001 per share. The Pre-Funded Warrants will be immediately exercisable (subject to the beneficial ownership cap) and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. For each Pre-Funded Warrant purchased (without regard to any limitation on exercise set forth therein), the number of shares of our Common Stock we are offering will be decreased on a one-for-one basis.

The securities will be offered at a fixed price and are expected to be issued in a single closing. We expect this offering to be completed no later than two business days following the commencement of sales in this offering (after the effective date of the registration statement of which this prospectus forms a part) and we will deliver all

securities to be issued in connection with this offering delivery versus payment or receipt versus payment, as the case may be, upon our receipt of investor funds. Accordingly, neither we nor the placement agent have made any arrangements to place investor funds in an escrow account or trust account since the placement agent will not receive investor funds in connection with the sale of the securities offered hereunder.

We have engaged Maxim Group LLC (the "placement agent" or "Maxim") to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. We have agreed to pay the placement agent the fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. There is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement as a condition of closing of this offering. We may sell fewer than all of the shares offered hereby, which may significantly reduce the amount of proceeds received by us. Because there is no escrow account and no minimum number of securities or amount of proceeds, investors could be in a position where they have invested in us, but we have not raised sufficient proceeds in this offering to adequately fund the intended uses of the proceeds as described in this prospectus. See "Risk Factors" for more information regarding risks related to this offering. We will bear all costs associated with the offering. See "Plan of Distribution" for more information regarding these arrangements.

	Per Unit Consisting of Common Stock and Warrants	Per Unit Consisting of Pre-Funded Warrant and Warrants	Total[2]
Public offering price	$ 0.6055	$ 0.6054	$1,500,000.31
Placement agent fees[1]	$ 0.0418	$ 0.0418	$ 103,500.02
Proceeds to us, before expenses[1]	$ 0.5637	$ 0.5635	$1,396,500.29

(1) The placement agent fees shall equal 6.9% of the gross proceeds of the securities sold by us in this offering. The placement agent will receive compensation in addition to the placement agent fees described above. See "Plan of Distribution" for a description of compensation payable to the placement agent.

(2) The foregoing assumes that the Pre-funded Warrants issued as part of the offering are exercised in full.

There is no established trading market for the Pre-Funded Warrants and we do not expect an active trading market to develop. We do not intend to list the Pre-Funded Warrants on any securities exchange or other trading market. Without an active trading market, the liquidity of these securities will be limited.

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 17 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.

We anticipate that delivery of the securities against payment will be made on or about February 19, 2026.

Sole Placement Agent

Maxim Group LLC

The date of this prospectus is February 17, 2026

TABLE OF CONTENTS

This prospectus provides additional information about us and the securities offered under this prospectus. This prospectus 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 shares 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 placement agent have 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 securities 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 securities hereunder. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the placement agent is not, making an offer of these securities in any jurisdiction where such offer is not permitted.

ABOUT THIS PROSPECTUS

We incorporate by reference important information into this prospectus. You should rely only on the information contained in this prospectus, including the information incorporated by reference into this prospectus, and in any free writing prospectus. We have not and the placement agent has not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. We take no responsibility for and cannot provide any assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, our securities only in jurisdictions where offers and sales are permitted.

Neither we nor the placement agent have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our securities and the distribution of this prospectus outside of the United States. This prospectus does not constitute an offer to sell to any person, or a solicitation of an offer to purchase from any person, the securities offered by this prospectus in any jurisdiction in which it is unlawful to make such offer or solicitation of an offer.

This prospectus provides you with general information regarding the securities being offered hereby. 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.

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.

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), and an option to license HCW9302 for in vivo applications in China or Asia. 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.

On February 13, 2026, Trimmune initiated payment of half of the $3.5 million upfront cash license fee to the Company ($1.75 million, before taxes), with the remainder to be paid on or before March 6, 2026. The $3.5 million upfront license fee, combined with the Company's minority co-founder equity position in Trimmune, currently valued at approximately $3.5 million, constitute consideration for the HCW11-006 license. In addition to the upfront license fee, the Company is eligible to receive significant development milestone payments and royalties on future product sales, as well as a portion of the proceeds from certain future transactions involving the licensed molecule, if and when such transactions occur.

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 ("Treg") cells in the body. Treg 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 Treg 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, which began with a hearing held on September 25, 2025 and may extend up to 30 days thereafter. At the hearing, the Company presented a detailed compliance plan, which included, among other things, the filing of this prospectus and the registration statement of which it is a part and the offering described herein. The Company is in the process of implementing its compliance plan and is considering all other options available to it to regain compliance with the Equity Rule.

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.

On January 7, 2026, the Company received written notice from the Staff that, as of December 31, 2025, the Company was compliant with the Equity Rule. The Company remains subject to the Panel's decision letter to

maintain compliance with all listing rules for continued listing through February 16, 2026. Pursuant to Listing Rule 5815(d)(4)(B), the Company will be subject to a Mandatory Panel Monitor for a period of one year from the date of this letter. If, within that one-year monitoring period, Staff finds the Company again out of compliance with the Equity Rule that was the subject of the exception, notwithstanding Rule 5810(c)(2), the Staff will issue a Delist Determination Letter. In such a case, the Company will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable.

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, on January 9, 2026 we filed a registration statement to register the resale of the New Warrant Shares.

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 issuance and sale of shares of Common Stock hereunder 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"), and under the Common Stock Purchase Warrant dated as of November 20, 2024 (the "Purchase Warrant") issued by the Company to Armistice Capital Master Fund Ltd. ("Armistice"), 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 September 30, 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 had significant obligations as a result of legal fees incurred but not paid for the defense of the Company, as well as our Chief Executive Officer. On December 30, 2025, the Company executed a settlement agreement relating to approximately $7.4 million of outstanding legal fees included in the Company's outstanding trade payables. The terms of the settlement include $2.0 million of cash settlement payments, consisting of a $500,000 payment on or before December 31, 2025 (which has been paid), and a $1.5 million payment to be made within one business day of receipt of payment of a license fee from Beijing Trimmune Biotech Co., Ltd. or its affiliates. The settlement also includes a contingent promissory note providing for certain potential payments in the event, and only to the extent, that the Company achieves certain defined milestones in the future, but such contingent promissory note does not include or represent a current liability or obligation that must be recognized by the Company as of December 31, 2025. The remaining outstanding legal fee obligations could have a negative material impact on our business and operations.
- After receiving written notice from the Nasdaq Listing Qualifications Staff that, as of June 30, 2025, the Company was not in compliance with the Equity Rule, the Company was granted a hearing on September 25, 2025, at which the Company presented a compliance plan for regaining and maintaining compliance with the Equity Rule and all listing rules for the Nasdaq Capital Market tier to a Nasdaq Hearings Panel. On January 7, 2026, the Company received written notice from the Staff that as of December 31, 2025, the Company was compliant with the Equity Rule. The Company remains subject to the Panel's decision letter to maintain compliance with all listing rules for continued listing through February 16, 2026. Pursuant to Listing Rule 5815(d)(4)(B), the Company will be subject to a Mandatory Panel Monitor for a period of one year from the date of this letter. If, within that one-year monitoring period, Staff finds the Company again out of compliance with the Equity Rule that was the subject of the exception, notwithstanding Rule 5810(c)(2), the Staff will issue a Delist Determination Letter and the Company will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable.
- 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.

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

Issuer:	HCW Biologics Inc.
Securities Offered by Us:	2,477,292 Units, each consisting of one share of our Common Stock (or one Pre-Funded Warrant to purchase one share of Common Stock) and one Common Stock Warrant that may be exercised to purchase one share of Common Stock. We are also offering to investors in shares that would otherwise result in the investor's beneficial ownership exceeding 4.99% of our outstanding Common Stock immediately following the consummation of this offering the opportunity to invest in Pre-Funded Warrants to purchase shares of our Common Stock each in lieu of one share of Common Stock. For each Pre-Funded Warrant purchased (without regard to any limitation on exercise set forth therein), the number of shares of Common Stock we are offering will be decreased on a one-for-one basis. Subject to limited exceptions, a holder of Pre-Funded Warrants will not have the right to exercise any portion of its Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, such limit may be increased to up to 9.99%) of the Common Stock outstanding immediately after giving effect to such exercise. Each Pre-Funded Warrant will be exercisable for one share of Common Stock. The purchase price of each Pre-Funded Warrant will be equal to the price per share of Common Stock, minus $0.0001, and the exercise price of each Pre-Funded Warrant will equal $0.0001 per share. The Pre-Funded Warrants will be immediately exercisable (subject to the beneficial ownership cap) and may be exercised at any time in perpetuity or until all of the Pre-Funded Warrants are exercised in full. This offering also relates to the shares of Common Stock issuable upon the exercise of the Pre- Funded Warrants. The Units will not be certificated or issued in stand-alone form. The shares of our Common Stock (or Pre-Funded Warrants in lieu thereof) and the Common Stock Warrants comprising the Units are immediately separable upon issuance and will be issued separately in this offering. The Common Stock Warrants will have an exercise price per share of 100% of the public offering price per Unit, will be exercisable upon Shareholder Approval and will expire on the fifth anniversary of the date of Shareholder Approval. Each warrant is exercisable for one share of Common Stock, subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our Common Stock as described herein. This offering also relates to the offering of the shares of Common Stock issuable upon the exercise of the Common Stock Warrants. For more information regarding the warrants, you should carefully read the section titled "Description of Our Securities — Warrants" in this prospectus.

Offering price:	$0.6055 per Unit
Shares of Common Stock outstanding as of the date of this prospectus(1):	3,279,812 shares.
Shares of Common Stock to be outstanding immediately after this offering(1):	5,757,104 shares (assuming the maximum number of shares covered by this prospectus and no issuance of Pre-Funded Warrants).
Use of Proceeds:	We currently intend to use the proceeds from this offering for funding the continued progress of our preclinical and clinical development, including the clinical trials for HCW9302, research and development costs, expansion of business development programs and identifying compounds appropriate for out-licensing arrangements or other collaborations, expansion of the Company's patent portfolio, studies required for pivotal scientific publications, and the remainder for general corporate purposes. General corporate purposes may include, among other things, working capital, capital expenditures and other general corporate purposes. See "Use of Proceeds" beginning on page 56 of this prospectus.
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 17 of this prospectus.
Reasonable best efforts offering:	We have agreed to offer and sell the securities offered hereby directly to the purchasers. We have retained Maxim Group LLC ("Maxim" or the "placement agent") to act as our exclusive placement agent to use its reasonable best efforts to solicit offers to purchase the securities offered by this prospectus. The placement agent is not required to buy or sell any specific number or dollar amount of the securities offered hereby. See "Plan of Distribution" beginning on page 82 of this prospectus.
Transfer Agent:	The transfer agent and registrar for our Common Stock is Equiniti Trust Company, LLC.
Lock-Up Restrictions:	We and each of our directors, officers and certain stockholders are subject to certain lock-up restrictions as identified in the section titled "Plan of Distribution" beginning on page 82 of this prospectus.
Nasdaq Symbol:	Our Common Stock is listed on Nasdaq under the symbol "HCWB". There is no established trading market for the Pre-Funded Warrants, and we do not expect a trading market to develop. We do not intend to list the Pre-Funded Warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Pre-Funded Warrants will be extremely limited.

Adjustment to Outstanding Warrants:	We may enter into privately negotiated agreements with the holders of certain existing outstanding warrants to purchase up to 3,020,410 shares of Common Stock (the "Prior Warrants") to, among other things, reduce the exercise price of such Prior Warrants to the public offering price per Unit paid in this offering (or such price as approved by the stockholders). There can be no assurance that we will amend the Prior Warrants or as to the final terms of any amendments to the Prior Warrants. The reduction of the exercise price of the Prior Warrants is subject to stockholder approval in accordance with applicable Nasdaq rules.

(1) The shares of Common Stock outstanding is based on 3,279,812 shares outstanding as of February 17, 2026. The number excludes the following:

- 126,540 shares issuable upon the conversion of outstanding warrants exercisable at $26.00 per share;
- 977,000 shares held in abeyance on behalf of Armistice Capital Master Fund Ltd.;
- 3,020,410 shares issuable upon the conversion of outstanding warrants exercisable at $2.41 per share (which exercise price may be amended to the public offering price per Unit paid in this offering, subject to stockholder approval);
- 42,845 shares issuable upon the exercise stock options of vested employee equity awards under the 2019 Equity Incentive Plan ("2019 Plan") and the 2021 Equity Incentive Plan ("2021 Plan");
- 1,383 shares for stock options underlying unvested employee equity awards under the 2019 Plan and 2021 Plan;
- 80,542 shares reserved for issuance under our 2021 Plan; and
- Shares valued up to $17.0 million, which may be issued through draws on our equity line of credit.

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"), 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

This is a reasonable best efforts offering, with no minimum amount of securities required to be sold, and we may sell fewer than all of the securities offered hereby.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the shares of our Common Stock in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to complete this offering. As there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth in this prospectus. We may sell fewer than all of the securities offered hereby, which would significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell all of the shares of our Common Stock offered in this offering. The success of this offering will impact our ability to use the proceeds to execute our business plans. We may have insufficient capital to implement our business plans, potentially resulting in greater operating losses or dilution unless we are able to raise capital from alternative sources.

Investors in this offering will experience immediate and substantial dilution in the book value of their investment.

The public offering price will be substantially higher than the net tangible book value per share of our outstanding shares of common stock. As a result, investors in this offering will incur immediate dilution of $0.22 per share based on the public offering price of $0.6055 per Unit. Investors in this offering will pay a price per share that substantially exceeds the book value of our assets after subtracting our liabilities. To the extent outstanding stock options or warrants are exercised, new stock options are issued or we issue additional shares of common stock in the future, there will be further dilution to new investors. As a result of the dilution to investors purchasing common stock in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. See "Dilution" for a more complete description of how the value of your investment will be diluted upon the completion of this offering.

Our management will have broad discretion over the use of the proceeds we receive in this offering and might not apply the proceeds in ways that increase the value of your investment.

Our management will have broad discretion over the use of our net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. We currently intend to use the net proceeds from this offering for funding the continued progress of our preclinical and clinical development, including the clinical trials for HCW9302, research and development costs, expansion of business development programs and identifying compounds appropriate for out-licensing arrangements or other collaborations, expansion of the Company's patent portfolio, studies required for pivotal scientific publications, and other general corporate purposes, including for working capital. Our management might not be able to yield a significant return, if any, on any investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

We will seek to raise additional funds, finance acquisitions or develop strategic relationships by issuing securities that would dilute your ownership. Depending on the terms available to us, if these activities result in significant dilution, it may negatively impact the trading price of our common stock.

Any additional financing that we secure may require the granting of rights, preferences or privileges senior to, or *pari passu* with, those of our Common Stock. Any issuances by us of equity securities may be at or below the prevailing market price of our Common Stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our Common Stock to decline. We may also raise additional funds through the incurrence of debt or the issuance or sale of other securities or instruments senior to our shares of Common Stock, which may be highly dilutive. The holders of any securities or instruments we may issue may have rights superior to the rights of holders of our Common Stock. If we experience dilution from the issuance of additional securities and we grant superior rights to new securities over holders of our Common Stock, it may negatively impact the trading price of our common stock and you may lose all or part of your investment.

The Common Stock Warrants and the Pre-Funded Warrants are speculative in nature and there is not expected to be an active trading market for the warrants.

The Pre-Funded Warrants offered in this offering do not confer any rights of Common Stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our Common Stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of Pre-Funded Warrants may exercise their right to acquire the Common Stock and pay an exercise price of $0.0001 per share. The Pre-Funded Warrants do not expire. In addition, there is no established trading market for the Pre-Funded Warrants and we do not expect an active trading market to develop. Without an active trading market, the liquidity of the Pre-Funded Warrants will be limited.

Holders of the Common Stock Warrants and the Pre-Funded Warrants will have no rights as a holder of Common Stock until they acquire our Common Stock.

Until holders of the Pre-Funded Warrants acquire shares of our Common Stock upon exercise of the Pre-Funded Warrants, the holders will have no rights with respect to shares of our Common Stock issuable upon exercise of the Pre-Funded Warrants. Upon exercise of the Pre-Funded Warrants, the holder will be entitled to exercise the rights of a holder of Common Stock as to the security exercised only as to matters for which the record date occurs after the exercise.

The Common Stock Warrants are not exercisable until Shareholder Approval and may not have any value.

Under Nasdaq listing rules, the Common Stock Warrants being offered in this offering are not exercisable without Shareholder Approval for the issuance of shares issuable upon exercise of such Common Stock Warrants. While we intend to use reasonable best efforts to seek Shareholder Approval to permit the issuance of shares of common stock issuable upon exercise of the Common Stock Warrants as applicable, there is no guarantee that Shareholder Approval will ever be obtained. The Common Stock Warrants will be exercisable commencing on the date Shareholder Approval is obtained, at an exercise price per share of $0.6055. If the price of a share of our common stock does not exceed the exercise price of the Common Stock Warrants during the period when the Common Stock Warrants are exercisable, the Common Stock Warrants may not have any value. If we are unable to obtain Shareholder Approval, the Common Stock Warrants will not be exercisable and therefore would have no value.

In addition, we may incur substantial cost, and management may devote substantial time and attention, in attempting to obtain Shareholder Approval of the issuance of shares of common stock upon exercise of the Common Stock Warrants issued in this offering.

Provisions of the Common Stock Warrants could discourage an acquisition of us by a third party.

Certain provisions of the Common Stock Warrants could make it more difficult or expensive for a third party to acquire us. The Common Stock Warrants prohibit us from engaging in certain transactions constituting

"fundamental transactions" unless, among other things, the surviving entity assumes our obligations under the Common Stock Warrants. These and other provisions of the warrants offered by this prospectus could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

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 technologies, 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 technologies, 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 September 30, 2025, we held $1.1 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 connection 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 January 7, 2026, the Company received written notice from the Staff that as of December 31, 2025, the Company was compliant with the Equity Rule. The Company remains subject to the Panel's decision letter to maintain compliance with all listing rules for continued listing through February 16, 2026.

On June 26, 2025, we received formal notice from the Nasdaq Listing Qualifications Staff (the "Staff") that we were in compliance with Listing Rule 5550(b)(1) (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'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.

On January 7, 2026, the Company received written notice from the Staff that as of December 31, 2025, the Company was compliant with the Equity Rule. The Company remains subject to the Panel's decision letter to maintain compliance with all listing rules for continued listing through February 16, 2026. Pursuant to Listing Rule 5815(d)(4)(B), the Company will be subject to a Mandatory Panel Monitor for a period of one year from the date of this letter. If, within that one-year monitoring period, Staff finds the Company again out of compliance with the Equity Rule that was the subject of the exception, notwithstanding Rule 5810(c)(2), the Staff will issue a Delist Determination Letter and the Company will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable.

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. After year end, we received a $2.0 million insurance payment which was used to offset obligations for legal fees for our Chief Executive Officer. 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, and a Case Management conference was held. The B&I MSJ is scheduled to be heard on February 19, 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 significant percentage of our stock and may be able to exert control over 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. 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 commencing clinical trials 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, which has been extended until November 2025. 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.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $980,000, after deducting placement agent fees and estimated offering expenses payable by us.

However, because this is a reasonable best efforts offering with no minimum number of securities or amount of proceeds as a condition to closing, the actual offering amount, placement agent fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus, and we may not sell all or any of the securities we are offering. As a result, we may receive significantly less in net proceeds.

We currently intend to use the net proceeds of this offering as follows:

- Expenses associated with preclinical and clinical development to prepare for submission of IND applications for molecules created with the TRBC drug discovery and development platform;
- Costs for clinical trials, including clinical trials to evaluate HCW9302 in patients with alopecia areata, and research to identify potential expanded indications;
- Funding for research and development, in particular continued development of TRBC molecules known as second generation T-Cell Engagers and second generation immune checkpoint inhibitors;
- Preparing for business development transactions, including the identification of appropriate compounds for out-licensing, especially the TRBC Class III molecules known as immune cell engagers, such as T-Cell Engagers;
- Expansion of patent portfolio for HCW9302 and other new TRBC-based compounds created with the TRBC drug discovery and development platform, in particular, the second generation T-Cell Engagers and the second generation immune checkpoint inhibitors;
- Costs for studies required for pivotal scientific publications; and
- The remainder for general corporate purposes. General corporate purposes may include, among other things, working capital, capital expenditures and other general corporate purposes.

The actual allocation of proceeds realized from this offering will depend upon our operating expenses, operating revenue, cash position, working capital requirements and other factors. We cannot currently allocate specific percentages of the net proceeds to us from this offering that we may use for the foregoing purposes. Therefore, as of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Accordingly, we will have discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the proceeds of this offering. Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including deposit accounts, short-term, investment-grade, interest-bearing instruments and U.S. government securities.

CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2025, on an actual basis, on an as adjusted basis to reflect the inducement transaction to purchase 1,510,205 shares which the Company entered on November 19, 2025, and on an as adjusted basis to reflect the issuance and sale by us of 2,477,292 Units in this offering at the public offering price of $0.6055 per Unit (assuming no issuance of Pre-Funded Warrants), after deducting placement agent fees and estimated offering expenses payable by us and the receipt by us of the proceeds of such sale and assuming no exercise of any outstanding warrants to purchase shares of Common Stock.

The information below is illustrative only. Our capitalization following the closing of this offering will change based on the actual public offering price and other terms of this offering determined at the time of pricing. You should read this table in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes included in our Quarterly Report on Form 10-Q for the period ended September 30, 2025 and subsequent filings pursuant to the Exchange Act.

The following sets forth our cash and capitalization as of September 30, 2025 on:

- an actual basis;
- a pro forma for the effect of the inducement of the exercise of warrants to purchase 1,510,205 shares of Common Stock at $2.66 per share, including 977,000 shares of Common Stock held in abeyance on behalf of Armistice Capital Master Fund Ltd. expected to be issued, after deducting commissions and transaction expenses; and
- a pro forma as adjusted basis, to give post offering effect to the sale of shares of Common Stock in this offering at the public offering price of $0.6055 per share (assuming the sale of the maximum offering amount), and after deducting commissions and estimated offering expenses payable by us.

	At September 30, 2025		
	Actual Basis (unaudited)	Pro Forma (unaudited)	As Adjusted Pro Forma (unaudited)
Cash	$ 1,096,909	$ 4,792,675	$ 5,772,675
Stockholders' (Deficit) Equity			
Shares of Common Stock, $0.0001 par value; 250,000,000 shares authorized and 1,113,532 shares issued at December 31, 2024, 250,000,000 shares authorized and 2,621,607 shares issued at September 30, 2025[1]	262	413	661
Additional Paid-in Capital	107,127,619	110,823,234	111,802,987
Accumulated Deficit	(109,235,078)	(109,235,078)	(109,235,078)
Total Stockholders' (Deficit) Equity	(2,107,197)	1,588,569	2,568,570
Total Capitalization	$ (1,010,288)	$ 6,381,245	$ 8,341,245

(1) On April 11, 2025, the Reverse Stock Split was effective. There was no change to authorized shares or par value. Shares outstanding for periods prior to April 11, 2025 are adjusted retrospectively for the Reverse Stock Split of 1-for-40 ratio.

The shares of Common Stock outstanding after pro forma and as adjusted for this offering are based on 2,621,607 shares outstanding as of September 30, 2025. The number excludes the following:

- Up to 2,477,292 Common Stock Warrants each to purchase one share of Common Stock which may be issued in this offering;
- 126,540 shares issuable upon the conversion of outstanding warrants exercisable at $26.00 per share;

- 3,020,410 shares issuable upon the conversion of outstanding warrants, issued on November 19, 2025 in connection with the Inducement Agreement, exercisable at $2.41 per share (which exercise price may be amended to the public offering price per Unit paid in this offering, subject to stockholder approval);
- 42,845 shares issuable upon the exercise stock options of vested employee equity awards under the 2019 Plan and the 2021 Plan;
- 1,383 shares for stock options underlying unvested employee equity awards under the 2019 Plan and 2021 Plan;
- 80,452 shares reserved for issuance under our 2021 Plan; and
- Shares valued up to $17.0 million, which may be issued through draws on our equity line of credit.

DILUTION

If you invest in our Common Stock in this offering, your investment will be immediately and substantially diluted to the extent of the difference between the public offering price per share of our Common Stock and the as adjusted net tangible book value per share of our Common Stock after giving effect to the offering.

Our net tangible book value (deficit) as of September 30, 2025 was ($2.1) million, or approximately ($0.80) per share. Net tangible book value per share represents our total tangible assets less total liabilities, divided by the number of shares of our Common Stock outstanding.

On November 19, 2025, the Company entered into an inducement agreement with Armistice Capital Master Fund Ltd. ("Armistice"), pursuant to which Armistice exercised warrants to purchase 1,510,205 shares of our Common Stock at $2.66 per share, resulting in net proceeds to the Company of approximately $3.7 million, after deducting commission and transaction fees payable by the Company (the "Inducement Transaction" or the "Inducement"). Of those shares of our Common Stock issued in the Inducement Transaction, 977,000 shares were held in abeyance, and 533,205 shares were issued to Armistice. The Company's as-adjusted tangible book value as of September 30, 2025 after giving effect to the Inducement Transaction was approximately $1.6 million, or approximately $0.38 per share of our Common Stock.

The Company's as-adjusted net tangible book value dilution per share of Common Stock (after giving effect to the Inducement Transaction) to new investors represents the difference between the amount per share of our Common Stock paid by investors in the offering and the as-adjusted net tangible book value per share of our Common Stock after giving effect to the Inducement Transaction and completion of this offering. After giving effect to the offering and our sale of the Units in the offering at a public offering price of $0.6055 per Unit, and after deduction of placement agent fees from gross proceeds raised in the offering and estimated offering expenses payable by us, our as-adjusted net tangible book value as of September 30, 2025 would have been approximately $2.6 million, or approximately $0.39 per share of our Common Stock. This represents an immediate increase in net tangible book value (after giving effect to the Inducement Transaction) as a result of this offering of approximately $0.01 per share of our Common Stock to existing stockholders and an immediate dilution in net tangible book value of $0.22 per share of our Common Stock to investors in the offering, as illustrated in the following table, based on shares outstanding as of September 30, 2025 as adjusted for shares issued in the Inducement Transaction.

The information below is illustrative only. The dilution caused by this offering will change based on the actual public offering price and other terms of this offering determined at the time of pricing. You should read this table in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes included in our Annual Report on Form 10-K for our fiscal year ended December 31, 2024 and subsequent Exchange Act reports.

Public offering price per share of our Common Stock		$ 0.6055
Net tangible book value (deficit) per share as of September 30, 2025	(0.80)	
As adjusted net tangible book value per share following the Inducement	0.38	
Increase in net tangible book value per share attributable to this offering	0.01	
As adjusted net tangible book value per share as of September 30, 2025, after giving effect to the Inducement and this offering		0.39
Decrease in net tangible book value per share to new investors purchasing shares of our common stock in this offering		$ 0.22

(1) The above discussion and table are based on 2,621,607 shares of our Common Stock outstanding as of September 30, 2025 and 1,510,205 shares issued in the Inducement Transaction. The number of shares outstanding as of September 30, 2025 and as adjusted for the Inducement Transaction excludes the following:

- Up to 2,477,292 Common Stock Warrants each to purchase one share of Common Stock which may be issued in this offering;
- 126,540 shares issuable upon the conversion of outstanding warrants exercisable at $26.00 per share;
- 3,020,410 shares issuable upon the conversion of outstanding warrants ”), issued on November 19, 2025 in connection with the Inducement Agreement, exercisable at $2.41 per share (which exercise price may be amended to the public offering price per Unit paid in this offering, subject to stockholder approval);
- 42,845 shares issuable upon the exercise stock options of vested employee equity awards under the 2019 Plan and the 2021 Plan;
- 1,383 shares for stock options underlying unvested employee equity awards under the 2019 Plan and 2021 Plan;
- 80,452 shares reserved for issuance under our 2021 Plan; and
- Shares valued up to $17.0 million, which may be issued through draws on our equity line of credit.

The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of shares that we offer in this offering, and other terms of this offering determined at the time of pricing. The foregoing discussion and table assume no issuance of Pre-Funded Warrants, which if sold, would reduce the number of shares that we are offering on a one-for-one basis. In addition, we may choose to raise additional capital due to market conditions or strategic considerations. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

Market Price of Our Common Stock

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

On February 17, 2026, the closing sale price of our Common Stock was $0.6011 per share.

As of February 17, 2026, 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.

EXECUTIVE COMPENSATION

Executive Officers and Directors

The following table sets forth information regarding our directors and executive officers as of January 30, 2026:

Name	Age	Position
Hing C. Wong, Ph.D.	72	Founder, Chief Executive Officer and Director
Rebecca Byam	70	Chief Financial Officer
Lee Flowers	80	Senior Vice President of Business Development
Peter Rhode, Ph.D.	68	Chief Scientific Officer and Vice President of Clinical Operations
Scott T. Garrett(1)(2)(3)	76	Chairman of the Board, Chairman of the Compensation Committee and Director
Lisa M. Giles(1)(2)(3)	67	Director
Rick S. Greene(1)(2)(3)	60	Chair of Audit Committee and Director

(1) Member of our audit committee
(2) Member of our compensation committee
(3) Independent Director (as defined under Nasdaq Stock Market rules)

Our board of directors chooses our executive officers, who then serve at the discretion of our board of directors.

Hing C. Wong, Ph.D. has served as our Founder and Chief Executive Officer since April 2018. Prior to founding our Company, Dr. Wong founded and served as the Chief Executive Officer of Altor BioScience Corporation, from 2002 to August 2017, when it was acquired by NantCell, Inc. (which subsequently became ImmunityBio, Inc.). After the acquisition of Altor, he served as the Chief Executive Officer of NantCell until March 2018. Prior to that, Dr. Wong founded and served as Chief Executive Officer of Sunol Molecular Corporation from 1996 to 2002; the Director, Biology Skills Center of Baxter Healthcare Inc. from 1992 to 1996; and the Director of Microbial Genetics of Cetus Corporation from 1983 to 1992. Dr. Wong received his Ph.D. degree in Microbiology and Immunology at the University of Massachusetts, Amherst and completed his postdoctoral training at the University of Washington.

Rebecca Byam has served as our Chief Financial Officer since October 2019. Prior to joining our company, Ms. Byam served as a Director of PricewaterhouseCoopers LLP from 2003 to 2019; the Chief Financial Officer of MaMaMedia Inc. from 1998 to 2002; the Chief Financial Officer of Momentum Partners from 1995 to 1998; and as an Investment Professional at Apax Partners LLP, where she specialized in biotechnology investments among other areas with strong intellectual property, from 1985 to 1995. Additionally, Ms. Byam served on the Investment Advisory Council, assisting the development of the Small Business Investment Company program of the U.S. Small Business Administration. Ms. Byam received a B.A. degree in liberal arts from Kenyon College and an M.B.A from the New York University Stern School of Business with a major in finance. She is currently registered as a Certified Public Accountant in the states of Florida and New York.

Lee Flowers has served as our Senior Vice President of Business Development since September 2019. Mr. Flowers is also the Co-Founder of HRS Consulting Inc. Prior to joining our company, in 2009, Mr. Flowers cofounded HRS Consulting, Inc., a Service Disabled Veteran Owned Small Business specializing in management consulting, which acquired the healthcare business of Convergent HRS, LLC and Convergent Knowledge Solutions, LLC, businesses he also cofounded in 2007 and 2003 respectively. He served as the CEO of Sunol Molecular, Inc from 2001 to 2002, CEO of Continuum Electro-optics, Inc from 1997 to 2001; Executive Vice President of Dade International, a spin-off of Baxter International Inc., from 1994 to 1996; the Vice President of Venture Development at Baxter Diagnostics, Baxter International Inc.'s largest subsidiary, from 1993 to 1994; and Division President at Baxter Diagnostics from 1992 to 1993. Upon the merger between American Hospital

Supply Corporation and Baxter International Inc.'s predecessor, Mr. Flowers served as Vice President of Global Marketing for the Dade Division from 1990 to 1991 and Vice President, Sales and Marketing for the Paramax Systems Division from 1986 to1989 at the merged entity. Mr. Flowers received his bachelor's degree in zoology from the University of Kentucky.

Peter Rhode, Ph.D. has served as our Chief Scientific Officer and Vice President of Clinical Operations since May 2019. Prior to joining our company, Dr. Rhode served as the Senior Vice President of Research and Development at Altor BioScience Corporation following its April 2017 acquisition by NantCell, Inc. (which subsequently became ImmunityBio, Inc.) until 2019. Prior to that, Dr. Rhode served as Vice President, Research and Development at Altor BioScience Corporation from its inception in 2002 until its acquisition by NantCell, Inc. Dr. Rhode was among the team of scientists that formed Sunol Molecular Corporation in 1996 and served as Research Director at Sunol Molecular from 1996 to 2002. Dr. Rhode also served as Senior Scientist at Baxter International Inc. from 1991 to 1996. Dr. Rhode received his B.S. degree at the University of California, Davis and his Ph.D. in Biochemistry/Biophysics at the University of Wisconsin, Madison. Additionally, Dr. Rhode was a postdoctoral fellow at the California Institute of Technology.

Scott T. Garrett has served on our board of directors since May 2021 and as Chairman of the board since June 2021. Mr. Garrett is currently a Senior Operating Partner at Water Street Healthcare Partners ("Water Street"). Prior to joining Water Street in 2011, Mr. Garrett served as Chairman, President and Chief Executive Officer of Beckman Coulter, Inc. from 2008 to 2011. Mr. Garrett joined Beckman Coulter, Inc. in 2002 as President, Clinical Diagnostics Division and was promoted to President and Chief Operating Officer in 2003. In January 2005, he became Chief Executive Officer and in 2008, added the position of Chairman. Prior to that, Mr. Garrett served as Vice Chairman and Interim Chief Executive Officer of Kendro Laboratory Products from 1999 to2001; Chairman, President and Chief Executive Officer of Dade Behring, a leading diagnostics company, from 1994 to 1998; and Managing Partner of Garrett Capital Advisors, First Chicago Equity Capital from 1998 to 2002. Mr. Garrett began his career at American Hospital Supply Corporation and continued there after the company was acquired by Baxter International, ultimately serving as Chief Executive of Baxter International's global laboratory business, Baxter Diagnostics from 1992 to 1994. Mr. Garrett also served on the board of Hologic, Inc. from 2013 until March 2025. He currently serves on the board of MeMed Diagnostics; and in his role at Water Street, he chairs the boards of various portfolio companies, including Alcor Scientific, Pathnostics and Avantik. He also serves on the board of the Advanced Medical Technology Association Diagnostics and its Executive Committee. Mr. Garrett received his B.S. degree in mechanical engineering from Valparaiso University and an M.B.A. from the Lake Forest Graduate School of Management. He also completed the Executive Management program at Stanford Graduate School of Business.

Lisa M. Giles has served on our board of directors since October 2021. Ms. Giles founded and has served as the Managing Director and Chief Executive Officer of Giles & Associates Consultancy, Inc. (GAC), a consulting firm in the life sciences industry and academic medical centers, since 2000. In addition to HCW Biologics, Ms. Giles currently serves as a member of the board of directors for Milestone Pharmaceuticals and the Northwestern Memorial Health System Foundation Board. She previously served as a member of the board of directors for GenMark Diagnostics from 2015 to 2021; Durata Therapeutics, Inc. from 2012 to 2014, and Intranasal Therapeutics, Inc. from 2005 to 2006. She also was the Founder and Chief Executive Officer of Optivara, Inc. a sister company to GAC, from 2013 to 2019. Prior to founding GAC, Ms. Giles was the Vice President of strategy development at G.D. Searle Pharmaceutical, a division of Monsanto, and held various leadership roles with Abbott Laboratories. Ms. Giles received her B.S. in economics from Juniata College and completed executive management programs at Stanford University and the University of Chicago.

Rick S. Greene has served on our board of directors since May 2021. Mr. Greene is currently the Chief Financial Officer of Specialized Dental Partners. Prior to joining Specialized Dental Partners in May 2023, Mr. Greene served as the Chief Financial Officer of Epiphany Dermatology from March 2018 to May 2023. Mr. Greene served as the Chief Financial Officer of Altor BioScience Corporation from 2015 to 2018, Vice President and Chief Financial Officer of Cumberland Pharmaceuticals from 2011 to 2015, Executive at Crowe

Horwath LLP from 2007 to 2011, Director at LBMC from 2005 to 2007, Chief Financial Officer at Surgical Alliance Corporation from 2002 to 2005, Senior Manager at Ernst & Young LLP from 1998 to 2002 and 1987 to 1997, and Director Financial Operations at Phycor Inc. from 1997 to 1998. Mr. Greene received his B.S. degree in accounting from Carson-Newman University and is currently registered as a Certified Public Accountant (inactive) in the state of Tennessee.

Family Relationships

There are no family relationships among any members of our executive management and directors.

Arrangements for Election of Directors and Members of Management

There are no arrangements or understandings with major shareholders, customers, suppliers or others pursuant to which any of our executive management or our directors were selected.

Executive Compensation

We became a public company in July 2021, and we are an "emerging growth company" under applicable federal securities laws and therefore permitted to take advantage of certain reduced public company reporting requirements. As an emerging growth company, we provide in this proxy statement the scaled disclosure permitted under the Jumpstart Our Business Startups Act of 2012, including certain executive compensation disclosures required of a "smaller reporting company," as that term is defined in Rule 12b-2 promulgated under the Exchange Act. In addition, as an emerging growth company, we are not required to conduct votes seeking approval, on an advisory basis, of the compensation of our named executive officers or the frequency with which such votes must be conducted. We will remain an emerging growth company until the earliest of (i) the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering, (ii) the last day of the first fiscal year in which our annual gross revenue is $1.235 billion or more, (iii) the date on which we have, during the previous rolling three-year period, issued more than $1 billion in non-convertible debt securities, or (iv) the date on which we are deemed to be a "large accelerated filer" as defined in the Exchange Act.

Named Executive Officers

Our named executive officers for 2025, which consist of our principal executive officer and the next two most highly compensated executive officers, are:

Hing C. Wong, Ph.D., our Founder and Chief Executive Officer;

Rebecca Byam, our Chief Financial Officer; and

Peter Rhode, Ph.D., our Chief Scientific Officer and Vice President of Clinical Operations.

Summary Compensation Table

The following table provides information concerning compensation awarded to, earned by and paid to each of our named executive officers for the years ended December 31, 2025 and 2024:

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(3)	All Other Compensation ($)(2)	Total ($)
Hing C. Wong, Ph.D.							
Chief Executive Officer	2025	421,785	—		—	16,871	438,656
	2024	349,219	$5,000		—	13,969	368,188
Rebecca Byam							
Chief Financial Officer	2025	297,412	—		—	11,479	308,891
	2024	143,496	5,000		—	5,740	154,236
Peter Rhode, Ph.D.							
Chief Scientific Officer and Vice President of Clinical Operations	2025	248,745	—			9,949	258,694
	2024	246,795	5,000		—	9,872	261,667

(1) The amounts reported in this column for 2025 represent the aggregate grant date fair value of the stock options granted under our 2019 Plan to our named executive officers in 2025 as computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the dollar amount recognized for financial statement reporting purposes of the equity awards reported in this column are set forth in Note 10 to our audited financial statements included in this proxy statement. Note that the amounts reported in this column reflect the accounting value for these equity awards and do not correspond to the actual economic value that may be received by our named executive officers from the equity awards.

(2) Represents matching contributions under our 401(k) plan.

(3) Represents performance-based bonuses.

Narrative Disclosure to Summary Compensation Table

Employment Agreement with Dr. Hing Wong

We entered into an employment agreement with Dr. Wong, our Founder and Chief Executive Officer, dated June 18, 2021, which became effective on July 2, 2021. The employment agreement provides the general terms of Dr. Wong's employment, including a $390,000 base salary, an opportunity to earn cash bonus incentives, an additional equity award after our initial public offering, and certain severance rights if he is terminated by us without cause or if he resigns for good reason (as each are defined in the employment agreement). Dr. Wong is employed by us at will.

Cash Bonus Opportunities

In accordance with the employment agreement, Dr. Wong is eligible for a cash bonus each calendar year up to an initial target amount of 60% of his annual base salary based on Dr. Wong's achievement of certain corporate objectives and individual performance goals established by our board of directors or the compensation committee of our board of directors, as disclosed in our Executive Incentive Bonus Plan. See the section entitled "– *Summary Compensation Table*" for Dr. Wong's bonus payment in 2024.

Equity Incentive Grant

Per Dr. Wong's employment agreement, during the 60-day period after our initial public offering, we promised to negotiate in good faith with him regarding the terms of a grant of a stock option, restricted stock

units and/or other equity incentives in accordance with the terms of our 2021 Plan. Per his employment agreement, on September 8, 2021, we granted Dr. Wong a stock option to purchase 800,000 shares of our common stock (pre-reverse stock split), which will vest over a four-year period. See the section entitled "*Outstanding Equity Awards at Fiscal Year-End Table*" for additional details about the stock option grant. The equity award also provides that if, in connection with a change of control of the Company (as defined in the 2021 Plan), the acquiror does not assume or substitute for the equity award, then it will vest in full effective as of immediately prior to the closing of such transaction.

Severance Benefits

If we terminate Dr. Wong's employment without cause or if he resigns from employment for good reason (as each are defined in his employment agreement), subject to his execution of a release of claims in favor of the Company, Dr. Wong is entitled to receive certain severance benefits, as described below.

Employment Agreement with Ms. Rebecca Byam

We entered into an employment agreement with Ms. Byam, the Company's Chief Financial Officer, dated October 9, 2019. The employment agreement provides the general terms of Ms. Byam's employment, including her initial base salary, the opportunity to earn cash bonus incentives, an initial stock option award under our 2019 Plan and the opportunity to receive additional stock option grants upon the achievement of certain events. The employment agreement provides for an initial four-year term of employment, which automatically renews for additional twelve-month terms unless earlier terminated in accordance with the terms of the employment agreement. Ms. Byam's employment is terminatable by us at any time, with or without cause, and upon 30 days or more advance written notice to her if for reasons other than for cause. Ms. Byam may terminate her employment at any time, with or without cause, and without advance written notice.

Cash Bonus Opportunities

In accordance with the employment agreement, Ms. Byam is eligible for a cash bonus each calendar year up to an initial target amount of 50% of Ms. Byam's annual base salary based on Ms. Byam's achievement of certain corporate objectives and individual performance goals established by our board of directors or the compensation committee of our board of directors, as disclosed in our Executive Incentive Bonus Plan. See the section entitled "*Summary Compensation Table*" for Ms. Byam's bonus payment in 2025.

Stock Option Grants

Per her employment agreement, on October 11, 2019, we granted Ms. Byam the initial stock option to purchase 135,000 shares of our common stock (all shares disclosed herein are pre-reverse stock split), which vests over a four-year period. Additionally, Ms. Byam is eligible to be granted the following stock option awards under the terms of her employment agreement: (i) a stock option to purchase 135,000 shares of our common stock, to be granted to Ms. Byam upon our closing of a private placement equity financing of at least $20 million; and (ii) a stock option to purchase 135,000 shares of our common stock, to be granted to Ms. Byam upon our initial public offering having a pre-money valuation of at least $200 million (collectively, the "Performance Options"). Per her employment agreement, on August 29, 2021 and September 8, 2021, the Company granted Ms. Byam stock options to purchase 135,000 and 80,000 shares of our common stock, respectively. See the section entitled "*Outstanding Equity Awards at Fiscal Year-End Table*" for additional details about the stock option grants.

Severance Benefits

If we terminate Ms. Byam's employment without cause (as defined in her employment agreement), subject to her execution of a release of claims in favor of the Company, Ms. Byam will be entitled to receive certain severance benefits, as described below.

Potential Payments Upon Termination or Change in Control

Dr. Wong

If we terminate Dr. Wong's employment without cause or if he resigns for good reason (as each are defined in his employment agreement), subject to his execution of a release of claims in our favor, Dr. Wong is entitled to receive (i) a lump sum cash severance payment equal to 2 times his then-current annual base salary, and (ii) the vesting of all of his then unvested and outstanding equity awards that would have become vested had he remained in the employ of the Company for the 24 month period following his termination of employment; provided, however that if Dr. Wong's termination occurs in connection with or within the 12 months following a change in control of the Company (as defined in the 2021 Plan), the equity awards will vest in full as of the date of his termination.

Ms. Byam

If we terminate Ms. Byam's employment without cause (as defined in her employment agreement), subject to her execution of a release of claims in our favor, Ms. Byam is entitled to receive (i) cash severance equal to nine months of her then-current base salary, provided that this amount will be increased to 12 months if the termination occurs within one year following the consummation of a change of control (as defined in her employment agreement) of the Company, and (ii) immediate vesting of each of her then-outstanding stock option awards which are described above.

In addition, if we decline to extend the term of Ms. Byam's employment under the employment agreement past the initial four-year term or past any subsequent 12-month term, subject to her execution of a release of claims in favor of the Company, Ms. Byam will be also entitled to the immediate vesting of each of her then-outstanding stock option awards which are described above. If Ms. Byam's employment is terminated due to disability (as defined in her employment agreement), she will receive the cash severance described above, and in the event of her death, the Performance Options, to the extent granted, will immediately vest in full.

Executive Incentive Bonus Plan

Our board of directors approved our Executive Incentive Bonus Plan, or the Bonus Plan, in June 2021.

General

The purpose of the Bonus Plan is to motivate and reward our eligible officers and employees, including our named executive officers, for their contributions toward the achievement of certain performance goals. The Bonus Plan is administered by the compensation committee of our board of directors, which shall have the discretionary authority to interpret the provisions of the Bonus Plan, including all decisions on eligibility to participate, the establishment of performance goals, the number of awards payable under the plan, and the payment of awards. The compensation committee, in its sole discretion and on such terms and conditions as it may provide, may delegate all or part of its authority and powers under the Bonus Plan to one or more of our directors and officers. The compensation committee may terminate the Bonus Plan at any time, provided such termination shall not affect the payment of any awards accrued under the Bonus Plan prior to the date of the termination. The compensation committee may, at any time, or from time to time, amend or suspend and, if suspended, reinstate, the Bonus Plan in whole or in part.

Targets and Performance Criteria

The compensation committee may establish cash bonus targets and corporate performance goals for a specific performance period or fiscal year pursuant to the Bonus Plan. Corporate performance goals may be based on wide-ranging criteria and metrics described in the Bonus Plan, which mirror those in our 2021 Plan. Awards issued to participants, however, may also take into account other factors, including subjective factors. Performance goals may differ from participant to participant, performance period to performance period, and from award to award.

Eligibility and Clawback

Unless otherwise determined by the compensation committee, a participant must be actively employed and in good standing with us on the date the award is paid. The compensation committee may make exceptions to this requirement in the case of retirement, death or disability, an unqualified leave of absence or under other circumstances, as determined by the compensation committee in its sole discretion.

Awards granted under the Bonus Plan are subject to any clawback policy as may be established and/or amended from time to time by us. The compensation committee may require a participant to forfeit or return to and/or reimburse us for any amounts paid with respect to an award, pursuant to the terms of such company policy or as necessary or appropriate to comply with applicable laws.

Hedging and Pledging Policy

Under the terms of our insider trading policy, no employees, contractors, consultants and members of our board of directors (and their respective family members and any affiliated entities, such as venture capital funds) may engage in hedging or monetization transactions involving our securities, such as prepaid variable forward contracts, equity swaps, collars or exchange funds. In addition, such persons may not hold our securities in a margin account or pledge our securities as collateral for a loan unless the pledge has been approved by our Compliance Officer.

Outstanding Equity Awards at Fiscal Year-End Table

The following table provides information regarding the outstanding stock option awards held by our named executive officers on December 31, 2025.

	Option Awards[1] Number of Securities Underlying Unexercised Options				
Name	Grant Date	(#) Exercisable	(#) Unexercisable	(#) Option Exercise Price ($)[2]	Option Expiration Date
Hing C. Wong, Ph.D.	9/8/2021	20,000	— [3]	172.40	9/8/2031
Rebecca Byam	8/29/2021	3,375	— [4]	160.00	8/29/2031
	9/8/2021	2,000	— [5]	172.40	9/8/2031
Peter Rhode, Ph.D	12/19/2019	561	— [6]	5.59	12/19/2029
	12/22/2020	172	— [7]	8.37	12/22/2030
	9/8/2021	500	— [8]	172.40	9/8/2031

(1) All of the outstanding equity awards were granted under our 2021 Plan and are subject to acceleration of vesting as described in above.
(2) This column represents the fair market value of a share of our common stock on the date of grant.
(3) These option shares were part of a stock option grant covering 20,000 shares of our common stock. All of the shares subject to the stock option grant have vested.
(4) These option shares were part of a stock option grant covering 3,375 shares of our common stock. All of the shares subject to the stock option grant have vested.
(5) These option shares were part of a stock option grant covering 2,000 shares of our common stock. All of the shares subject to the stock option grant have vested.
(6) These option shares were part of a stock option grant covering 2,143 shares of our common stock. All of the shares subject to the stock option grant have vested.
(7) These option shares were part of a stock option grant covering 215 shares of our common stock. All of the shares subject to the stock option grant have vested.
(8) These option shares were part of a stock option grant covering 500 shares of our common stock. All of the shares subject to the stock option grant have vested.

Note: Our named executive officers held the provided number of shares subject to outstanding stock options as of December 31, 2025 (pre-reverse stock split). On April 11, 2025, the Company effected a one-for-forty reverse stock split of its common stock. Our audited consolidated 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 proxy are presented without giving effect to the reverse stock split.

Director Compensation

Director Compensation Table

The following table provides information concerning compensation awarded to, earned by or paid to each person who served as a non-employee member of our board of directors during the fiscal year ended December 31, 2025. Dr. Wong is not included in the table below, as he is employed as our Chief Executive Officer, and receives no compensation for his service as a director. The compensation received by Dr. Wong as an employee is shown in "Executive Compensation-Summary Compensation Table" below.

Name	Fees Earned or Paid in Cash ($)	Awards ($)(1)(2)	Total ($)
Scott T. Garrett	60,000	—	60,000
Lisa M. Giles	40,000	—	40,000
Rick S. Greene	50,000	—	50,000
Gary M. Winer	40,000	—	40,000

(1) The amounts reported in this column represent the aggregate grant date fair value for financial statement reporting purposes of stock options granted 2025 as determined in accordance with FASB ASC Topic 718. These amounts reflect our accounting expense for these stock options and do not represent the actual economic value that may be realized by each non-employee director. There can be no assurance that these amounts will ever be realized. For information on the assumptions used in valuing these awards, refer to Note 10 to the historical financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions.

(2) Our non-employee directors that served during year 2025 held the following number of stock options as of December 31, 2025:

Name	Shares Subject to Outstanding Stock Options(1)
Scott T. Garrett	2,198
Lisa M. Giles	2,599
Rick S. Greene	2,198
Gary M. Winer	2,599

(1) Our non-employee directors that served during the year 2025 held the provided number of shares subject to outstanding stock options as of December 31, 2025 (pre-reverse stock split). On April 11, 2025, the Company effected a one-for-forty reverse stock split of its common stock. Our audited consolidated 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 proxy are presented without giving effect to the reverse stock split.

Non-Employee Director Compensation Arrangements

Our non-employee director compensation policy is designed to obtain and retain the services of qualified persons to serve as members of our board of directors.

The policy provides for the following annual cash retainers, which are payable quarterly in arrears and pro-rated for partial quarters of service:

Annual Cash Retainer

All other non-employee directors: $40,000;

Non-employee chairperson of the audit committee: $50,000 (in lieu of the above); and

Non-employee chairperson of the board of directors: $60,000 (in lieu of the above).

Equity Grants

The policy also provides for grants of nonstatutory stock options to purchase shares of our common stock under the HCW Biologics Inc. 2021 Equity Incentive Plan (the "2021 Plan") to the non-employee directors upon their initial election or appointment to our board of directors and annually during their continued service thereafter. Any stock options granted will have an exercise price equal to 100% of the fair market value of our common stock on the date of grant.

Each non-employee director who is elected or appointed for the first time to our board of directors is granted an equity award with a grant date value of $100,000. The initial grant fully vests on the one-year anniversary of the date of appointment to our board of directors.

At our 2025 annual meeting, we deferred the grant of stock options to purchase shares of our common stock with a grant date fair value (disregarding estimated forfeitures related to service-based vesting) to continuing non-employee directors who had served on our board of directors for at least 6 months prior to such annual meeting. The Board and management are reviewing the equity plan and future grants.

Our board of directors also has the discretion to continue the vesting of any non-employee director option beyond the date of the director's termination of service, if warranted by the circumstances, and to make discretionary stock award grants to our non-employee directors.

All stock options granted to non-employee directors will be made pursuant to our 2021 Equity Incentive Plan and will vest in full immediately prior to, and contingent upon, the consummation of a change in control of our company, subject to the director's continued service as a member of our board of directors through the change in control.

Expense Reimbursement

We also reimburse our directors for their reasonable out-of-pocket expenses in connection with attending meetings of our board of directors and committees.

The non-employee director compensation program is intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders.

BENEFICIAL OWNERSHIP OF SECURITIES

The following table sets forth certain information with respect to the beneficial ownership of our Common Stock as of February 17, 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 January 31, 2026 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 February 17, 2026 (after adjustment for the Reverse Stock Split). 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 (6 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.

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 senior secured notes to certain accredited investors (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, a 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 owners 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, Former Director	$ 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 pledge of our equity ownership interest in Wugen, (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 (adjusted for the Reverse Stock Split), 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 that certain Second Amendment to Amended and Restated Senior Secured Note Purchase Agreement and Related Agreements dated as of May 1, 2025 (the "Conversion Amendment"). On May 7, 2025, pursuant to the Conversion Amendment, the Secured Notes held by the participating noteholders were cancelled, and the Company issued 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 126,542 shares of Common Stock at an exercise price of $26.00 per share. On January 29, 2026, the SEC declared effective a resale registration statement on Form S-1 (File Number 333-292652) covering the resale of shares of Common Stock and warrants issued to such note holders.

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 February 17, 2026, HCWB had 3,279,812 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.

Warrants

Common Stock Warrants

Overview. The following summary of certain terms and provisions of the Common Stock Warrants offered hereby is not complete and is subject to, and qualified in its entirety by the form of Common Stock Warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the form of Common Stock Warrant. Each warrant issued in this offering entitles the registered holder to purchase one share of our Common Stock at a price equal to $0.6055 per share, subject to adjustment as discussed below, immediately following the issuance of such warrant and terminating at 5:00 p.m., New York City time, on the fifth anniversary of the original issuance date. The Common Stock Warrants will be issued in certificated form.

Exercisability. The Common Stock Warrants are exercisable upon the date of Shareholder Approval until the fifth anniversary of the date of Shareholder Approval. The Common Stock Warrants may be exercised upon surrender of the warrant, with the exercise form included with the Common Stock Warrant completed and executed as indicated. If we fail to maintain the effectiveness of the registration statement and current prospectus relating to the Common Stock issuable upon exercise of the Common Stock Warrants, the holders of the warrants shall have the right to exercise the warrants via a cashless exercise feature provided for in the Common Stock Warrants, until such time as there is an effective registration statement and current prospectus. See "— *Cashless Exercise*" below.

Exercise Limitation. A holder (together with its affiliates) may not exercise any portion of the Common Stock Warrants to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Common Stock Warrants up to 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Common Stock Warrants.

Exercise Price. The exercise price per whole share of our Common Stock purchasable upon the exercise of the Common Stock Warrants is $0.6055 per share of Common Stock. The warrants will be exercisable upon Shareholder Approval and may be exercised at any time up to the date that is the fifth anniversary of the date of Shareholder Approval. The exercise price and number of shares of Common Stock issuable upon exercise of the

warrants may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation. However, the Common Stock Warrants will not be adjusted for issuances of Common Stock at prices below their exercise price.

Cashless Exercise. If, at any time after the issuance of the Common Stock Warrants, a holder of the warrants exercises the warrants and a registration statement registering the issuance of the shares of Common Stock underlying the warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of Common Stock underlying the warrants), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of Common Stock determined according to a formula set forth in the Common Stock Warrants.

Fractional Shares. No fractional shares of Common Stock will be issued upon exercise of the warrants. If, upon exercise of a Common Stock Warrant, the holder would be entitled to receive a fractional interest in a share, we will, in our discretion and upon exercise, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price or round up to the next whole share.

Transferability. Subject to applicable laws, the Common Stock Warrants may be offered for sale, sold, transferred or assigned at the option of the holder without our consent.

Fundamental Transactions. In the event of a "fundamental transaction," as described in the Common Stock Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding shares of Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding Common Stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders of the Common Stock Warrants have the right to require us or a successor entity to redeem the Common Stock Warrants for cash in the amount of the Black-Scholes Value (as defined in the Common Stock Warrants) of the unexercised portion of the Common Stock Warrants concurrently with or within 30 days following the consummation of a fundamental transaction.

Rights as a Stockholder. Except by virtue of such holder's ownership of shares of our Common Stock, the holder of a Common Stock Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the warrant.

Pre-Funded Warrants

Overview. The following summary of certain terms and provisions of the Pre-Funded Warrants offered hereby is not complete and is subject to the form of Pre-Funded Warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the form of Pre-Funded Warrant. Each Pre-Funded Warrant issued in this offering entitles the registered holder to purchase one share of our Common Stock at a purchase price equal to $0.6054 (equal to the purchase price per shares, minus $0.0001), subject to adjustment as discussed below, immediately following the issuance of such warrant and terminating at the time no Pre-Funded Warrants are outstanding. The Pre-Funded Warrants will be issued in certificated form.

Exercisability. The Pre-Funded Warrants are immediately exercisable at any time after their original issuance date until the Pre-Funded Warrants are exercised in full. The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below).

Exercise Limitation. A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrants to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Pre-Funded Warrants up to 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants.

Exercise Price. The exercise price per whole share of our Common Stock purchasable upon the exercise of the Pre-Funded Warrants is $0.0001 per share of Common Stock. The exercise price and number of shares of Common Stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation.

Cashless Exercise. If, at any time after the issuance of the Pre-Funded Warrants, a holder of the warrants exercises the warrants and a registration statement registering the issuance of the shares of Common Stock underlying the warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of Common Stock underlying the warrants), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of Common Stock determined according to a formula set forth in the Pre-Funded Warrants.

Fractional Shares. No fractional shares of Common Stock will be issued upon exercise of the warrants. If, upon exercise of a Pre-Funded Warrant, the holder would be entitled to receive a fractional interest in a share, we will, in our discretion and upon exercise, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price or round up to the next whole share.

Transferability. Subject to applicable laws, the Pre-Funded Warrants may be offered for sale, sold, transferred or assigned at the option of the holder without our consent.

Fundamental Transactions. In the event of a "fundamental transaction," as described in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding shares of Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding Common Stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

Rights as a Stockholder. Except by virtue of such holder's ownership of shares of our Common Stock, the holder of a Pre-Funded Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the warrant.

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

We are offering on a reasonable best efforts basis up to 2,477,292 Units, based on a public offering price of $0.6055 per Unit for gross proceeds of up to approximately $1.5 million before deduction of placement agent fees and offering expenses. The final public offering price per share will be determined between us and the placement agent based upon a number of factors, including based on market conditions at the time of pricing, our history and our prospects, the industry in which we operate, our past and present operating results and the general condition of the securities markets at the time of this offering and may be at a discount to the current market price. There is no minimum amount of proceeds that is a condition to closing of this offering. The actual amount of gross proceeds, if any, in this offering could vary substantially from the gross proceeds from the sale of the maximum amount of securities being offered in this prospectus.

Pursuant to a placement agency agreement, dated February 17, 2026, we have engaged Maxim to act as our exclusive placement agent to solicit offers to purchase the securities offered by this prospectus. The placement agent is not purchasing or selling any securities, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use its "reasonable best efforts" to arrange for the sale of the securities by us. Therefore, we may not sell the entire amount of securities being offered. The terms of this offering are subject to market conditions and negotiations between us, the placement agent and prospective investors. The placement agent does not guarantee that it will be able to raise new capital in any prospective offering. The placement agent may engage sub-agents or selected dealers to assist with the offering. The placement agency agreement provides that the placement agent's obligations are subject to conditions contained in the placement agency agreement.

Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to the rights and remedies available to all investors in this offering under federal and state securities laws, the investors who enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering.

There is no minimum number of shares to be sold or minimum aggregate offering proceeds for this offering to close. We expect this offering to be completed not later than two trading days following the commencement of this offering and we will deliver all securities issued in connection with this offering delivery versus payment ("DVP")/receipt versus payment ("RVP") upon our receipt of investor funds. Accordingly, neither we nor the placement agent has made any arrangements to place investor funds in an escrow account or trust account since the placement agent will not receive investor funds in connection with the sale of securities offered hereunder.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about February 19, 2026, subject to satisfaction of certain conditions.

Placement Agent Fees and Expenses

Upon the closing of this offering, we will pay the placement agent a cash transaction fee equal to 6.9% of the aggregate gross cash proceeds to us from the sale of the securities in the offering. In addition, we will reimburse the placement agent for certain of its out-of-pocket expenses incurred in connection with this offering, including the placement agent's legal fees, and actual travel and reasonable out-of-pocket expenses if this offering is completed, in an amount not to exceed $65,000.

The following table shows the public offering price, placement agent fees and proceeds, before expenses, to us, assuming the sale of all shares in this offering and no sale of any Pre-Funded Warrants in this offering.

	Per Unit Consisting of Common Stock and Warrants	Per Unit Consisting of Pre-Funded Warrants and Warrants	Total[2]
Public offering price	$ 0.6055	$ 0.6054	$1,500,000.31
Placement agent fees[1]	$ 0.0418	$ 0.0418	$ 103,500.02
Proceeds to us, before expenses	$ 0.5637	$ 0.5635	$1,396,500.29

(1) The placement agent fees shall equal 6.9% of the gross proceeds of the securities sold by us in this offering.
(2) The foregoing assumes that the Pre-funded Warrants issued as part of the offering are exercised in full.

We estimate that the total expenses of the offering, including registration and filing fees, printing fees and legal and accounting expenses, but excluding the placement agent fees, will be approximately $415,000, all of which are payable by us. This figure includes, among other things, the placement agent's expenses (including the legal fees, costs and expenses for the placement agent's legal counsel) that we have agreed to reimburse.

In accordance with FINRA Rule 5110, we disclose that within the 180-day period prior to the filing of this registration statement, we paid Maxim, who is acting as placement agent in this offering, an aggregate of approximately $290,000 for a cash fee and reimbursements of certain out-of-pocket expenses in connection with financial advisory services provided to the Company. Such payments were made in connection with services rendered prior to this offering and were not paid in connection with the distribution of the securities offered hereby. These amounts are deemed underwriting compensation for purposes of FINRA Rule 5110.

Lock-Up Agreements

We have agreed to use our best efforts to cause each of our officers, directors and holders of five percent (5.0%) or more of our outstanding shares of common stock have agreed for a period of six (6) months after this offering is complete, subject to certain exceptions not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any shares of our common stock or other securities convertible into or exercisable or exchangeable for our common stock for a period without the prior written consent of the placement agent, subject to certain exceptions.

The placement agent may in its sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the lock-up period. When determining whether or not to release shares from the lock-up agreements, the placement agent will consider, among other factors, the security holder's reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time.

We have also agreed to similar lock-up restrictions on the issuance and sale of our securities for 45 days following the closing of this offering, subject to certain exceptions. In addition, subject to an exception, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of our Common Stock or upon a specified or contingent event in the future, or enter into any agreement to issue securities at a future determined price for a period of 60 days following the closing date of this offering.

Tail

Upon the closing or termination (other than for cause as defined in FINRA Rule 5110(g)(5)(B)) of this offering, then if within six (6) months following such time, the Company, or any successor to or any subsidiary of the Company, completes any public or private offering of equity, equity-linked or debt securities or other capital

raising activity of the Company with, or receives any proceeds from, any of the investors who were contacted by the placement agent in connection with the Offering, then the Company or such successor or subsidiary will pay the placement agent upon the closing of such financing or receipt of such proceeds the compensation equivalent to 6.9% of the gross proceeds of such financing.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the placement agent may be required to make for these liabilities.

Regulation M

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent acting as principal. Under these rules and regulations, the placement agent (i) may not engage in any stabilization activity in connection with our securities and (ii) may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Determination of Offering Price

The actual public offering price of the securities we are offering were negotiated among us, the placement agent and the investors in the offering based on the trading of our Common Stock prior to the offering, among other things. Other factors considered in determining the public offering price of the securities we are offering include our history and prospects, the market price of our Common Stock on Nasdaq, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, the general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the placement agent or an affiliate. Other than this prospectus, the information on the placement agent's website and any information contained in any other website maintained by the placement agent is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent, and should not be relied upon by investors. In connection with the offering, the placement agent or selected dealers may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

Other than the prospectus in electronic format, the information on the placement agent's website and any information contained in any other website maintained by the placement agent is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent in its capacity as placement agent and should not be relied upon by investors.

Certain Relationships

The placement agent and its affiliates have and may in the future provide, from time to time, investment banking and financial advisory services to us in the ordinary course of business, for which they may receive customary fees and commissions.

Selling Restrictions

Other than in the United States, no action has been taken by us or the placement agent that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published, in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to this offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia. No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (ASIC), in relation to the offering.

This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act) and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the securities may only be made to persons (the Exempt Investors) who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the securities without disclosure to investors under Chapter 6D of the Corporations Act.

The securities applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring securities must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Brazil. The offer of securities described in this prospectus will not be carried out by means that would constitute a public offering in Brazil under Law No. 6,385, of December 7, 1976, as amended, under the CVM Rule (Instrução) No. 400, of December 29, 2003. The offer and sale of the securities have not been and will not be registered with the Comissão de Valores Móbilearios in Brazil. The securities have not been offered or sold, and will not be offered or sold in Brazil, except in circumstances that do not constitute a public offering or distribution under Brazilian laws and regulations.

Canada. The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31 103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus supplement (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33 105 Underwriting Conflicts (NI 33 105), the placement agent is not required to comply with the disclosure requirements of NI 33-105 regarding conflicts of interest in connection with this offering.

Cayman Islands. No invitation, whether directly or indirectly, may be made to the public in the Cayman Islands to subscribe for our securities.

European Economic Area. In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any securities may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by us or any placement agent of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase any securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Hong Kong. The contents of this prospectus have not been reviewed by any regulatory authority in Hong Kong. You are advised to exercise caution in relation to the offer. If you are in any doubt about any of the contents of this prospectus, you should obtain independent professional advice. Please note that (i) our shares may not be offered or sold in Hong Kong, by means of this prospectus or any document other than to "professional investors" within the meaning of Part I of Schedule 1 of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) (SFO) and any rules made thereunder, or in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong) (CO) or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO, and (ii) no advertisement, invitation or document relating to our shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere) which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the SFO and any rules made thereunder.

Israel. This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the shares is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

The People's Republic of China. This prospectus may not be circulated or distributed in the PRC and the shares may not be offered or sold, and will not offer or sell to any person for re-offering or resale directly or indirectly to any resident of the PRC except pursuant to applicable laws, rules and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

Switzerland. The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (the SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). Accordingly, no public distribution, offering or advertising, as defined in CISA, its implementing ordinances and notices, and no distribution to any non-qualified investor, as defined in CISA, its implementing ordinances and notices, shall be undertaken in or from Switzerland, and the investor protection afforded to acquirers of interests in collective investment schemes under CISA does not extend to acquirers of securities.

Taiwan. The securities have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the securities in Taiwan.

United Kingdom. This prospectus has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000, or the FSMA) as received in connection with the issue or sale of our Common Stock in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to our Common Stock in, from or otherwise involving the United Kingdom.

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 Princeton, New Jersey. Ellenoff Grossman & Schole LLP, New York, New York, is acting as counsel to the placement agent in connection with certain legal matters related to this offering.

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 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 20, 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 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

Table of Contents

HCW BIOLOGICS INC.

2,477,292 Units, each consisting of:

One Share of Common Stock or One Pre-Funded Warrant to Purchase One Share of Common Stock and One Common Stock Warrant Each to Purchase One Share of Common Stock

2,477,292 Shares of Common Stock or Shares of Common Stock Underlying Pre-Funded Warrants

2,477,292 Shares of Common Stock Underlying Common Stock Warrants

PROSPECTUS