UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number 001-40591

HCW Biologics Inc.

(Exact name of registrant as specified in its Charter)

Delaware	**82-5024477**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2929 N. Commerce Parkway Miramar, Florida	**33025**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (954) 842–2024

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	HCWB	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $6.2 million based on the closing price of the shares of $3.9650 per share as reported on the Nasdaq Capital Market on such date. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

The number of shares of the registrant's common stock outstanding as of March 25, 2026 is 6,734,104.

DOCUMENTS INCORPORATED BY REFERENCE

Part III incorporates by reference certain information from the registrant's definitive proxy statement (the "Proxy Statement") relating to its 2025 Annual Meeting of Stockholders. The Proxy Statement will be filed with the United States Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (the "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success of prospective products, plans and objectives of management for future operations, future capital-raising activities, adequacy of our cash resources and working capital, persistent staffing issues at clinical sites, as well as delays and backlog at testing facilities needed to perform IND-enabling activities, and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

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

References in this Annual Report to "we," "our," "us," "HCW Biologics," "HCWB," and the "Company" refer to HCW Biologics Inc.

HCW BIOLOGICS® and TOBI™ are trademarks of HCW Biologics Inc. All other brand names or trademarks appearing in this Annual Report are the property of their respective holders. Solely for convenience, the registered and unregistered trademarks and service marks in this Annual Report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PART I

Item 1. Business.

Overview

HCW Biologics Inc. ("HCW Biologics" or the "Company") is a clinical-stage biopharmaceutical company developing transformative fusion immunotherapeutics to support or treat diseases promoted by chronic inflammation. We have created novel compounds that represent a new class of drugs that we believe have the potential to fundamentally change the treatment of autoimmune disorders and other proinflammatory diseases, cancer and senescence-associated dysplasia. Among other things, we have begun commercialization of certain commercial-ready proprietary compounds for use as reagents in the production of immunotherapeutics for the treatment of infectious diseases and cancer. We want our products to improve patients' healthspan as well as their quality of life, and possibly extend longevity.

Chronic inflammation is believed to be a significant contributing factor to the cause for many diseases and conditions that diminish health span and quality of life. The induction and retention of low-grade inflammation in the human body is mainly the result of persistent activation of immune cells and the accumulation of non-proliferative but metabolically active senescent cells.

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 promote the release of highly proinflammatory cytokines. Unresolved activation of immune cells leads to chronic low-grade inflammation, which perpetuates this cycle.

Two of the Company's proprietary molecules, HCW9201 and HCW9206, are commercial-ready to be used as reagents in the production of immunotherapeutic treatments. On March 13, 2026, Science Advances, a peer-reviewed, high-impact journal, released a publication with the Company's data that showed the Company's proprietary, commercial-ready compound, HCW9206, could fundamentally change how CAR-T cell therapies are manufactured and potentially improve how they perform against diseases such as cancer and HIV. These findings support the Company's belief that HCW9206 is a leap forward in both clinical potential and manufacturing efficiency.

The Company has developed two proprietary drug discovery and development platforms which we use to create novel fusion immunotherapeutics:

The TOBI™ (Tissue factOr-Based fusIon) platform. The TOBI™ platform is designed to engineer multi-functional fusion protein molecules and protein complexes that rebalance the immune system. 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 T-cell Receptor β Chain constant region ("TRBC") platform. The TRBC platform is designed to engineer multi-function fusion protein molecules and protein complexes that rejuvenate the immune system. It employs a protein-based scaffold that can be packaged with multiple elements, including multi-specific cytokines, immune checkpoint inhibitors, and immune-cell engagers.

Our clinical development programs are based on a few select lead product candidates which will be advanced in Company-sponsored clinical trials or in partnership with a corporate partner. Our clinical development and financing strategy consider business development transactions as a key component for our plans to develop breakthrough therapeutics. We regularly assess our product portfolio to determine if clinical development through a corporate partnership is the optimal means to advance clinical development and commercialization.

Lead Product Candidates in Clinical Development

- HCW9302 is a clinical-stage compound that is an injectable, first-in-kind interleukin 2 ("IL-2") fusion protein complex constructed using the Company's proprietary TOBI platform technology. Its mechanism of action involves binding to IL-2αβγ receptors predominantly expressed on regulatory T ("T_{reg}") cells, thereby activating and expanding T_{reg} cells that can suppress unwanted immune and inflammatory responses. Beijing Trimmune Biotech Co., Ltd. ("Trimmune") has an option to license the rights to the China market for HCW9302. On November 17, 2025, the first patient was dosed at The Ohio State University Wexner Medical Center for the Company-sponsored, multi-center first-in-human clinical trial to evaluate HCW9302 in patients with alopecia areata (NCT07049328).
- HCW11-018b is a preclinical molecule that is a novel, tetra-valent T-Cell engager we call the Big BiTE, since it consists of a BiTE (common for all T-Cell Engagers) and an Enhancer (which makes the HCWB T-Cell Engager the "BIG BiTE"). HCW11-018b is designed to address key challenges for first generation T-Cell Engagers: manufacturability, preclinical safety profile, and ability to treat solid tumors.
- HCW11-040 is a preclinical molecule that is a unique combination of cytokines and pembrolizumab, a generic form of Keytruda®, in a multi-functional fusion molecule. This lead product candidate exhibits the ability to expand Tpex cells without a cytokine storm in preclinical studies. In addition, it exhibits superior immune-cell activation, expansion, and cytotoxicity against cancer cells and tumors when compared to pembrolizumab in in-vitro and in-vivo studies.

Programs being Developed through Corporate Partnership

- HCW11-006 is a preclinical molecule that combines several different immune functional domains as part of a group of compounds characterized as multi-functional immune cell stimulators. This lead product candidate will be developed in partnership with Trimmune, the licensee responsible for the development and commercialization of HCW11-006. HCW11-006 will be developed by Trimmune, our licensee with exclusive worldwide rights for *in vivo* applications of this compound. Trimmune intends to begin Phase 1 clinical trials in China in mid-2027. The Company has an Opt-In Right for the Americas market that we may choose to exercise, based on the results of the first Phase 1 studies in China. We will continue to monitor the results of IND-enabling studies and results of the clinical study before making a decision on whether to exercise our Opt-In Right.

Commercial-Ready Reagents for Production of Immunotherapeutic Treatments

- HCW9206 is a proprietary fusion protein designed as a reagent to use in the production of CAR-therapies for the treatment of infectious diseases, including HIV, and cancer. HCW9206 is a novel class of immunotherapeutic that enables a single molecule to deliver synergistic signals from three different immune-stimulatory cytokines.
- HCW9201 is a proprietary fusion protein designed as a reagent to use in the production of Natural Killer ("NK") cell-based therapies. It is a unique cytokine-induced memory-like phenotype that supports enhanced anti-tumor activity, robust trafficking, superior proliferation capacity, and metabolic flexibility, all of which contribute to treatment resilience in the adverse tumor microenvironment.

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

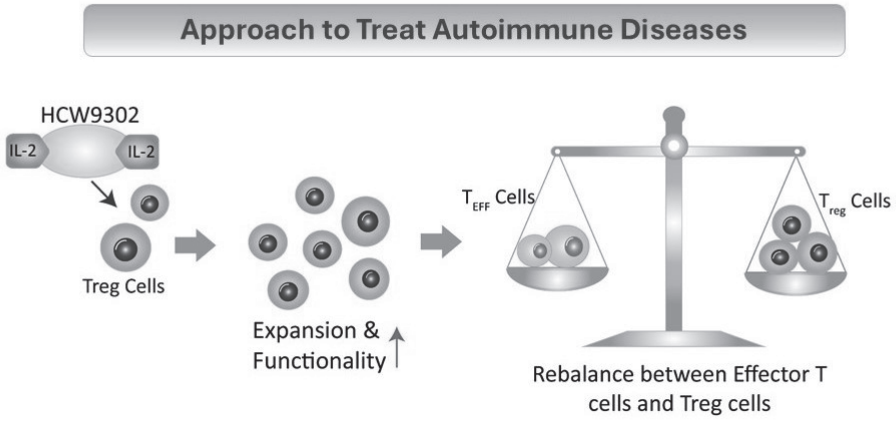
Our Approach

Our approach is to develop immunotherapies that reduce or eliminate the main drivers of chronic inflammation by addressing the underlying development and sustainment of these processes. Several common molecular pathways have been identified that are associated with chronic low-grade inflammation. Our view is that the two primary underlying processes that drive chronic inflammation are persistent activation of immune cells and accumulation of senescent cells. Both of these processes generate pro-inflammatory factors that are an underlying cause of disease. While inflammation is part of the normal repair response for healing, when it becomes prolonged and persists, it is damaging and destructive.

By leveraging our immunology expertise, we are developing potentially transformative immunotherapy candidates that use T_{reg} cell expansion and senescent cell reduction to address chronic inflammation linked autoimmune disorders and other proinflammatory diseases, cancer and senescence-associated dysplasia. Using our drug discovery platforms, we have created over 50 molecules, all of which can be administered by subcutaneous injection as well as used in adoptive cell therapy approaches. These modular and tunable technologies have allowed us to generate a novel pipeline of internally developed product candidates we believe are capable of activating and targeting desired immune responses and blocking unwanted immunosuppressive activities.

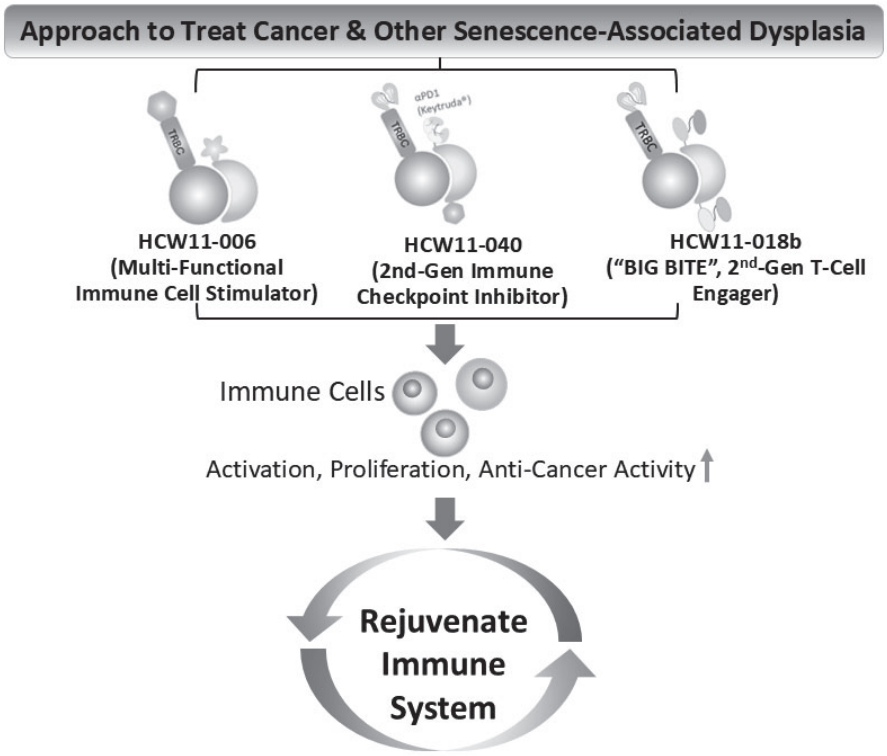
Rebalancing the Immune System: Inflammation Promoted by Persistently Activated Immune Cells

Immune cells defend against infection or tissue injury. If these activated immune cells persist, even in the absence of infection, they regulate the release of pro-inflammatory factors. As inflammatory factor levels increase, this fuels a feedback cycle of inflammasome activation and leads to the persistent, low-grade body-wide inflammation associated with many diseases, such as autoimmune disorders and other proinflammatory diseases.



Rejuvenating the Immune System: Inflammation Promoted by Senescence and SASP Factors

Cellular senescence is a biological condition resulting from the impact of stressors, such as chemotherapy, radiation, and pollutants, on human cells. These stressors reduce natural human cell cytotoxicity, leading to the accumulation of senescent cells and SASP factors. Considered harmful to neighboring cells, secreted SASP factors also activate proinflammatory cells that have the ability to promote a persistent cycle of inflammation that leads to disease, including cancer and other senescence-associated dysplasia. Our proprietary immunotherapeutics rejuvenate the immune system and allow it to reduce accumulated senescent cells and silence the proinflammatory conditions promoted by SASP factors.



Our Strategy

Our strategy includes the following key components:

Focus on diseases with no known FDA-approved treatments.

- Diseases to be targeted include autoimmune diseases and other proinflammatory diseases, cancer and senescence-associated dysplasia, such as Bronchopulmonary Dysplasia ("BPD"), the chronic lung disease occurring in newborns.

Focus on an autoimmune indication for the initial indication for clinical development for our lead product candidate, HCW9302.

- On November 17, 2025, the first patient was dosed at The Ohio State University Wexner Medical Center in the Company-sponsored, multi-center first-in-human clinical trial to evaluate HCW9302 in patients with alopecia areata (NCT07049328).
- Enrollment and treatment of subjects in this dose-escalation clinical trial is ongoing.
- As of December 31, 2025, the Company had two active clinical sites enrolling patients at The Ohio State University and James A. Haley Veterans' Hospital.

Once the Recommended Phase 2 Dose and safety are established for HCCW9302 in a successful Phase 1 study, evaluate other carefully selected indications in Phase 2.

- The Company will refine potential additional indications for Phase 2 clinical studies during Phase 1, based on the results of further preclinical research with support from Phase 1 clinical data from ancillary studies as well as human data read-outs.
- For HCW9302, we are focused on autoimmune diseases, including alopecia areata, and inflammatory conditions, such as other dermatological conditions, graft rejection, and neurodegenerative diseases.

Prepare for IND-applications for preclinical programs in 2027.

- We intend to complete IND-enabling studies and submit an IND application to evaluate HCW11-018b, our tetra-valent T-cell engager, in patients with solid tumors in the first half of 2027.
- We intend to complete IND-enabling studies and submit an IND application to evaluate HCW11-040, our second-generation immune checkpoint inhibitor, in patients with BPD in the second half of 2027.

Continue to build our relationships with leading clinical research centers.

- We believe we can reduce risks related to potential low patient recruitment and enrollment by continuing to build our relationships with clinical sites who specialize in indications that are being studied in clinical trials.
- We intend to work with the strongest principal investigators who have a passion for the underlying science and search for breakthrough therapeutics. These investigators tend to have recognized standing at their institutions and the broader scientific and medical communities. We find they can often be advocates for HCW Biologics and our clinical studies.

With each milestone for lead product candidates, assess the optimal approach to advance clinical development or commercialization.

- We continually assess our programs to determine the optimal path for development. Clinical development and commercialization may be accomplished with an internal program or corporate partnership.

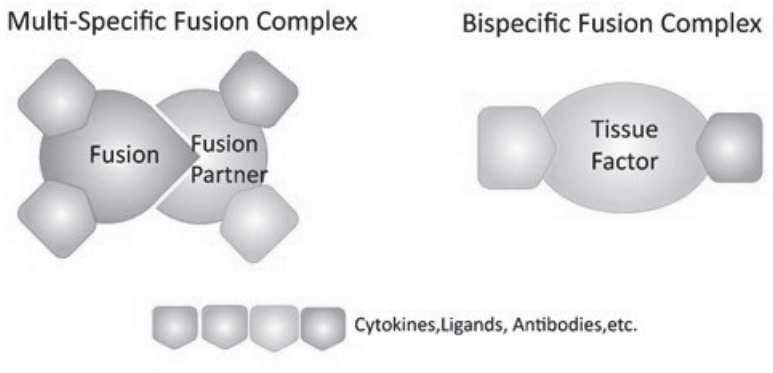
Our Drug Discovery and Development Platforms

HCW Biologics has combined a deep understanding of disease-related immunology with expertise in advanced protein engineering to develop fusion immunotherapeutics using its two proprietary drug design and discovery platforms. These two platforms enabled the Company to create over 50 novel immunotherapeutics which can be used to treat a wide range of disease indications.

TOBI™ (Tissue factOr-Based fusIon) Platform

Our TOBI™ (Tissue factOr-Based fusIon) Drug Discovery and Development Platform is a proprietary immunotherapeutic drug discovery and development technology which the Company used to construct multi-domain cytokine-based immunotherapeutics using a Tissue-Factor ("TF") scaffold.

Tissue factOr-Based fusIon Drug Discovery and Development Platform



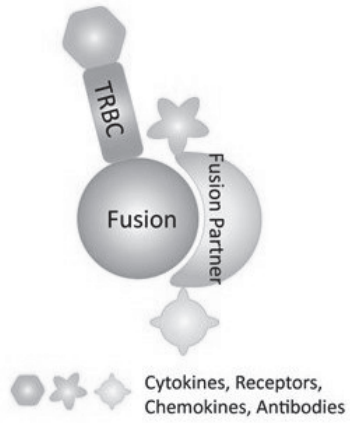
The domains of TOBI-based molecules are discrete. We have evaluated a TOBI-based molecule in clinical trials and have generated human data that shows that this molecule is capable of achieving the desired immune responses against solid tumors, including ovarian and pancreatic cancer. Based on other research, we believe that other TOBI-based molecules could activate the designed immune responses against other diseases or infected cells by blocking unwanted autoimmune / inflammatory activities.

Based on a TF scaffold, the TOBI™ platform packs multiple protein targets, including cytokines, single- chain antibodies, and ligands, into a fusion molecule. These molecules are capable of engaging immunostimulatory functions and addressing many signaling pathways simultaneously. Some of these fusion protein complexes have ex vivo and in vivo applications. Moreover, the TOBI™ platform is reproducible and suitable for cGMP manufacturing.

T-Cell Receptor β Chain Constant Region ("TRBC") Platform

Our proprietary T-Cell Receptor β Chain Constant Region ("TRBC") Drug Discovery and Development Platform is an immunotherapeutic drug discovery and development technology that the Company used to construct fusion immunotherapeutics that activate immune responses and specifically target cancerous or infected cells. The platform utilizes the TRBC protein as a scaffold to build multi-chain chimeric polypeptides, which include target-binding domains and affinity domains, enabling the targeting of specific antigens. We believe these polypeptides stimulate immune cells, modulating immune functions and signaling pathways.

T-Cell Receptor β Chain Constant Region Drug Discovery and Development Platform

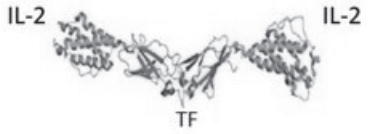


Molecules created with the TRBC platform integrate multiple protein targets, such as cytokines, single-chain antibodies, and ligands, into a single fusion complex designed to engage immunostimulatory functions and modulate various signaling pathways. This versatile scaffold enables the creation of multiple functional immune cell stimulators, second-generation immune checkpoint inhibitors, and second-generation immune cell engagers.

Clinical-Stage Program for Autoimmune and Proinflammatory Diseases

HCW9302: IL-2 Based Fusion Protein Molecules for T_{reg} Expansion

HCW9302 is a novel fusion protein molecule that contains two IL-2 domains linked by an extracellular tissue factor domain. IL-2 signaling is essential for homeostasis of T_{reg} cells. Unfortunately, recombinant IL-2 has an unfavorable pharmacokinetic profile and induces cytokine release syndrome limiting its therapeutic use. HCW9302 provides a potential solution to this problem. It is designed to have the therapeutic advantages of IL-2 while being well tolerated.



HCW9302

We are currently evaluating HCW9302 in a clinical study to verify our preclinical studies that found HCW9302 functions as a potent agent to stimulate and expand T_{reg} cells that suppress the activity of proinflammatory cells and factors. We have observed a long serum half-life compared with recombinant interleukin-2 (rhIL-2), a US FDA licensed drug for renal cell carcinoma and metastatic melanoma, which contributed to the ability of subcutaneously administered HCW9302 to activate and expand T_{reg} cells in mice in a well-tolerated dose range without activating proatherogenic CD4+ T cells. This finding also suggests that greater CD25-mediated T_{reg} activation may be superior to "mutein"-based strategies to prevent or diminish IL-2 binding to IL-2Rβγ on effector cells. In addition, preclinical studies have shown HCW9302 can be administered at a dosing range that expanded and activated T_{reg} cells but not CD4+ effector T cells. CD4+ effector T cells (also known as helper T cells) are crucial for immune responses, but under certain conditions, their excessive activation can lead to negative effects.

For information about the bi-specific TOBI fusion, HCW9302, and its effects on T_{reg} responses in an inflammatory disease, see *Frontiers in Immunology*, "A Novel Interleukin-2-Based Fusion Molecule, HCW9302, Differentially Promotes Regulatory T Cell Expansion to Treat Atherosclerosis in Mice," Zhu, X., et al., January 2023. The reference to our paper does not constitute incorporation by reference of the information contained in the paper.

Alopecia Areata

On January 28, 2025, the Company obtained clearance from the FDA to evaluate HCW9302 in a Phase 1 clinical trial in patients with alopecia areata ("alopecia"). In preclinical studies using an alopecia murine model, treatment with HCW9302 protected mice from disease, reducing pathogenic immune cell populations in the skin and skin-draining lymph nodes. HCW9302 treatment also led to a protective shift in T_{reg} : T_{eff} balance, with T_{reg} cells dominating in the skin leading to suppression of unwanted autoimmune activity. These findings suggest HCW9302-induced T_{reg} expansion can alter the course of alopecia areata and promote tolerance, warranting further studies in human patients.

Alopecia is characterized by hair loss in localized areas, the entire scalp, or, in some cases, the whole body. It occurs when the immune system mistakenly attacks hair follicles, leading to hair loss without causing permanent damage to the follicles. Patients often experience recurring episodes of hair loss throughout their lives. While not life threatening, alopecia areata can have a significant negative impact on patients' quality of life and psychological health. Existing approved treatments may provide some relief of symptoms, but there are often dangerous side effects.

Alopecia is one of the most prevalent autoimmune diseases in the world, affecting approximately 1 in 1,000 people, with a lifetime incidence of 2% worldwide, or 160 million people. According to the National Alopecia Areata Foundation, about 7 million people in the United States have alopecia areata. The condition primarily affects individuals under the age of 30, occurring at similar rates in both males and females.

Many insurance plans may not fully cover alopecia areata treatments, leading to significant out-of-pocket expenses. More extensive hair loss usually requires more intensive treatment, leading to higher costs. Hair transplants are considered among the most expensive treatment options, with costs ranging from $7,400 to $25,000 depending on the procedure and the clinic. Patients report even higher costs due to the need for medications like Janus kinase ("JAK") inhibitors which can reach upwards of $50,000 annually. JAK inhibitors have boxed warnings in their labeling due to an increased risk of serious heart-related events, cancer, blood clots, and death.

(See StatsPearls, National Library of Medicine of National Institutes of Health, National Alopecia Areata Foundation.)

Potential Additional Phase 2 Indications

The goals of the Phase 1 clinical trial are to assess whether the safety profile is acceptable to conduct further studies and establish a recommended phase 2 dose ("RP2D") that can increase T_{reg} cell activity in patients participating in the study. If we achieve the Phase 1 study objectives, the Company plans to progress the clinical development of HCW9302 in patients with alopecia areata as well as other autoimmune diseases and inflammatory conditions, including organ transplant rejection, neurodegenerative diseases, and other dermatologic diseases, such as atopic dermatitis and vitiligo.

Organ Transplant Rejection

Through collaborative research, the Company has performed preclinical research using HCW9302 in organ transplant rejection. According to the United Network for Organ Sharing, in 2025, there were a record-breaking 46,632 organ transplants performed in the United States. This includes both deceased and living donors. Graft rejection in organ transplantation refers to the phenomenon where the recipient's immune system identifies the transplanted organ as foreign tissue and attacks it, leading to damage and potential failure of the transplanted organ, essentially rejecting it from the body. This is a major complication following organ transplantation and occurs due to differences in the recipient's immune system compared to the donor's tissue antigens. Chronic transplant rejection may develop months or years after organ or tissue transplantation. This condition involves chronic inflammation and immune responses against the transplanted graft, leading to complications and symptoms that vary depending on the transplanted organ.

(See: United Network for Organ Sharing.)

Neurodegenerative Diseases

The Company's preclinical work in neurodegenerative diseases to date has focused on Alzheimer's Disease. According to the Alzheimer's Association, for the United States, health care and long-term care costs for people living with dementia were projected to reach $384 billion in 2025 and nearly $1 trillion in 2050.

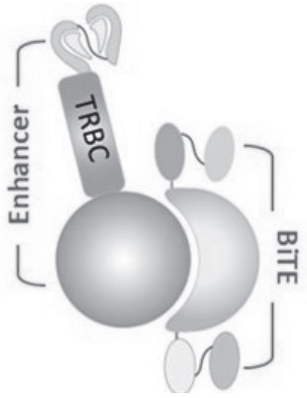
Further statistics from the Alzheimer's Association offer a partial explanation for these staggering costs. Again, these are statistics just for the United States.

- An estimated 7.2 million Americans aged 65 and older are living with Alzheimer's in 2024. Seventy-four percent are age 75 or older.
- Almost two-thirds of Americans with Alzheimer's are women.
- About 1 in 9 people aged 65 and older (11%) has Alzheimer's.
- Alzheimer's disease was the sixth-leading cause of death among people aged 65 and older in 2022.
- By 2050, the number of Americans with Alzheimer's is projected to rise to nearly 13 million.

(See: Alzheimer's Association.)

Preclinical Stage Clinical Development Programs

HCW11-018b: The Big BiTE - Tetra-Valent T-Cell Engager



HCW11-018b

HCW11-018b is a novel, tetra-valent T-Cell engager we call the Big BiTE, since it consists of a BiTE (common for all T-Cell Engagers) and an Enhancer (which makes the HCWB T-Cell Engager the "BIG BiTE"). It is designed to address key challenges for first generation T-Cell Engagers: manufacturability, preclinical safety profile, and ability to treat solid tumors. In our extensive preclinical studies, it induces robust, sustained, antigen-specific tumor killing, enhances $CD8^+$ T-cell activation, survival, and effector functions and promotes tumor infiltration into solid tumors. It combines a tissue factor-targeting BiTE with IL-15 immune stimulation and a TGF-β trap to overcome immunosuppression and poor T-cell infiltration of conventional BiTEs in solid tumors.

In non-human primate studies, HCW11-018b has demonstrated favorable tolerability, long serum half-life and favorable pharmacokinetics, without using the Fc fusion technology commonly found in bi-specific or tri-specific fusion molecules. Extensive preclinical studies further show that HCW11-018b does not trigger cytokine release syndrome when administered in doses within its therapeutic window. Cytokine release syndrome is a common, often manageable systemic inflammatory response in the current generation of BiTE antibody therapies.

IND-enabling studies are expected to be completed in first half of 2027.

Target Indications: Solid Tumors

Pancreatic Cancer

Pancreatic cancer, as one of most fatal malignancies, remains a critical issue in the global burden of disease. This cancer has the highest mortality rate of all major cancers. In the U.S., pancreatic cancer is currently the third leading cause of cancer-related death after lung and colon and is expected to become the second leading cause of cancer-related death by 2030. In the U.S. alone, an estimated 66,440 Americans were diagnosed with pancreatic cancer and more than 51,750 died from the disease in 2024.

For all stages combined, the five-year relative survival rate is 13%. For the small percentage (15%) of people diagnosed with local disease, the five-year survival rate is only 44%. Survival is higher when pancreatic cancer is detected early. Early diagnoses is difficult because there are few signs or symptoms before the cancer has spread outside of the pancreas.

China, the United States, and Japan had the highest number of pancreatic cancer cases in 2022. Worldwide there were approximately 550,000 new cases and 500,000 deaths in 2025. The table below shows the number of new cases estimated in 2025.

Country	**New Cases of Pancreatic Cancer**
World	550,000
China	128,000
United States	66,000
Japan	50,000

(See: World Journal of Gastronomy, American Cancer Society, National Cancer Institute, World Cancer Research Fund.)

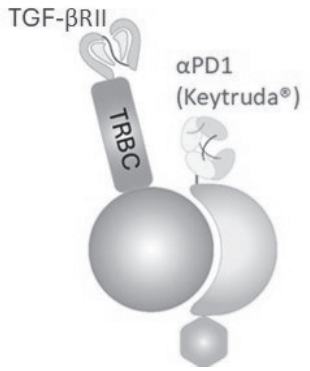
Ovarian Cancer

Ovarian cancer is one of the leading causes of cancer deaths among women and the deadliest of gynecologic cancers. Although risk of developing and dying from ovarian cancer is almost twice as high in developed countries, the actual burden (number of cases) is much higher in less developed countries due to population sizes. For example, China has the largest number of diagnoses per year (34,575), followed by India (26,934), then the United States. In the United States, ovarian cancer accounts for 2.5% of cancers in women. In the United States, while ovarian cancer is the 11th most common cancer among women, it is the fifth leading cause of cancer-related death among women. For 2026, the American Cancer Society estimates an overall five-year survival of about 49%–54%. Survival is highly stage-dependent, exceeding 90% for early-stage (localized) detection, but dropping to 30%–40% for distant, late-stage diagnosis.

Ovarian cancer is often referred to as “the silent killer” for a good reason: It ranks as the fifth deadliest cancer among women, according to the American Cancer Society. Overall, survival rates fall well below that for other cancers, such as breast cancer. Treatment for ovarian cancer usually involves a combination of surgery and chemotherapy. This cancer mainly develops in older women. About half of the women who are diagnosed with ovarian cancer are aged 63 years or older. The most important risk factor for ovarian cancer other than age is a family history of breast or ovarian cancer. This includes those with inherited gene changes like BRCA1, BRCA2, and Lynch syndrome.

(See: American Cancer Society, World Ovarian Cancer Coalition.)

HCW11-040: Second-Generation Immune Checkpoint Inhibitor



HCW11-040

HCW11-040 is a multifunctional fusion molecule that is a unique combination of cytokines and pembrolizumab, a generic form of Keytruda®. It is designed to expand progenitor T (Tpex) cells, which are the primary cells to respond to ICI therapy, without triggering cytokine storm in preclinical studies. Tpex cells have self-renewal capabilities and are considered a primary driver for the success of ICI therapies, making them an attractive target for improving treatment outcomes. Subcutaneous administration is expected to improve safety and quality-of-life for patients.

In preclinical studies, HCW11-040 has exhibited superior immune-cell activation, expansion, and cytotoxicity against cancer cells and tumors over Keytruda® in in-vitro and in-vivo studies. Further preclinical studies have been conducted in a senescence-associated dysplasia indication that have generated promising data. Based on these results, the Company has selected Bronchopulmonary Dysplasia ("BPD"), a chronic lung disease that affects preterm infants, as the initial indication for clinical studies.

IND-enabling studies are expected to be completed in the second half of 2027.

Target Indications: Bronchopulmonary Dysplasia and Other Senescence-Associated Dysplasia

The number of newborns suffering with Bronchopulmonary Dysplasia ("BPD") is growing due to rising premature birth rates and improved survival rates of extremely preterm infants, particularly in infants born at 23–27 weeks gestation, affecting 10,000–15,000 babies annually in the U.S. There is no known cure for BPD, which involves high morality and morbidities.

(See BioSpace, Bronchopulmonary Dysplasia Market Size to Reach USD 472.0 Million by 2035, Impelled by Increasing Premature Birth Rates, January 27, 2025.)

There are several quality-of-life indications which are classified as senescence-associated dysplasia. Senile lentigo (age spots) and chronic deep wrinkles are two such conditions. Aesthetics treatments represent a large and growing market due to the aging population. For example, the global botulinum toxin market was valued at $6.4 billion (USD) in 2022 and growing at a CAGR of 11.50% from 2022 to 2030. The market is expected to reach $15.2 billion (USD) by 2030.

See: Global Growth Report, Fortune Business Insights.)

Program being Co-Developed in Partnership with Trimmune

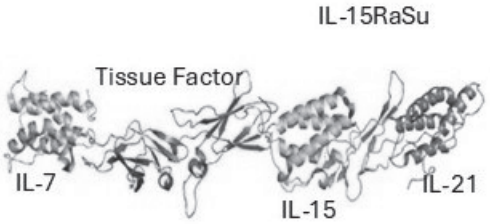
HCW11-006

HCW11-006 is a novel fusion molecule which combines several different immune functional domains as part of a group of compounds characterized as multi-functional immune cell stimulators, which will be developed in partnership with Trimmune, the licensee responsible for the development and commercialization of HCW11-006.

Trimmune holds the exclusive worldwide rights for in vivo applications of HCW11-006. Based on promising data seen in preclinical *in-vitro* and *in-vivo* studies conducted by HCW Biologics, Trimmune expects to initiate a Phase 1 clinical trial in China in the first half of 2027 to evaluate HCW11-006 in the treatment of solid tumors. The Company has a payment-free, milestone-free, and royalty-free option to recapture all rights to the development and commercialization of HCW11-006 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 in China. If the Company exercises the option, thereafter, HCW Biologics and Trimmune will be co-development partners. The parties have also agreed to build unified clinical programs, and, when the HCW11-006 co-development project generates key clinical data, to actively work together in pursuing business development opportunities with multi-national corporations. Each party will be financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the licensed molecule in its territory. Therefore, expenses to complete the first Phase 1 clinical trial in China will be paid by Trimmune. This arrangement allows the Company to have direct access to the Phase 1 results without financial responsibility for the cost.

Commercial-Ready Molecules Used As Reagents

HCW9206: Multi-Cytokine Protein Fusion Immunotherapeutic Reagent



HCW9206

HCW9206 is a commercial-ready, novel immunotherapeutic reagent engineered to deliver synergistic signaling from three immune-stimulatory cytokines within a single molecule, which provides a revolutionary approach to generate chimeric T-cell receptor - T cells (CAR-Ts) for immunotherapy with increased function in a cost-effective manner. HCW9206, a first-in-class cytokine-scaffold-based platform, enables production of more potent CAR-T-based immunotherapies by generating a CAR-T population which is highly functional and markedly enriched for long-live T-memory stem cells (T_{scm}). This strategy is broadly applicable to increase persistence and functionality of CAR-Ts, potentially enhancing their clinical efficacy for treating infectious diseases and cancer. Treating T cells with HCW9206 can quickly and effectively produce HIV- and CD19-specific CAR-T cells that are highly enriched for the T_{scm} memory phenotype, as well as effector T cells that have been shown in mouse models to be capable of maintaining suppression of HIV and leukemic cell proliferation.

Therefore, generating CAR-T cells through HCW9206 treatment could provide a new, improved, and highly scalable method for generating CAR-T cells to treat patients with infectious disease and cancer and replace standard CAR-T cell production using αCD3/28 activation. This has widespread implications for the generation of more robust CAR-T cell-based immunotherapies to potentially improve CAR-T cell functional persistence and efficacy for treatment of HIV and cancer. (See: Cole et al., "IL-7/IL-15/IL-21 cytokine-fusion scaffold generates highly functional CAR-T cells enriched in long-live T memory stem cells," Science Advances, 13 Mar 2026, Vol 12, Issue 11.)

Beyond CAR-T applications, HCW9206 has also been utilized to expand Cytokine-Induced Memory-Like (CIML) NK cells using a feeder cell-free "Prime and Expand" strategy (10.1007/s00262-024-03765-8). In this approach, HCW9206 is combined with an IgG1 antibody that recognizes the scaffold domain of HCW9206, enabling CD16-mediated NK cell engagement during the expansion phase. This cytokine- and CD16-dependent process generates CIML NK cells with enhanced metabolic fitness, stable epigenetic *IFNG* promoter demethylation, improved anti-tumor activity *in vitro* and *in vivo*, and superior persistence in NSG mouse models. The platform represents a streamlined, feeder cell–free manufacturing strategy designed to support multi-dose infusion and off-the-shelf adoptive cell therapy (ACT).

Collectively, these findings position HCW9206 as a next-generation CAR-T and NK cells manufacturing reagent capable of streamlining production, reducing reliance on multi-component activation systems, and potentially lowering manufacturing costs. By improving CAR-T functionality and durability -- long-standing challenges in the field -- HCW9206 may enhance long-term therapeutic outcomes in malignancies, chronic infections, and autoimmune diseases, while also supporting emerging *in vivo* CAR-T manufacturing technologies.

The GMP master cell bank and manufacturing process for HCW9206 have been established, and a Drug Master File for its use as an *ex vivo* reagent has been filed with the FDA. HCW9206 is currently positioned as a commercial-ready product as a reagent for CAR-T–based manufacturing applications.

HCW Biologics holds the perpetual, exclusive worldwide license to develop immunotherapeutic treatments based on HCW9206 for all disease indications, with a Right of First Refusal to ImmunityBio for cancer indications.

HCW9201: Generation of CIML NK-Cells Reagent

HCW9201 is a commercial-ready, novel fusion immunotherapeutic reagent constructed with IL-12, IL-15 and IL-18 that activates and expands NK cells. NK cells are a promising cellular therapy for cancer, with challenges in the field including persistence, functional activity, and tumor recognition. Brief priming of blood NK cells with HCW9201 results in differentiation of memory-like NK cells, which have the potential for enhanced responses against cancer by activating and proliferating NK cells. HCW9201 stimulation improved NK cell metabolic fitness, and resulted in the DNA methylation remodeling characteristic of memory-like differentiation. HCW9201 increases in short-term and memory-like NK cell cytotoxicity and Interferon-Gamma production against leukemia targets. See Shrestha et al., "A "Prime and Expand" strategy using the multifunctional fusion proteins to generate memory-like NK cells for cell therapy Cancer Immunol Immunother. 2024 73:179.

HCW9201 represents a protein engineering approach that solves many problems associated with multi-signal receptor engagement on immune cells, and HCW9201-primed NK cells will be advanced as an ideal approach for clinical GMP-grade memory-like NK cell production for cancer therapy. In addition, the molecule has been shown to be compatible with NK cell manufacturing platforms, further supporting its versatility in immune cell therapy production.

The GMP master cell bank and manufacturing process for HCW9201 have been established, and a Drug Master File for its use as an *ex vivo* reagent has been filed with the FDA. HCW9201 is currently positioned as a commercial-ready product as a regent for Cytokine Induced Memory Like (CIML) NK cells–based manufacturing applications.

HCW Biologics Pipeline

The status of our lead immunotherapeutic programs is summarized in the table below:

Molecule Name	Mechanism	Indications	Preclinical	IND-Enabling	Phase 1	Phase 2	Phase 3	Commercial-Ready
HCW9302	T_{reg} Expansion	Autoimmune Diseases						
		Atopic Dermatitis/ Organ Transplant Rejection						
		Neurodegenerative Diseases						
HCW11-018b	Enhanced T-Cell Engager	Solid Tumors (i.e. Pancreatic/ Ovarian Cancer)						
HCW11-040	Targeted Immune Checkpoint Inhibitors	Cancers/Bronchopulmonary Dysplasia						
HCW11-006[a]	Immune-Cell Activation	Not Disclosed						
HCW9201	Memory-like NK Cell Expansion &Activation	Manufacturing of CIML-NK Products						✓
HCW9206	CAR-T (CAR-Tscm) Expansion	Manufacturing CAR-T Cells without αCD3/αCD28 and IL-2 products						✓

a) Beijing Trimmune Biotech Co., Ltd. holds the exclusive worldwide license rights to HCW11-006 for in vivo applications.

HCW9302: Novel Immunotherapeutic for T_{reg} Expansion being Evaluated in Autoimmune Disorder

On November 17, 2025, the Company initiated its first-in-human Phase 1 dose escalation clinical trial to evaluate one of its lead drug candidates, HCW9302, in patients with alopecia areata, a common autoimmune disease in humans that currently has no curative FDA approved treatments.

This trial is a Phase 1, open-label, multi-center Company-sponsored trial with competitive enrollment. The Company currently has two active clinical sites at The Ohio State University and James A. Haley Veterans' Hospital. The study involves dose escalation to determine the toxicity profile of HCW9302 and to designate a dose level for the Phase 2 expansion phase, or the Recommended Phase 2 Dose ("RP2D"). Up to five dose levels are being evaluated. In the first stage of the study, HCW9302 is being administered subcutaneously in a single dose. Enrollment and treatment of subjects in this dose-escalation clinical trial is ongoing with no dose limiting toxicities reported as of March 16, 2026. Depending on the results of the single ascending dose stage, a multi-dose study of HCW9302 administered subcutaneously every 28 days for four consecutive treatments will be considered.

With the start of the first-in-human clinical trial for HCW9302 in alopecia areata, we are one step closer to advancing a potentially transformative immunotherapeutic treatment of autoimmune diseases. This trial is a milestone for our Company, and the beginning of clinical development of treatments for quality-of-life indications. While not life-threatening, alopecia areata has no cure and diminishes the quality of life for those suffering with this disease. Existing treatments may provide some relief of symptoms, but there are often serious side effects. If this Phase 1 study is successful, we intend to rapidly advance clinical development of HCW9302 in Phase 2 studies in patients with other autoimmune diseases and serious inflammatory conditions, including graft rejection, neurodegenerative diseases, and other dermatological conditions, such as atopic dermatitis and vitiligo.

Business Development and Out-License Programs

We have created over 50 immunotherapeutic molecules with our proprietary drug discovery and development platforms. We use out-licensing as a strategy for financing as well as clinical development of selected programs, molecules or markets. We expect out-licensing to provide non-dilutive financing to bolster resources available to fund our core markets and programs and possibly commercialize molecules, with the hope that our licensees achieve success through our licenses.

Wugen Exclusive Worldwide License Agreement

In December 2020, we entered into an exclusive worldwide license agreement with Wugen, under which Wugen licensed limited rights to develop, manufacture, and commercialize cell-based therapy treatments for cancer using two of our internally-developed, multi-cytokine fusion protein molecules, HCW9201 and HCW9206. Since inception, the Company has recognized $16.2 million of revenues derived from the Wugen License, including upfront license fees in cash and shares of Wugen common stock, payments for vials of materials, and for manufacturing of development supplies for clinical trials.

The Company continues to hold the 2.2 million shares of Wugen common stock we received as consideration for the Wugen License. These shares represent a 1.61% ownership interest in Wugen as of December 31, 2025. In January 2026, Wugen received a Breakthrough Therapy Designation from the U.S. Food and Drug Administration ("FDA") for its investigational CAR-T cell therapy, Sofi-cel. Sofi-cel is an investigational, potential first-in-class, allogeneic, anti-CD7 CAR-T cell therapy currently under evaluation in a pivotal trial (T-RRex) for patients with relapsed or refractory (R/R) T cell acute lymphoblastic leukemia or T cell lymphoblastic lymphoma (T-ALL/LBL). Breakthrough Therapy Designation is intended to expedite the development and review of medicines for serious or life-threatening conditions with evidence of a substantial clinical improvement. Wugen plans to submit a Biologics License Application ("BLA") to the FDA in 2027. This therapy holds the potential to be the first approved "off-the-shelf" CART-T for T-cell malignancies.

On May 29, 2025, the Company agreed to a request from Wugen to suspend the Wugen License, including Wugen's clinical trial due diligence obligations and its obligation to pay up to $500,000 annually to reimburse the Company for certain research and development expenses. The suspension will run for a period of one year from the effective date of the suspension and will end on May 29, 2026. During the suspension, the Company has the exclusive right to seek alternate licensees and terminate the Wugen license in order to enter other business development transactions related to the *ex vivo* use of the licensed molecules.

Trimmune Exclusive Worldwide License 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 ("Trimmune License") following the assignment of the original License, Research and Co-Development Agreement, which includes an exclusive license to HCW11-006 for in vivo applications ("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 and an option to license HCW9302 for in vivo applications in China or Asia. In the Trimmune License, the parties agreed to restructure the upfront license fee to consist of a $3.5 million cash payment from which the government of China would withhold taxes which are refundable, and a transferable minority equity ownership interest in Trimmune. In addition, the parties agreed that for additional consideration, Trimmune has an option to license the exclusive China rights to clinical development and commercialization for in vivo applications of HCW9302, the Company's clinical-stage molecule currently being evaluated for the treatment of an autoimmune disorder.

In addition to the upfront license fee, the Company is eligible to receive additional development milestone payments and double-digit royalties on future product sales. The Company will receive a substantial portion of the proceeds from certain future transaction(s) involving the molecule, if such a transaction(s) occur. We also have a payment-free, milestone-free, and royalty-free option to recapture the development and commercialization rights for this molecule for the United States, Canada, Central America, and South America (Opt-in Territory) after the conclusion of the Phase 1 clinical trial in China. Trimmune is financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the molecule. Each party will be financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the licensed molecule in its territory. Therefore, expenses to complete the first Phase 1 clinical trial in China will be paid by Trimmune. This arrangement allows HCW Biologics to have direct access to the Phase 1 results without financial responsibility for the costs incurred prior to the time a decision must be made regarding the Opt-In Right.

In accordance with the terms of the Trimmune License, the deal closing took place upon receipt of the upfront payment. As of March 16, 2026, the Company has received the full upfront license fee, which consisted of $3.5 million in gross proceeds, or $2.9 million net of taxes, and a transferable minority equity interest in Trimmune. See Note 18. Subsequent Events.

Commercial-Ready Molecules Used as Reagents: Active Search for Corporate Partner

As a result of the amendment to the license agreement with Wugen Inc. ("Wugen"), the Company has an opportunity, until May 28, 2026, to enter into a new license agreement based on using HCW9206 as a reagent in the manufacture of CAR-T products. During this time, the Company has the exclusive right to seek alternate licensees and terminate the license with Wugen in order to enter other business development transactions related to the ex vivo use of HCW9206 and HCW9201. Both of these molecules have a GMP master cell bank and manufacturing process, as well as a Drug Master File for use as an ex vivo reagent filed with the FDA.

Manufacturing

For TOBI™ molecules, we have established internally developed large scale manufacturing processes for producing these fusion molecules from Chinese hamster ovary ("CHO") cells in a cGMP-compliant setting.

We have a long-standing relationship with a contract manufacturing organization, EirGenix, Inc. ("EirGenix"), a third-party global contract development and cGMP manufacturer of biologics, for the manufacture of our internally-developed molecules. By the end of 2019, we successfully launched cGMP production with manufacturing runs of clinical grade materials adequate for support of our clinical trials. As of December 31, 2025, we have successfully completed cGMP production of four of our molecules (HCW9101, HCW9201, HCW9206, and HCW9302). The production campaigns include sufficient quantities of clinical grade materials required to complete the Phase 1 or Phase 2 clinical trials we have planned for HCW9302 during 2026 and 2027.

We currently rely on EirGenix and other third-party manufacturers for the cGMP production of sufficient quantities of our drug product candidates for our clinical trials. Our management team and other internal personnel have extensive cGMP manufacturing experience which allows for seamless technology transfer of our proprietary manufacturing methods, as well as the ability to manage the manufacturing and development processes conducted by third-party manufacturers. Our agreements with third-party manufacturers include confidentiality and intellectual property provisions as well as routine quality audits. However, we currently obtain our products from these manufacturers on a per project basis and do not have long-term supply arrangements in place. Should any of these manufacturers become unavailable to us for any reason, we believe that there are a number of potential alternative contract manufacturers available to us on commercially reasonable terms to meet our future production requirements, although we may incur some delay and cost in qualifying and re-establishing the manufacturing processes at an alternative facility. We endeavor to mitigate this risk by maintaining an inventory of clinical material that is adequate to complete the clinical trials we expect to initiate in the next 12 months.

On August 15, 2022, we purchased a 36,000 square foot building located in Miramar, Florida that is intended to serve as our new headquarters. After refitting this building, we expect to have the capabilities for small scale drug manufacturing, storage, distribution, and quality testing. We expect to relocate to this building upon completion; however, the date of completion is uncertain at this time. Our staff has expertise in building and running cGMP manufacturing facilities for immunotherapeutics. In addition, our manufacturing process is wholly-owned and developed by us, so we do not expect to be reliant on a third-party for manufacturing expertise or processes. We have the flexibility to complete the buildout of the manufacturing facility on a longer schedule, should we choose to delay completion. In the meantime, we intend to continue manufacturing clinical-grade material using third-party manufacturers.

Intellectual Property

Overview

We strive to protect and enhance internally-developed technology, inventions, and improvements that are commercially important to the development of our business, including seeking, maintaining, and defending patent rights, for our internally-developed molecules and manufacturing processes. We also rely on trade secrets relating to our technology platform and on know-how, continuing technological innovation to develop, strengthen, and maintain our proprietary position in the field of inflammaging and the diseases it promotes that may be important for the development of our business.

As with other biotechnology and pharmaceutical companies, our ability to secure and maintain intellectual property protection for our product candidates, future products, and other internally-developed technologies will depend on our success in obtaining effective patent coverage and enforcing those patents if granted. However, we cannot guarantee that our pending patent applications, and any patent applications that we may file in the future, will result in the issuance of patents, or that any issued patents we have obtained or may obtain will provide sufficient proprietary protection from competitors. Any issued patents that we obtain may be challenged, invalidated, or circumvented by third parties.

In addition to patents, we also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our internally-developed technology, in part, through confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and potential collaborators. We also rely on trade secrets relating to our manufacturing process and on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of inflammaging that may be important for the development of our business. We additionally may rely on regulatory protection afforded through data exclusivity, market exclusivity, and patent term extensions, where available.

Internally-Developed Intellectual Property

TOBI™ Platform and TOBI™-Based Molecules

As of December 31, 2025, the United States Patent and Trademark Office (the "USPTO") has granted fifteen patents, including fundamental patents that protect the underlying technology for our lead product candidate, HCW9302, as well as patents that protect the underlying technology and use of the molecule HCW9206, which is licensed to Wugen, conveying rights to develop cell-based therapies for cancer. In respect of Wugen, we retain all other rights to HCW9206, including manufacturing rights. As part of a confidential Settlement Agreement with ImmunityBio, Inc. in 2024, the Company assigned certain patents and patent applications to ImmunityBio, Inc., yet the Company retained a world-wide exclusive license in respect of the use of TOBI™ molecules outside of oncology indications. Licensed patents that protect the underlying technology for proprietary molecules include:

- The USPTO granted U.S. Patent No. 11,401,324 to HCW Biologics on August 2, 2022. This patent contains claims for immunotherapeutic single-chain chimeric polypeptides comprising two target-binding domains on a scaffold made of a soluble tissue factor domain, supporting our lead drug candidate, HCW9302.
- The USPTO granted U.S. Patent No. 11,884,712 to HCW Biologics on January 30, 2024. This patent contains compositions claims encompassing HCW9206.

As of December 31, 2025, in addition to a license to fourteen issued U.S. patents, we have a license to seven issued Japanese patents, three issued Australian patents, one issued Singaporean patent, four issued Chinese patents, two issued European patents, two issued Israeli patents, and two New Zealand patents, and 67 pending patent applications worldwide, including 10 pending U.S. utility patent applications, seven Hong Kong applications, and 50 total pending non-U.S. national phase patent applications and Taiwanese patent applications. HCW Biologics owns one issued U.S. patent and 13 pending patent applications worldwide including three pending provisional U.S. patent applications, one Hong Kong application, and nine total pending non-U.S. national phase patent applications and Taiwanese patent applications. Our policy is to file patent applications to protect technology, inventions and improvements to inventions that are commercially important to the development of our business. We seek United States and foreign patent protection for a variety of technologies, including: our internally-developed platform, specific chimeric polypeptides developed using our platform, methods of using the chimeric polypeptides both in vivo and in cellular therapy to treat various conditions, methods for treating diseases of interest, and methods for manufacturing our products. We also intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used in combination with our products in the development of novel products or methods of use. We seek protection, in part, through confidentiality and proprietary information agreements.

Our intellectual property portfolio is continually evolving during prosecution of our applications. We own or license multiple families of patent applications that are directed to our TOBI™ platform technology and our single-chain and multi-chain chimeric polypeptides and methods of use of these polypeptides alone and in combination.

Single-Chain Chimeric Polypeptides Licensed Patent Family

This family includes licensed patents and patent applications with claims directed to compositions of various single-chain chimeric polypeptides created using the TOBI™ platform. These licensed applications also include methods of use and manufacture thereof and methods of promoting the activation and proliferation of NK cells or T cells using our single-chain chimeric polypeptides. As of December 31, 2025, this family, which includes HCW9302, includes U.S. Patent Nos. 11,401,324, 11,987,619, and 12,018,071, two pending U.S. utility patent applications, one issued Australian patent, one issued Chinese patent, one issued Israeli patent, two issued Japanese patents, one issued New Zealand patent, and 10 pending patent applications filed in Europe, Australia, Canada, Israel, Japan, South Korea, China, Singapore, Hong Kong and Taiwan. The earliest predicted expiration date of any patent issuing from a patent application in this family is 2039.

Multi-Chain Chimeric Polypeptides Licensed Patent Family

This family includes licensed patents and patent applications with claims directed to compositions of various multi-chain chimeric polypeptides created using the TOBI™ platform. These licensed applications also include methods of use and manufacture thereof and methods of promoting the activation and proliferation of NK cells or T cells using our multi-chain chimeric polypeptides. As of December 31, 2025, this family, which includes claims encompassing HCW9218, HCW9201, HCW9206, HCW9228, HCW9207, and HCW9212, includes U.S. Patent Nos. 11,518,792, 11,884,712, 12,269,654, 12,398,186, and 12,509,494, three pending U.S. utility patent applications, one issued Japanese patent, one issued Australian patent, one issued European patent, one issued Israel patent, one issued New Zealand patent, one issued Singaporean patent, and eleven pending patent applications filed in Europe, Australia, Canada, Japan, South Korea, China, Singapore, Hong Kong, and Taiwan. The earliest predicted expiration date of any patent issuing from a patent application in this family is 2039.

With respect to HCW9218, as of December 31, 2025, the composition is broadly or narrowly claimed in U.S. Patent No. 11,518,792, four patents issued in Australia, Europe, Israel, New Zealand, Singapore, and Japan, and six pending patent applications filed in Canada, Japan, South Korea, China, Taiwan, and Hong Kong.

With respect to HCW9201, December 31, 2025, the composition is broadly or narrowly claimed in U.S. Patent No. 12,269,654, one issued European patent, one issued Israeli patent, one issued Singaporean patent, one issued Japanese patent, one issued New Zealand patent, and seven pending patent applications filed in Europe, Canada, Japan, China, Singapore, Hong Kong and Taiwan. Wugen has obtained an exclusive license to these patent applications limited to use of the licensed chimeric polypeptides in manufacturing certain cellular therapy products.

With respect to HCW9206, December 31, 2025, the composition is broadly or narrowly claimed in U.S. Patent No. 11,884,712 , one issued Singaporean patent, one issued Japanese patent, one issued European patent, one Israeli patent, one New Zealand patent, and eight pending patent applications filed in Europe, Australia, Canada, Japan, China, Singapore, Hong Kong and Taiwan. Wugen has obtained an exclusive license to these patent applications limited to use of the licensed polypeptides in manufacturing certain cellular therapy products.

Methods of Culturing and Methods of Expansion and Proliferation

These two families include licensed patents and patent applications with claims directed to methods of promoting the activation and proliferation of NK cells through the use of our single-chain or multi-chain chimeric polypeptides for ex vivo cell therapy use. As of December 2025, these two families, which include methods of using HCW9201 and HCW9206, include U.S. Patent No. 11,730,762, U.S. Patent No. 11,738,052, U.S. Patent No. 12,479,899, one pending U.S. utility patent application, one issued Australian patent, two issued Chinese patents, one issued European patent, two issued Japanese patents, and 14 pending patent applications filed in Europe, Australia, Canada, Israel, Japan, South Korea, Singapore, Hong Kong and China. The earliest predicted expiration date of any patent issuing from a patent application in the first of these two families is 2039. The earliest predicted expiration date of any patent issuing from a patent application in the second of these two families is 2040. Wugen has obtained an exclusive license to these two patent families limited to use in manufacturing certain cellular therapy products.

Treating Age Related Disorders

These three families include licensed patent and patent applications with claims directed to methods of killing or reducing the number of senescent cells in a subject using our single-chain or multi-chain chimeric polypeptides. As of December 2025, these three families, which include methods of using HCW9218, HCW9228 and HCW9302, include U.S. Patent Nos. 11,672,826, 12,024,545, and 12,115,191, three pending U.S. utility patent applications, one issued Chinese patent, two issued Japanese patents, and 22 pending patent applications filed in Europe, Australia, Canada, Israel, Japan, Hong Kong, South Korea, New Zealand, Singapore, and China. The earliest predicted expiration date of any patent issuing from a patent application in the first of these three families is 2039. The earliest predicted expiration date of any patent issuing from a patent application in the second of these families is 2041. The earliest predicted expiration date of any patent issuing from a patent application in the third of these families is 2040.

Methods of Activating Regulatory T Cells

This family includes patent applications with claims directed to methods of promoting the activation and proliferation of Regulatory T cells through the use of our single-chain or multi-chain chimeric polypeptides for *ex vivo* cell therapy use. As of December 2025, this family, which includes methods of using HCW9213 and HCW9302, includes U.S. Patent No. 12,398,189, and 10 pending patent applications filed in Australia, New Zealand, Singapore, Israel, Europe, Canada, Japan, China, Hong Kong, and South Korea. The earliest predicted expiration date of any patent issuing from a patent application in this family of applications is 2041.

Antibodies

This family includes patent applications with claims directed to anti-CD26 scFv antibodies. As of December 2025, this family, which includes composition claims for HCW9106, includes U.S. Patent No. 12,497,462, one issued Japanese patent, and five pending patent applications filed in Australia, Canada, Europe, China, and Hong Kong. The earliest predicted expiration date of any patent issuing from a patent application in this family of applications is 2041.

The various methods of use of our chimeric polypeptides covered in our portfolio include: *ex vivo* cellular therapy use; in vivo or injectable use; methods of inducing differentiation of an immune cell into a memory or memory-like immune cell (in vitro or in vivo); methods of stimulating an immune cell (in vitro or in vivo); and methods of inducing or increasing proliferation of an immune cell (in vitro or in vivo). Indications covered in the portfolio broadly include cancers, including solid tumors and hematological cancers; age-related diseases; and infectious diseases. We are also pursuing innovative combinations of use with our chimeric polypeptides and antibodies, which include both known and internally-developed antibodies. Patents that may issue from these HCW Biologics Inc. owned or licensed applications are generally expected to expire between the years 2039 to 2041, subject to possible patent term adjustment and/or extension.

The term of individual future patents may vary based on the countries in which they are obtained. Generally, patents issued from applications filed in the United States are effective for 20 years from the earliest effective non-provisional filing date. In certain cases, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of a U.S. patent, though the total patent term, including any extension, must not exceed 14 years following FDA approval. A U.S. patent can only be extended once, such that, if a single patent is applicable to multiple products, it can only be extended based on one product.

The term of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective national filing date. Similar patent term extension provisions are available in Europe and other foreign jurisdictions to extend the term of a patent covering an approved drug. When possible, we expect to apply for patent term extensions for future patents covering our product candidates and their methods of use.

New Chimeric Polypeptide Platform

As of December 31, 2025, HCW Biologics has filed three U.S. provisional patent applications, two U.S. utility patent applications, one Taiwan patent application, and three international patent applications related to a new chimeric polypeptide platform. The new chimeric polypeptide platform will be useful in the generation of polypeptides with therapeutic potential (e.g., useful in the field of inflammaging).

Trademarks

We have two registered U.S. trademarks and two pending U.S. trademark applications for our corporate name and corporate logo. We have an International Registration for the mark HCW BIOLOGICS for pharmaceutical research and development services, among other related services, in Class 42 and four national trademark applications pending therefrom with two registrations issued in the European Union and Japan. In the future, we intend to file applications for trademark registrations in connection with our product candidates, and other technologies in various jurisdictions, including the United States as the products are further developed.

Trade Secret Protection

Finally, we may rely, in some circumstances, on trade secrets to protect our technology. We seek to protect our internally-developed technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

In addition to the above, we have established expertise and development capabilities focused in the areas of preclinical research and development, manufacturing and manufacturing process development, quality control, quality assurance, regulatory affairs, and clinical trial design and implementation. We believe that our focus and expertise will help us develop products based on our internally-developed intellectual property.

Contracts and Agreements

Wugen Exclusive Worldwide License Agreement

In December 2020, we entered into an exclusive worldwide license agreement with Wugen, under which Wugen licensed limited rights to develop, manufacture, and commercialize cell-based therapy treatments for cancer based on two of our internally-developed, multi-cytokine fusion protein molecules, HCW9201 and HCW9206. The license included patents and applications that protect the underlying technology and use of the molecule HCW9201 and HCW9206, conveying rights to develop cell-based therapies for cancer. In respect of Wugen, we retain all other rights to HCW9206, including manufacturing rights. As part of a confidential Settlement Agreement with ImmunityBio, Inc. in 2024, the Company assigned certain patents and patent applications to ImmunityBio, Inc., yet the Company retained a world-wide exclusive license in respect of the use of TOBI™ molecules outside of oncology indications.

On May 29, 2025, the Company agreed to a request from Wugen to suspend the Wugen License, including Wugen's clinical trial due diligence obligations and its obligation to pay up to $500,000 annually to reimburse the Company for certain research and development expenses. The suspension will run for a period of one year from the effective date of the suspension and will end on May 29, 2026. During the suspension, the Company has the exclusive right to seek alternate licensees and terminate the Wugen license in order to enter other business development transactions related to the *ex vivo* use of the licensed molecules. For further information, see "Item 1. Business – Business Development and Out-License Programs."

Trimmune Exclusive Worldwide License 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 ("Trimmune License") following the assignment of the original License, Research and Co-Development Agreement, which includes an exclusive license to HCW11-006 for in vivo applications ("WY Biotech License") from WY Biotech Co., Ltd. to Trimmune. The deal also includes an option to license the exclusive China rights to clinical development and commercialization for in vivo applications of HCW9302. The parties agreed to build unified clinical programs, and to work together in the business development operations when the HCW11-006 co-development project generates key clinical data, to actively explore business development opportunities with multi-national corporations.

HCW also has a payment-free, milestone-free, and royalty-free option to recapture the development and commercialization rights of this molecule for the United States, Canada, Central America, and South America (Opt-in Territory) after the conclusion of the Phase 1 clinical trial. Trimmune is financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the molecule. For further information, see "Item 1. Business – Business Development and Out-License Programs."

Contract Research Agreements

We have certain contract research agreements with contractors that we entered during the two years ended December 31, 2025 for the (i) hybridoma development, (ii) cell line improvement for higher manufacturing productivity, and (iii) collaborative research to support pre-clinical studies. In respect of the hybridoma development and cell line improvement agreements, we own all rights to the resulting intellectual property, including the antibodies, sequences, and data. To date, we have received several sequences from the contractors. For certain contractors, we are obligated to pay one future milestone payment upon filing and acceptance of an IND for each respective human antibody or protein from cell line; however, no additional future development or financial obligations are due under these contract research agreements. For certain research collaborations agreements, the resulting research intellectual property may be jointly owned or ownership may be based upon inventorship. In those circumstances, the Company has the option to obtain an exclusive license for the research intellectual property

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on internally-developed products. We believe that our immunotherapeutic approach, internally-developed technology, expertise, scientific knowledge, track record in successfully developing drugs from bench to commercialization and intellectual property provide us with competitive advantages. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Any product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

Many of the companies we are competing against, or which we may compete against in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. In addition, we face a constantly changing competitive landscape because of numerous mergers and acquisitions in the pharmaceutical and biotechnology industry, which will concentrate resources among a smaller number of large pharmaceutical companies. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements and co-development deals with large and established companies. These competitors also compete with us in establishing clinical trial sites and patient registration for clinical trials necessary to advance the clinical development of our product candidates.

Although we believe our novel approaches are different from most other existing or investigational therapies across the disease areas where we are focusing our development, we will need to compete (or be combined) with currently approved therapies, and potentially those currently in development if they are approved. We are aware of several marketed and investigational products in our leading disease areas, including but not limited to the products and competitors discussed below.

We compete in the segments of the pharmaceutical, biotechnology, and other related markets that develop cancer therapies. There are many other companies that have commercialized or are developing cancer therapies, including large pharmaceutical and biotechnology companies, such as AbbVie, Amgen, AstraZeneca/MedImmune, Bristol Myers Squibb Company, Merck & Co., Novartis Pharmaceuticals, Pfizer, Sanofi and Genentech, a member of The Roche Group. We face significant competition from pharmaceutical and biotechnology companies that target specific tumor-associated antigens using immune cells or other cytotoxic modalities. These generally include immune cell redirecting therapeutics (e.g., T-cell engagers), adoptive cellular therapies (e.g., CAR-Ts), antibody drug conjugates, targeted radiopharmaceuticals, targeted immunotoxins, and targeted cancer vaccines.

Aging-related diseases are becoming a major focus in biopharma, as researchers and companies work to develop treatments for conditions like Alzheimer's. Biotech innovators like Altos Labs, Calico Life Sciences, Rubedo Life Sciences and Unity Biotechnology are at the forefront, exploring ways to target aging itself by removing senescent cells and modifying metabolic pathways. In oncology, there's growing interest in using senescence removal to improve the effectiveness of cancer treatments. Big names in pharma like Pfizer, Johnson & Johnson, and Roche are investing heavily in aging research, seeing not only its potential for regenerative therapies but also its enormous market potential. As the global population ages, this field is rapidly advancing and becoming a critical area of growth in healthcare.

With respect to our other lead product candidate, HCW9302, there is a growing momentum behind modulating T_{reg} cells as a potential treatment for autoimmune diseases. We are not aware of other competing clinical-stage companies with a first-in-class immunotherapeutic compound for deactivation of persistently activated immune cells, inflammasomes and reduction of inflammatory cytokines they release through the activation of T_{reg} cells.

Autoimmune diseases, including alopecia areata, atopic dermatitis, and neurodegenerative disorders, are gaining increasing attention in biopharma. We initiated a Phase 1clinical study in this area using HCW9302, for alopecia areata. We are aware of several other companies developing programs that utilize IL-2 for the selective expansion of T_{reg} cells, including Amgen, Coya Therapeutics, Nektar Therapeutics, Genentech, a member of The Roche Group, Merck & Co., Bristol Myers Squibb Company, and Celgene, a subsidiary of Bristol Myers Squibb Company. We are also aware of other companies with research or preclinical-stage programs in this area, including Synthorx, Moderna, and Xencor. We are also aware of other companies with PD-1 or CTLA-4 agonist programs for the treatment of autoimmune diseases and transplants, including Coya Therapeutics, AnaptysBio, Celgene, a subsidiary of Bristol Myers Squibb Company, and Eli Lilly & Company. Additionally, preclinical studies are underway to explore HCW9302's potential in targeting neurodegenerative diseases. Collaborations are ongoing with various institutions to better understand the biology of HCW9302 in both transplant models and alopecia. Several small and large pharmaceutical companies are currently working on low-dose IL-2 treatments for autoimmune diseases. Moreover, numerous mid- to large-sized biotech companies are seeking partnership opportunities to further explore the potential of HCW9302 in autoimmune diseases. HCW9302 is suitable for both in vivo subcutaneous injection strategies and T_{reg} cell therapy. In addition to alopecia areata, future plans include testing this molecule in transplant models and atopic dermatitis, expanding its potential therapeutic applications.

Numerous companies, including Kite Pharma, Novartis, Bristol Myers Squibb Company, Bluebird Bio, and Autolus Therapeutics, renowned for their CAR-T cell therapies in oncology, are expanding their research to explore the potential of CAR-T therapies in autoimmune diseases. For instance, Kite Pharma and Novartis are investigating CAR-T treatments for autoimmune conditions like multiple sclerosis (MS) and systemic lupus erythematosus. Similarly, Bluebird Bio is exploring CAR-T cell therapy for diseases such as sickle cell disease and beta-thalassemia, which involve autoimmune components. Autolus Therapeutics is also targeting both cancer and autoimmune diseases like multiple myeloma, acute lymphoblastic leukemia, multiple sclerosis, and systemic sclerosis with CAR-T therapies. This trend underscores a burgeoning interest in utilizing CAR-T cell therapy beyond oncology to tackle autoimmune disorders.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety, and convenience of our therapeutics, the ease of use and effectiveness of any complementary diagnostics and/or companion diagnostics, and price and levels of reimbursement.

We have a novel approach to the treatment of senescence-associated diseases. BPD presents unmet needs, particularly in addressing long-term lung damage and inflammation in premature infants. With growing pharma competition, treatments targeting senescent cell removal from the lungs are emerging as a promising approach to improve lung function and reduce BPD-related complications. Our recent research suggests that immunotherapeutic agent contain TGF-β Trap and IL-15 could be potential therapy for human BPD specifically targeting the mechanism that impairs lung development.

Our multispecific T-cell engager program, the Company's BIG-BiTE, consists of bi-specific and tri-specific T-cell engagers designed to recruit and activate endogenous T cells against tumor antigens, enhancing potency and selectivity compared to conventional bispecific formats. The oncology T-cell engager landscape is highly competitive, with established and emerging programs from biotech and pharmaceutical companies, including AbbVie, BMS, Sanofi, Lilly, Amgen's bispecifics, Genmab/Daiichi Sankyo's multispecific platforms, and numerous CD3-engager programs in development targeting both hematologic and solid tumors. Unlike some competitors whose constructs are limited to dual targeting or may exhibit on-target/off-tumor toxicities, HCW BIG-Bites' multispecific architecture is engineered for optimized synapse formation, improved tumor specificity, and reduced cytokine-release risk. We believe this differentiated design may enable broader tumor coverage, deeper responses, and an improved safety profile. The market opportunity for effective T-cell engagers is substantial, with expanding indications and significant unmet needs in both hematologic malignancies and solid tumors. Our clinical goals are to validate safety and robust anti-tumor activity in early-phase studies, advance select candidates toward development, and position HCW BIG-Bites for potential commercial success.

Several immune checkpoint inhibitors have been approved for the treatment of a limited number of cancer indications. There are several clinical studies underway for therapeutics to be used in combination with immune checkpoint inhibitors to broaden the number of indications and improve response rates. This market is dominated by a few companies, predominantly Merck & Co. and its product, Keytruda®. Recently, several pharmaceutical companies have been licensing various versions of PD-1 from China and other small biotech firms like Summit Therapeutics, Akeso Biopharma, further reflecting the growing interest in innovative immune-modulating therapies. The opportunity presented by the patent expiry of approved immune checkpoint inhibitors lies in the potential for increased competition and availability of generic or biosimilar versions of these drugs which may result in a loss of market

exclusivity and revenue as competition. It may also incentivize innovation and the development of new formulations, combinations, or delivery methods to maintain market share and competitive advantage. The following list summarizes key immune checkpoint inhibitors along the companies that own these drugs and their patent expiration dates:

Product	Associated Company	Key Patent Expiration Date
Pembrolizumab (Keytruda®)	Merck & Co	2028
Nivolumab (Opdivo)	Bristol Myers Squibb	2028
Atezolizumab (Tecentriq)	Genentech (Roche)	2024
Durvalumab (Imfinzi)	AstraZeneca	2034
Cemiplimab (Libtayo)	Regeneron Pharmaceuticals and Sanofi	2035
Avelumab (Bavencio)	Merck KGaA and Pfizer	2024

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Review and Approval Process

In the United States, biological products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (the "FDC Act"), and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act, with the exception that the section of the FDC Act which governs the approval of drugs via New Drug Applications ("NDAs"), does not apply to the approval of biologics. In contrast, biologics are approved for marketing under provisions of the Public Health Service Act ("PHSA") via Biologics License Applications ("BLAs"). However, the application process and requirements for approval of BLAs are very similar to those for NDAs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Biological product development for a new product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug or biologic for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including Good Laboratory Practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as tests of reproductive toxicity and carcinogenicity in animals, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with Good Clinical Practice ("GCP"), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. participants and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial participants. Imposition of a clinical hold may be full or partial. The study protocol and informed consent information for participants in clinical trials must also be submitted to an institutional review board ("IRB"), for approval before each trial begins. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Investigator-initiated trials may proceed under an IND held by a clinical investigator or academic sponsor rather than the Company. In such cases, the investigator is responsible for compliance with FDA requirements relating to informed consent, safety reporting, recordkeeping, and trial oversight.

Clinical trials to support BLAs for marketing approval are typically conducted in three sequential phases. In Phase 1, the initial introduction of the investigational drug or biologic into research participants, the product is tested to assess safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug or biologic exposure, and to obtain early evidence of a treatment effect if possible. A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the clinical trial was conducted in accordance with GCPs and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Phase 2 usually involves trials in a limited population to determine the effectiveness of the investigational biologic for a particular indication, determine optimal dose and regimen, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical effects and confirm efficacy and safety in a larger number of participants, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the investigational biologic and to provide adequate information for the labeling of the product.

In many cases, particularly for prevalent diseases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the biologic. In many other conditions, a single Phase 3 trial may be sufficient when in conjunction with confirmatory evidence. A single Phase 3 trial may also be sufficient, though it is less common, when the trial is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible Approval on the basis of a single trial may be subject to a requirement for additional post-approval studies.

These phases may overlap or be combined. For example, a Phase 1/2 clinical trial may contain both a dose-escalation stage and a dose-expansion stage, the latter of which may confirm tolerability at the recommended dose for expansion in future clinical trials (as in traditional Phase 1 clinical trials) and provide insight into the anti-tumor effects of the investigational therapy in selected subpopulation(s). Typically, during the development of oncology therapies, all subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for non-oncology therapies.

In addition, the manufacturer of an investigational biologic in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanding access to such investigational drug or biologic.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and also must develop additional information about the chemistry and physical characteristics of the investigational biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the investigational medicines do not undergo unacceptable deterioration over their shelf life.

After successful completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing and distribution of the product may begin in the United States. The BLA must include the results of all nonclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting a BLA is substantial. The submission of most BLAs is additionally subject to a substantial application user fee. Under an approved BLA, the applicant is also subject to an annual program fee. These fees typically increase annually. A BLA for a biologic that has been designated as an orphan drug is not subject to an application fee, unless the BLA includes an indication for other than a rare disease or condition. The FDA has 60 days from its receipt of a BLA to determine whether the application will be filed based on the FDA's determination that it is adequately organized and sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals to complete the review of BLAs. Most applications are classified as Standard Review products that are reviewed within ten months of the date the FDA files the BLA; applications classified as Priority Review are reviewed within six months of the date the FDA files the BLA. A BLA can be classified for Priority Review when the FDA determines the investigational biologic has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority reviews may be extended by the FDA for three months to consider information that the FDA deems to be a major amendment to the BLA.

The FDA may also refer applications for novel biologic products, as well as biologic products that present difficult questions of safety or efficacy, to be reviewed by an advisory committee—typically a panel that includes clinicians, statisticians and other experts—for review, evaluation, and a recommendation as to whether the BLA should be approved. The FDA is not bound by the recommendation of an advisory committee, but generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic product is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the BLA contains data that demonstrate that the biologic is safe, pure, potent, and effective, in the claimed indication.

After the FDA evaluates the BLA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies the FDA identified during its review of the BLA and may require substantial additional testing, or information, in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval.

An approval letter authorizes commercial marketing and distribution of the biologic with specific prescribing information for specific indications. As a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS"), to help ensure that the benefits of the biologic outweigh the potential risks to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use ("ETASU"). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy and may limit further marketing of the product based on the results of this post-approval testing or surveillance.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved BLA, including changes in indications, product labeling, manufacturing processes or facilities, require submission and FDA approval of a new BLA, or supplement to an approved BLA, before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing original BLAs.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs as well as clinical trial design.

Expedited Development and Review Programs

Fast Track Designation and Priority Review

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational biologic. For example, an investigational biologic is eligible for fast track designation if it is intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrates the potential to address unmet medical needs for the disease or condition. Fast track designation applies to both the product and the specific indication for which it is being studied.

The sponsor of an investigational biological product may request that the FDA designate the product candidate for a specific indication as a fast track product concurrent with, or after, the submission of the IND for the product candidate. FDA must determine if the product candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. For fast-track products, sponsors may have more frequent interactions with the applicable FDA review team during product development. With regard to a fast track investigational biologic, the FDA may initiate review of sections of a fast-track product's BLA on a rolling basis before the application is complete. This "rolling review" is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast-track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. Fast track designation may be withdrawn if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. The FDA determines at the time of filing the BLA whether the proposed product would be a significant improvement and therefore receive a priority review designation. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of original BLAs under its current review goals.

Breakthrough Therapy Designation

The FDA is also required to expedite the development and review of applications for approval of biologics that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the investigational biologic, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Under the breakthrough therapy program, the sponsor of a new product candidate may request that the FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. This designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the investigational biologic, including involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team, and taking other steps to design the clinical studies in an efficient manner.

Accelerated Approval

Accelerated approval may be granted for a product that is intended to treat a serious or life-threatening condition and that generally provides a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either 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. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large studies to demonstrate a clinical or survival benefit. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's 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. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. The FDA must also specify conditions of any required post-approval study, which may include milestones such as a target date of study completion. Sponsors must submit progress reports for required post-approval studies and any conditions required by the FDA not later than 180 days following approval and not less frequently than every 180 days thereafter until completion or termination of the study. The FDA can initiate an 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.

Regenerative Medicine Advanced Therapy Designation

The Regenerative Medicine Advanced Therapy ("RMAT") designation is an expedited program for the advancement and approval of regenerative medicine products that are intended to treat, modify, reverse, or cure a serious condition and where preliminary clinical evidence indicates the potential to address unmet medical needs for life-threatening diseases or conditions. Similar to Breakthrough Therapy designation, the RMAT allows companies developing regenerative medicine therapies to work earlier, more closely, and frequently with the FDA, and RMAT-designated products may be eligible for priority review and accelerated approval. Regenerative medicine therapies include cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the PHSA and Title 21 of the Code of Federal Regulations Part 1271. For product candidates that have received a RMAT designation, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, the PREA does not apply to any biological product for an indication for which orphan designation has been granted except that PREA will apply to an original BLA for a new active ingredient that is orphan-designated if the drug is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

The Best Pharmaceuticals for Children Act ("BPCA") provides a six-month extension of any non-patent exclusivity for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new biologic in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend biologics licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases within the United States.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the lot manufacturing history and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before allowing the manufacturer to release the lots for distribution. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. After approval of a BLA, biologics manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Post-Approval Requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet. Biologics may be marketed only for the approved indications and in a manner consistent with the approved labeling.

Adverse event reporting and submission of periodic reports are required following the FDA approval of a BLA. The FDA also may require post-marketing testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging, and labeling procedures must continue to conform to cGMP after approval. Biologics manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Biosimilars

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilars are licensed based on the FDA's findings of safety, purity and potency for a previously-FDA-licensed product called a reference product. There must be no differences in route of administration, dosage form, and strength, and there must be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency in at least one or more conditions of use for which the reference product is approved. Biosimilarity must be shown through analytical trials, animal trials, and a clinical trial or trials, unless the Secretary of U.S. Department of Health and Human Services ("HHS") waives a required element. A biosimilar product may also meet the higher hurdle of interchangeability such that it can be substituted for a reference product without the intervention of the prescribing health care provider if the sponsor can demonstrate that the biosimilar product can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. The first biosimilar was approved in 2015, and the first interchangeable product was approved in 2021. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to biosimilar product implementation, which are still being evaluated by the FDA.

A reference product is granted 12 years of exclusivity from the time of first licensure, or BLA approval, of the reference product, and during that 12 years of data exclusivity, no application for a biosimilar relying on the reference product can be submitted for four years. The first biologic product submitted under the biosimilar abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar is approved if a patent lawsuit is ongoing within the 42-month period.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry. These laws include anti-kickback, false claims, transparency and health information privacy laws, and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, (collectively, the "ACA"), amended the intent element of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal civil False Claims Act.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates and their subcontractors that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA.

Further, pursuant to the federal Physician Payments Sunshine Act, enacted as part of the ACA, the Centers for Medicare & Medicaid Services ("CMS"), issued a final rule that requires certain manufacturers of approved prescription drugs that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to collect and annually report information on certain payments or transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), physician assistants, certain types of advance practice nurses and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties.

We may also be subject to analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor. In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals.

Further, certain states require the posting of information relating to clinical studies and their outcomes. A growing number of states require the reporting of certain drug pricing information, including information pertaining to and justifying price increases and the price set for newly launched drugs, or to prohibit prescription drug price gouging. In addition, certain states require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Certain states and local jurisdictions also require the registration of pharmaceutical sales representatives. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Efforts to ensure that business arrangements with third parties comply with applicable state, federal, and foreign healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

Data Privacy and Security

Numerous state, federal and foreign laws govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. 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, HIPAA, as amended by HITECH, and their respective implementing regulations, imposes privacy, security and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal and administrative fines and penalties, and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health

information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

Even when HIPAA does not apply, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

In addition, certain state and non-U.S. laws, such as the General Data Protection Regulation (the "GDPR") govern the privacy and security of personal information, including health-related information, in certain circumstances. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Consumer Privacy Act ("CCPA"), which went into effect on January 1, 2020, imposes data privacy obligations for covered companies, including, but not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. On January 1, 2023, the California Privacy Rights Act ("CPRA"), which imposes additional obligations on covered companies and substantially modifies the CCPA, went into effect. The CCPA and CPRA provide for unlimited civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Virginia's Consumer Data Protection Act, which took effect on January 1, 2023, requires businesses subject to the legislation to conduct data protection assessments in certain circumstances and requires opt-in consent from consumers to acquire and process their sensitive personal information, which includes information revealing a consumer's physical and mental health diagnosis and genetic and biometric information that can identify a consumer. Colorado enacted the Colorado Privacy Act, and Connecticut enacted the Connecticut Data Privacy Act, each of which took effect on July 1, 2023, and Utah enacted the Consumer Privacy Act, which became effective on December 31, 2023, and each of these laws may increase the complexity, variation in requirements, restrictions, and potential legal risks, and could require increased compliance costs and changes in business practices and policies. Other states have also enacted, proposed, or are considering proposing, data privacy laws, which could further complicate compliance efforts, increase our potential liability and adversely affect our business. In Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of individuals within the European Economic Area ("EEA"). Further, recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of personal data from the EEA. For example, on July 16, 2020, the Court of Justice of the European Union invalidated the EU-U.S. Privacy Shield Framework (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.

Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Additionally, following the United Kingdom's withdrawal from the European Union and the EEA, companies have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend in part on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance, and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement

for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement, and requirements for substitution of generic products. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices, and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

United States Healthcare Reform

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. Several healthcare reform proposals culminated in the enactment of the Inflation Reduction Act ("IRA") in August 2022, which, among other things, requires 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 biologics that have been approved for at least 11 years (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. In addition, CMS has selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs, which will become effective in 2027. For 2028, CMS has selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or Part D drugs will be selected. Currently, 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. However, as a result of a statutory amendment enacted in July 2025, beginning with the 2028 negotiated price applicability year, a drug may be designated for more than one rare disease or condition and still be excluded from price negotiation, as long as the only approved indications are for such rare diseases or conditions. The IRA also imposes rebates on Medicare Part B and Part D 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 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 significant civil monetary penalties. These provisions have been and may continue to 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 biopharmaceutical industry and the pricing of prescription drug products.

The Trump Administration is pursuing policies to reduce regulations and expenditures across government including at HHS, which include the FDA and CMS, and related agencies. For example, on May 12, 2025, President Trump issued an Executive Order that, among other things, required HHS, within 30 days, to establish and communicate to drug manufacturers most favored nation ("MFN") price targets designed to bring drug prices for American patients in line with those in comparably developed nations. If significant progress towards MFN pricing is not achieved, the Executive Order requires HHS to propose a rulemaking to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to reduce prices of at least some drugs in the United States, if they are also sold in comparator countries. Even if a company does not market its drugs in such countries, the company could be indirectly affected if its drugs compete with drugs whose prices were reduced as a result of MFN pricing initiatives.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, the FDA issued a final rule in 2020 providing guidance for states to build and submit importation proposals for drugs from Canada, and the FDA authorized the first such plan in Florida in 2024, but implementation of Florida's plan has been extended until May 6, 2026. It is unclear how this program will be implemented, including which drugs will be chosen, and

whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA

We expect that additional state and federal healthcare reform measures could be adopted in the future.

Other Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing, and other promotional practices involving biological products as well as authorization, approval as well as post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application (a "CTA"), much like the IND prior to the commencement of human clinical trials.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing, and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

Regulation in the European Union

Drug and Biologic Development Process

The conduct of clinical trials is currently governed by the EU Clinical Trials Directive 2001/20/EC ("Clinical Trials Directive"), and will be replaced by the EU Clinical Trials Regulation (EU) No. 536/2014 ("Clinical Trials Regulation"), once the latter comes into effect. The Clinical Trials Regulation introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU. Currently it is not expected to come into force before December 2021.

Under the current regime, before a clinical trial can be initiated, it must be approved in each EU Member State where there is a site at which the trial is to be conducted. The approval must be obtained from two separate entities: the National Competent Authority ("NCA"), and one or more Ethics Committees. The NCA of the EU Member States in which the clinical trial will be conducted must authorize the conduct of the trial, and the independent Ethics Committee must grant a positive opinion in relation to the conduct of the clinical trial in the relevant EU Member State before the commencement of the trial. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be submitted to or approved by the relevant NCA and Ethics Committees. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the NCA and to the Ethics Committees of the EU Member State where they occur.

A more unified procedure will apply under the new Clinical Trials Regulation. A sponsor will be able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal. One national regulatory authority (the reporting EU Member State proposed by the applicant) will take the lead in validating and evaluating the application and the other regulatory authorities will have limited involvement. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned Member States. However, a concerned EU Member State may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial form being conducted in such Member State. The Clinical Trials Regulation also aims to streamline and simplify the rules on safety reporting and introduces enhanced transparency requirements such as mandatory submission of a summary of the clinical trial results to the EU Database.

Under both the current regime and the new Clinical Trials Regulation, national laws, regulations, and the applicable Good Clinical Practice and Good Laboratory Practice standards must also be respected during the conduct of the trials, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH"), guidelines on Good Clinical Practice ("GCP"), and the ethical principles that have their origin in the Declaration of Helsinki.

During the development of a medicinal product, the European Medicines Agency ("EMA"), and national regulators within the EU provide the opportunity for dialogue and guidance on the development program, usually in the form of scientific advice. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing, and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs.

Drug Marketing Authorization

In the European Union, medicinal products, including advanced therapy medicinal products ("ATMPs"), are subject to extensive pre- and post-market regulation by regulatory authorities at both the European Union and national levels. ATMPs comprise gene therapy products, somatic cell therapy products, and tissue engineered products, which are genes, cells, or tissues that have undergone substantial manipulation and that are administered to human beings in order to cure, diagnose or prevent diseases or regenerate, repair or replace a human tissue. Pursuant to the ATMP Regulation, the Committee on Advanced Therapies ("CAT"), is responsible in conjunction with the Committee for Medicinal Products for Human Use ("CHMP") for the evaluation of ATMPs. The CHMP and CAT are also responsible for providing guidelines on ATMPs. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, among other things, the preclinical studies required to characterize ATMPs; the manufacturing and control information that should be submitted in a marketing authorization application; and post-approval measures required to monitor patients and evaluate the long-term efficacy and potential adverse reactions of ATMPs. Although such guidelines are not legally binding, compliance with them is often necessary to gain and maintain approval for product candidates.

In the European Union and in Iceland, Norway, and Liechtenstein (together the EEA), after completion of all required clinical testing, medicinal products may only be placed on the market after a related Marketing Authorization ("MA"), has been granted. MAs can be obtained through, amongst others, a centralized procedure, which is compulsory for certain medicinal products such as ATMPs. The centralized procedure provides for the grant of a single MA by the European Commission ("EC"), that is valid for all 27 EU Member States and, after respective national implementing decisions, in the three additional EEA Member States (Iceland, Norway, and Liechtenstein). The centralized procedure is compulsory for certain medicinal products, including medicinal products derived from biotechnological processes, orphan medicinal products, ATMPs, and products with a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases, and viral diseases. It is optional for medicinal products containing a new active substance not yet authorized in the EEA before May 20, 2004, that constitute significant therapeutic, scientific or technical innovations, or for which the grant of a MA through the centralized procedure would be in the interest of public health at the EU level. The timeframe for the evaluation of an application under the centralized procedure is 210 days, excluding clock stops. Typically, the overall process takes a year or more unless the application is eligible for an accelerated assessment.

All new marketing authorization applications must include a Risk Management Plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. RMPs and Periodic Safety Update Reports ("PSURs") are routinely available to third parties requesting access, subject to limited redactions.

Additionally, the holder of a marketing authorization for an ATMP must put in place and maintain a system to ensure that each individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport, and delivery to the relevant healthcare institution where the product is used.

MAs have an initial duration of five years. The authorization may subsequently be renewed for an unlimited period unless the European Commission or the national competent authority grants only a five-year renewal.

Data and Market Exclusivity

As in the United States, the European Union also provides opportunities for market and/or data exclusivity. For example, New Chemical Entities ("NCE"), approved in the European Union generally qualify for eight years of data exclusivity and ten years of market exclusivity. Data exclusivity is the period during which another applicant cannot rely on the MA holder's pharmacological, toxicological, and clinical data in support of another MA for the purposes of submitting an application, obtaining marketing

authorization or placing the product on the market. But after eight years, a generic or biosimilar product application may be submitted and generic companies may rely on the MA holder's data.

However, even if a generic or biosimilar product is authorized it cannot be placed on the market in the European Union until the expiration of the 10-year market exclusivity period. An additional non-cumulative one-year period of marketing exclusivity is possible if during the data exclusivity period (the first eight years of the 10‑year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

Products may not be granted data exclusivity since there is no guarantee that a product will be considered by the European Union's regulatory authorities to include an NCE. Even if a compound is considered to be an NCE and the MA applicant is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the medicinal product if such a company can complete a full marketing authorization application with their own complete database of pharmaceutical tests, preclinical studies, and clinical trials and obtain MA for its product.

Post-Approval Regulation

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission, and/or the competent regulatory authorities of the EU Member States. This oversight applies both before and after grant of manufacturing licenses and marketing authorizations. It includes control of compliance with EU good manufacturing practices rules, manufacturing authorizations, pharmacovigilance rules, and requirements governing advertising, promotion, sale, and distribution, recordkeeping, importing, and exporting of medicinal products.

Failure by us or by any of our third-party partners, including suppliers, manufacturers, and distributors to comply with EU laws and the related national laws of individual EU Member States governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products, and marketing of such products, both before and after grant of marketing authorization, statutory health insurance, bribery and anti-corruption, or other applicable regulatory requirements may result in administrative, civil, or criminal penalties.

These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties.

The holder of a marketing authorization for a medicinal product must also comply with EU pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. These pharmacovigilance rules can impose on holders of MAs the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed medicinal products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming and expensive and could impact our profitability. MA holders must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of PSURs in relation to medicinal products for which they hold MAs. The EMA reviews PSURs for medicinal products authorized through the centralized procedure. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing MA for the product be suspended, withdrawn or varied. The agency can advise that the MA holder be obliged to conduct post-authorization Phase IV safety studies. If the EC agrees with the opinion, it can adopt a decision varying the existing MA. Failure by the marketing authorization holder to fulfill the obligations for which the EC's decision provides can undermine the ongoing validity of the MA.

More generally, non-compliance with pharmacovigilance obligations can lead to the variation, suspension or withdrawal of the MA for the product or imposition of financial penalties or other enforcement measures.

Sales and Marketing Regulations

The advertising and promotion of our products is also subject to EU laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other national legislation of individual EU Member States may apply to the advertising and promotion of medicinal products and may differ from one country to another. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC") as approved by the competent regulatory authorities.

The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription-only medicines is also prohibited in the European Union. Violations of the rules governing the promotion of medicinal products in the European Union could be penalized by administrative measures, fines, and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on its promotional activities with healthcare professionals.

Anti-Corruption Legislation

In the EU, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at the EU level and in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Other Markets

Following the UK's formal departure from the EU on January 31, 2020, the UK entered a transition period to last until December 31, 2020, during which time EU medicines laws will remain applicable to the UK. After the transition period, however, changes may be forthcoming as the terms of the UK and EU's future relationship are negotiated. The UK Medicines and Healthcare Products Regulatory Agency has proposed that, subject to being approved by the UK Parliament, a centralized MA will automatically convert into a UK MA. However, the draft of the "Medicines and Medical Devices Bill 2019-21" currently discussed in the UK House of Lords does not contain such a provision, but would only authorize the UK government to become active in the field of legislation concerning market authorizations in relation to human medicines.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Human Capital Management

Our approach to human capital resource management starts with our mission to discover and develop novel immunotherapies to lengthen health span and improve quality of life for people suffering from diseases promoted by low-grade chronic inflammation. Our industry exists in a complex regulatory environment. The unique demands of our industry, together with the challenges of running an enterprise focused on the discovery, development, manufacture and commercialization of innovative medicines, require talent that is highly educated and/or has significant industry experience. Additionally, for certain key functions, we require specific scientific expertise to oversee and conduct R&D activities and the complex manufacturing requirements for biopharmaceutical products.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. We recognize that attracting, motivating and retaining talent at all levels is vital to our continued success. Our employees are a significant asset and we aim to create an equitable, inclusive and empowering environment in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. By focusing on employee retention and engagement, we also improve our ability to support our clinical trials, our pipeline, our platform technologies, business and operations, and also protect the long-term interests of our stockholders. Our success also depends on our ability to attract, engage and retain a diverse group of employees.

Our base pay program aims to compensate management and staff members relative to the value of the contributions of their role, which takes into account the skills, knowledge and abilities required to perform each position, as well as the experience brought to the job. We also provide annual incentive programs to reward our management team and staff members in alignment with achievement of Company-wide goals that are established annually and designed to drive aspects of our strategic priorities that support and advance our strategy across our Company. Our management team and staff members are eligible for the grant of equity awards under our long-term incentive program that are designed to align the experience of these staff with that of our stockholders. All management team and staff members also participate in a regular performance measurement process that aligns pay to performance and through which they receive performance and development feedback.

Our benefit programs are also generally broad-based, promote health and overall well-being and emphasize saving for retirement. All management team and regular staff members are eligible to participate in the same core health and welfare and retirement savings plans. Other employee benefits include medical plans, health savings plan, dental plans, vacation and sick-pay plans, employee assistance programs, life and accident insurance and short and long-term disability benefits.

Our Compensation Committee provides oversight of our compensation plans, policies and programs.

As of December 31, 2025, we had 35 full-time employees, 25 of whom were engaged in research, clinical development, manufacturing, and quality control activities, and 10 of whom were engaged in administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate Information

We are located in Miramar, Florida and were incorporated in the state of Delaware in April 2018.

Available Information

We make available, free of charge, on or through our website (http://www.hcwbiologics.com), our annual reports on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K, and amendments to those reports, filed or furnished pursuant to Sections 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after they have been electronically filed with, or furnished to, the SEC. References to website addresses in this report are intended to be inactive textual references only, and none of the information contained on our website is part of this report or incorporated in this report by reference.

Item 1A Risk Factors.

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

Summary of Key Risk Factors

- We have incurred significant 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 December 31, 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.
- For the year ended December 31, 2025, the Company identified a material weakness related to proper assessment of whether impairment occurred for its long-lived assets. As a result the Company was at risk of a material misstatement in its financial statements by failing to recognize an impairment of $1.5 million for an impairment of the Company's building, which could have resulted in overstating the value of long-term assets by $1.5 million. The Company will implement a remediation of this material weakness and 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 $7.5 million of outstanding legal fees included in the Company's outstanding trade payables. The terms of the settlement included $2.0 million of cash settlement payments, consisting of a $500,000 payment made on or about December 31, 2025 and a $1.5 million payment to be made within one business day of receipt of payment of net proceeds of $3.1 million from the upfront cash license fee payable by Beijing Trimmune Biotech Co., Ltd. or its affiliates. As of March 20, 2026, these terms were amended. The parties agreed that the Company would pay $750,000 immediately, with the remaining $750,000 due upon the earlier of completing a financing in excess of $4.0 million in gross proceeds or August 31, 2026. 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 material negative impact on our business and operations.
- After receiving written notice from the Nasdaq Listing Qualifications Staff (the "Staff") that, as of June 30, 2025, the Company was not in compliance with Nasdaq Listing Rule 5550(b)(1) (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. On February 26, 2026, the Nasdaq Hearings Panel found that the Company regained compliance with all continued listing rules of The Nasdaq Capital Market. Pursuant to Listing Rule 5815(d)(4)(B), the Company will be subject to a Mandatory Panel Monitor per the January 7, 2026 letter. If, within that one-year monitoring period, the Staff again finds the Company to be 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. On March 26, 2026, the Company received a written notice from the Staff which notified the Company that, for the 30 consecutive business days, the Company's security did not maintain a minimum bid price of $1 per share, in

accordance with Nasdaq Listing Rule 5810(c)(3)(A) ("Bid Price Rule"). Due to the fact that the Company effected a 1-for-40 reverse stock split on April 11, 2025, the Company was not afforded a 180-calendar day period to demonstrate compliance. The Company plans to request an appeal of this determination in a timely manner.

- 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.

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 incurred legal fees of nearly $28.4 million for its own defense and the defense of Dr. Wong. For the years ended December 31, 2024 and 2025, we reported a net loss of $30.0 million and $8.0 million, before equity dividend to investor, respectively. These losses are inclusive of nonoperating expenses of $1.3 million for the year ended December 31, 2024. As of December 31, 2025, we had $2.0 million in cash and cash equivalents reported in the audited balance sheet included elsewhere in this Annual Report. From inception to December 31, 2025, we incurred cumulative net losses of $105.8 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 Wugen License 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 December 31, 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 elsewhere in this Annual 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 current disputes 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 our Wugen License and the clinical material supply agreement. 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.

There is substantial doubt about our ability to continue as a going concern. 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 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 December 31, 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 December 31, 2025, we had cash and cash equivalents of $2.0 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 included elsewhere in this Annual 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, royalty financing or debt 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.

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

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

We cannot assure you that the measures we have taken to date to strengthen internal controls over financial reporting, or any measures we may take in the future, will be sufficient to avoid potential future material weaknesses.

As of December 31, 2025, management identified a material weakness related to management's assessment of long-lived assets for impairment. As a result the Company was at risk of a material misstatement in its financial statements by failing to recognize an impairment of $1.5 million for an impairment of the Company's building, which could have resulted in overstating the value of long-lived assets by $1.5 million.

Material weaknesses in the Company's internal controls over financial reporting were identified in previous reporting periods not presented in the Annual Report. Upon detecting material weaknesses, the Board of Directors and management implemented a remediation plan to strengthen internal controls, resulting in remediation of previously identified material weaknesses. As we continue to evaluate and work to improve our internal control over financial reporting, we may take additional measures to address control deficiencies or determine to modify remediation measures. We cannot assure you that the measures we have taken to date, and may take in the future, will be sufficient to remediate the control deficiencies that led to the material weakness in internal control over financial reporting or that we will prevent or avoid potential future material weaknesses. Effective internal controls are necessary for us to provide reliable financial reports. These remediation measures may be time consuming and costly and there is no assurance that these initiatives will ultimately have the intended effects.

We will require additional funding in order to complete development of our product candidates and commercialize our products, if approved. However, this additional financing may not be available on acceptable terms, or at all. If we are unable 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 December 31, 2025, we held $2.0 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 included elsewhere in this Annual Report. We expect our expenses to increase in connections with our ongoing clinical development activities, particularly as we continue to initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding for our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to:

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

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

We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our technologies or product candidates, we will seek to finance our future cash needs through equity offerings, royalty-based or debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

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

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

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq, a failure of which could result in a delisting of our securities.

On June 26, 2025, we received formal notice from the Nasdaq Listing Qualifications Staff (the "Staff") that we were in compliance with the Equity Rule for continued listing of our securities on the Nasdaq Capital Market tier. We were also notified that we will remain subject to a "Panel Monitor," as that term is defined in Nasdaq Listing Rule 5815(d)(4)(B), for a period of one year from the date of the Nasdaq notice, through June 23, 2026. If, during the term of the Panel Monitor, we do not continue to remain in compliance with the Equity Rule, we will not have the opportunity to submit a compliance plan for review by the Staff and will instead need to 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 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 remained subject to the Panel's decision letter to maintain compliance with all listing rules for continued listing through February 16, 2026. On February 26, 2026, the Nasdaq Hearings Panel found that the Company had regained compliance with all continued listing rules of The Nasdaq Capital Market. Pursuant to Listing Rule 5815(d)(4)(B), the Company will be subject to a Mandatory Panel Monitor per the January 7, 2026 letter. 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. On March 26, 2026, the Company received a written notice from the Staff which notified the Company that, for the 30 consecutive business days, the Company's security did not maintain a minimum bid price of $1 per share, in accordance with Nasdaq Listing Rule 5810(c)(3)(A) ("Bid Price Rule"). Due to the fact that the Company effected a 1-for-40 reverse stock split on April 11, 2025, the Company was not afforded a 180-calendar day period to demonstrate compliance. The Company plans to request an appeal of this determination in a timely manner.

Nasdaq also recently proposed a rule that, if approved, would require companies to maintain a minimum market value of listed securities ("MVLS") of at least $5 million. If we are unable to satisfy these standards, or if Nasdaq's proposed rule is approved and we fail to maintain a MVLS of at least $5 million for 30 consecutive trading days, we could be subject to delisting, which would have a negative effect on the price of our Common Stock, impair your ability to sell or purchase our Common Stock or Warrants when you wish to do so, and potentially cause you to lose the value of your investment in us. In the event of a delisting, we would expect to take actions to restore our compliance with the listing standards, but we can provide no assurance that any action we take to restore our compliance would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below the minimum bid price requirement, or prevent future noncompliance with the listing requirements.

If we are delisted from Nasdaq, our Common Stock may be eligible for trading on an over-the-counter market. If we are not able to obtain a listing on another stock exchange or quotation service for our Common Stock, it may be extremely difficult or impractical for stockholders to sell their shares of Common Stock. Moreover, if we are delisted from Nasdaq, but obtain a substitute listing for our Common Stock, it will likely be on a market with less liquidity, and therefore experience potentially more price volatility than experienced on Nasdaq. Stockholders may not be able to sell their shares of Common Stock on any such substitute market in the quantities, at the times, or at the prices that could potentially be available on a more liquid trading market. As a result of these factors, if our Common Stock is delisted from Nasdaq, the value and liquidity of our Common Stock would likely be significantly adversely affected. A delisting of our Common Stock from Nasdaq could also adversely affect our ability to obtain financing for our operations and/or result in a loss of confidence by investors, employees and/or business partners.

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 in the accompanying audited financial statements as of December 31, 2025 are $13.1 million of obligations included in accounts payable that represent amounts past due. Past due amounts include $6.2 million due for legal fees incurred as a result of mounting a defense for the Company and our Founder and Chief Executive Officer in a long-running arbitration proceeding that was settled on July 13, 2024 and dismissed at the end of 2024. In January 2025, we received a $2.0 million insurance payment which was used to offset obligations for legal fees for our Founder and Chief Executive Officer. Also included in outstanding obligations is $4.3 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") and past due amounts owed for contract development and manufacturing services. As of December 31, 2025, certain subcontractors had filed mechanics liens related to unpaid invoices issued in connection with the facility. 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 elected to file counterclaims and cross-claims as part of their responses to the BE&K Complaint. On August 8, 2025, B&I Contractors, Inc. ("B&I"), 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 responded to the BE&K and Fisk Complaints and cross-claims and filed a timely response to the B&I MSJ. The cases have been consolidated. On February 19, 2026, a stipulation was submitted to the Court for a settlement and release agreement between the Company and B&I calling for payment of a total of $860,000 in installments in settlement of amounts owed and an allowance for interest and other fees the last installment of which is payable on or before May 31, 2026. The Company has continued to pursue financing alternatives to provide the funding needed to come current in past amounts due and complete the construction and renovation of the Property.

Risks Related to our Business

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

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

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

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

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

The success of our business development efforts, including license agreements, depends on our ability to realize and anticipate the 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 December 31, 2025, we had 35 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 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 disease or condition that addresses an unmet medical need 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. 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.

Further, the FDA is authorized to require a post-approval study to be underway prior to approval or within a specified time period following approval. The FDA must also specify conditions of any required post-approval study, which may include milestones such as a target date of study completion. Applicants must submit progress reports for required post-approval studies and any conditions required by the FDA not later than 180 days following approval and not less frequently than every 180 days thereafter until completion or termination of the study. The FDA can initiate an 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.

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

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

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

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

In addition, if we have any product candidate approved, our product labeling, advertising, and promotion will be subject to regulatory requirements and continuing regulatory review. In the United States, the FDA and the Federal Trade Commission ("FTC"), strictly regulate the promotional claims that may be made about pharmaceutical products to ensure that any claims about such products are consistent with regulatory approvals, not misleading or false in any particular 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. 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, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations, and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. 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 claims involving healthcare items or services reimbursed by non-governmental third-party payors, 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, disruptions at FDA or other government agencies, including statutory, legislative, and policy changes, reduced funding of government agencies, and government shutdowns could also impact the ability of regulatory authorities and government agencies to function normally and support our operations. For example, starting in January 2025, the U.S. government has reduced the number of federal employees, including at FDA, by establishing voluntary termination programs, by position eliminations or by involuntary terminations. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. In addition, the U.S. federal government has shut down repeatedly since 1980, including for a period of 43 days in 2025. 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, requires 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. In addition, CMS has selected and announced the negotiated maximum fair price for 15 additional Medicare Part D drugs, which will become effective in 2027. For 2028, CMS selected an additional 15 drugs, comprised of drugs covered under Medicare Part D and, for the first time, drugs payable under Medicare Part B. For 2029 and subsequent years, 20 Part B or Part D drugs will be selected. Currently, 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. However, as a result of a statutory amendment enacted in July 2025, beginning with the 2028 negotiated price applicability year, a drug may be designated for more than one rare disease or condition and still be excluded from price negotiation, as long as the only approved indications are for such rare diseases or conditions. 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 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.

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, which include the FDA and CMS, and related agencies. For example, on May 12, 2025, President Trump issued an Executive Order that, among other things, required HHS, within 30 days, to establish and communicate to drug manufacturers most favored nation, or MFN, price targets designed to bring drug prices for American patients in line with those in comparably developed nations. If significant progress towards MFN pricing is not achieved, the Executive Order requires HHS to propose a rulemaking to implement MFN pricing. Recently, on December 23, 2025, CMS issued proposed regulations to establish, under the Center for Medicare and Medicaid Innovation, two mandatory MFN demonstration models under Medicare Parts B and D, respectively. If these rules or other MFN pricing rules are finalized, they are likely to reduce prices of at least some drugs in the United States, if they are also sold in comparator countries. Even if we do not market drugs in such countries, we will be indirectly affected if our drugs competed with drugs whose prices were reduced as a result of MFN pricing initiatives.

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 issued 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 May 2026. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drug products that we successfully commercialize or put pressure on our product pricing.

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

Risks Related to Commercialization of Our Product Candidates

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

Pharmaceutical manufacturers are also subject to extensive post-marketing oversight by the FDA and comparable regulatory authorities in the jurisdictions where the product is marketed, which include periodic unannounced and announced inspections by the FDA to assess compliance with cGMP requirements. If an FDA inspection of a manufacturer's facilities reveals conditions that the FDA determines not to comply with applicable regulatory requirements, the FDA may issue observations through a Notice of Inspectional Observations, commonly referred to as a "Form FDA 483". If observations in the Form FDA 483 are not addressed in a timely manner and to the FDA's satisfaction, the FDA may issue a warning letter or pursue other forms of enforcement action. Any failure by one of our contract manufacturers to comply with cGMP or to provide adequate and timely corrective actions in response to deficiencies identified in a regulatory inspection could result in enforcement action that could lead to a shortage of products and harm our business, including withdrawal of approvals previously granted, seizure, injunction or other civil or criminal penalties. The failure of a manufacturer to address any concerns raised by the FDA or foreign regulators 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 proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

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

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

In addition, indemnity provisions in various agreements and our corporate documents potentially expose us to substantial liability for intellectual property infringement and other claims. In the ordinary course of business, we enter into agreements that may include indemnification provisions under which we agree to indemnify them for losses suffered or incurred as a result of claims of intellectual property infringement or other liabilities relating to or arising from our clinical trials, breach of warranties or other contractual obligations. In some cases, the indemnification will continue after the termination of the applicable agreement. In addition, in accordance with our bylaws and pursuant to indemnification agreements entered into with directors, officers and certain employees, we have indemnification obligations for claims brought against these persons arising out of certain events or occurrences while they are serving at our request in such capacities. For example, our founder and chief executive officer is subject to a claim from a former employer. We agreed to advance certain defense costs and other expenses, subject to an undertaking to repay us such amounts if, and to the extent that, it is ultimately determined that he is not entitled to indemnification, 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 are currently facing in our legal proceedings with Altor/NantCell, 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. Additionally, we may implement, and we continue to evaluate, artificial intelligence-based information technology systems in certain aspects of our operations. The use of such systems presents risks, including data security, privacy, regulatory compliance risks, and the potential for system errors or misuse, which could adversely affect our business, financial condition, or results of operations.

Our potential use of new and evolving technologies, such as artificial intelligence, may present risks and challenges that can impact our business, including by posing cybersecurity and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use and integrate artificial intelligence (AI) into our business processes through implementation of AI and through the adoption of commercially available tools. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, artificial intelligence hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, environmental harms, and other harms may flow from any use or deployment of AI technologies. If we enable or use solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability.

A growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI, and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU's Artificial Intelligence Act ("AI Act") is now in effect and is expected to undergo amendments, as introduced in the EU's November 2025 Digital Omnibus. As enacted, the AI Act imposes significant obligations on providers and deployers of AI systems, and encourages providers and deployers of AI systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines.

In the U.S., the AI regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including regarding deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which

may be litigated in state and federal courts. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued guidance on the use of AI in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems governed by these laws or regulations, we will need to meet various standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain such systems to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The use of certain AI technologies can also give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of artificial intelligence tools.

Our vendors may in turn incorporate AI tools into their products or services, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. The integration of AI systems, by us or by our vendors, may increase cybersecurity risk. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Risks Related to Ownership of Our Common Stock

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

The market price of our Common Stock may be highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. The market price of our Common Stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors described in this "Risk Factors" section and elsewhere in this Annual Report.

On June 26, 2025, we received formal notice from Nasdaq that we were in compliance with the Equity Rule for continued listing of our securities on the Nasdaq Capital Market tier. We were also notified that we will remain subject to a "Panel Monitor," as that term is defined in Nasdaq Listing Rule 5815(d)(4)(B), for a period of one year from the date of the Nasdaq notice, through June 23, 2026. If, during the term of the Panel Monitor, we do not continue to remain in compliance with the Equity Rule, we will not be provided with the opportunity to submit a compliance plan for review by the Staff and must instead request a hearing before Nasdaq 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. On February 26, 2026, the Nasdaq Hearings Panel found that the Company regained compliance with all continued listing rules of The Nasdaq Capital Market. Pursuant to Listing Rule 5815(d)(4)(B), the Company will be subject to a Mandatory Panel Monitor per the January 7, 2026 letter. 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. On March 26, 2026, the Company received a written notice from the Staff which notified the Company that, for the 30 consecutive business days, the Company's security did not maintain a minimum bid price of $1 per share, in accordance with Nasdaq Listing Rule 5810(c)(3)(A) ("Bid Price Rule"). Due to the fact that the Company effected a 1-for-40 reverse stock split on April 11, 2025, the Company was not afforded a 180-calendar day period to demonstrate compliance. The Company plans to request an appeal of this determination in a timely manner.

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

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

As of December 31, 2025, our executive officers, directors and their respective affiliates beneficially owned approximately 17.7% of our outstanding voting stock (excluding any stock options exercisable within 60 days of such date held by such persons and shares of Common Stock held in abeyance on behalf of a third-party investor due to ownership blockers). These stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval, in matters where they are eligible to vote. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Common Stock that you may feel are in your best interest as one of our stockholders.

We are an emerging growth company as well as a "smaller reporting company", and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies or smaller reporting companies could make our Common Stock less attractive to investors.

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

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

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

- the last day of the fiscal year in which we have more than $1.235 billion in annual revenue;
- the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- December 31, 2026.

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 end of that year's second fiscal quarter, 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 end of that year's second fiscal quarter.

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management 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.

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

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

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

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

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

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

other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder, or maintain profitability.

General Risk Factors

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

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

Our money market or other investments or bank deposits may be subject to market, interest and credit risk that may reduce in value.

The value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our money market or other investments and instability in the global financial markets that reduces the liquidity of securities included in our portfolio. In addition, we are aware of the closure of Silicon Valley Bank and appointment of the Federal Deposit Insurance Corporation as receiver. Furthermore, a possible recession, rising inflation, or a future pandemic may continue to adversely affect the financial markets in some or all countries worldwide. Each of these events may cause us to record charges to reduce the carrying value of our money market or other investments or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio's overall risk profile, the value of our investments may nevertheless decline.

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

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

Item 1B Unresolved Staff Comments.

None.

Item 1C Cybersecurity.

Risk Management

We recognize the importance of assessing, identifying, and managing material risks associated with cybersecurity threats, as such term is defined in Item 106(a) of Regulation S-K. These risks include, among other things, operational risks; intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy or security laws and other litigation and legal risk; and reputational risks.

We also maintain an incident response plan to coordinate the activities we take to protect against, detect, respond to and remediate cybersecurity incidents, as such term is defined in Item 106(a) of Regulation S-K, as well as to comply with potentially applicable legal obligations and mitigate brand and reputational damage. As of the reporting date, the Company updated and published other cybersecurity policies and procedures for access control, including remote access; business continuity; information security related to governance, managing and planning; risk management; use of AI applications; and vendor risk and management, which leverages and coordinates with procedures in place for the accounting payable process.

In the year ended December 31, 2025, the Company undertook a data migration to move our data storage and shared files to a SharePoint-based data storage system, which offers a secure, cloud-based document management system that enhances collaboration, organization, and security through centralized storage. Key advantages for cybersecurity include facilitating efficient workflows and remote work. Recent security issues, such as the active exploitation of critical vulnerabilities, have highlighted the risks of on-premises servers, particularly as it relates to ransomware and remote exploitation. The data migration project was a project undertaken to improve our information systems, as such the term is defined in Item 106(a) of Regulation S-K is scheduled on 2024 IT plan. We anticipate that our data migration project will be completed in Q2 2026.

Our approach includes, among other things:

- conducting limited, point-in-time network and endpoint security controls;
- requiring regular cybersecurity training programs for employees, management and directors;
- comparing our processes to standards set by the National Institute of Standards and Technology ("NIST");
- leveraging the NIST incident handling framework to help us identify, protect, detect, respond, and recover when there is an actual or potential cybersecurity incident;
- conducting firm-wide annual training exercises for employees and contractors with access to the Company's system to raise awareness to possible threats such as phishing email simulations;
- maintaining copies of production data in two separate locations;
- running a backup for our data on a daily basis and these files are held for several months;
- testing the backup and recovery systems;
- employing a multi-factor authorization in order to mitigate risks of compromising email accounts; and
- holding an insurance policy to mitigate risks for cybersecurity incidents.

Our process for identifying and assessing material risks from cybersecurity threats operates alongside our broader overall risk assessment process, covering all Company risks. As part of this process, appropriate our personnel collaborate with subject matter specialists, as necessary, to gather insights for identifying and assessing material cybersecurity threat risks, their severity, and potential mitigation. A key element of managing cybersecurity risk is the ongoing assessment and testing of our processes and practices through auditing, assessments, drills and other exercises focused on evaluating the sufficiency and effectiveness of our risk mitigation. We engage third parties to perform assessments of our cybersecurity measures, including information security maturity assessments and independent reviews of our information security control environment and operating effectiveness. Certain results of such assessments and reviews are reported by the key members of management, the and the board of directors, as appropriate.

Our policy is to conduct an annual cybersecurity assessment and make adjustments to our cybersecurity processes and practices as necessary based on the information provided by the third-party assessments and reviews. Upon completion of the data migration project, the Company will make further improvements to improve our controls, particularly for logging and monitoring and vulnerability assessments. To strengthen our cybersecurity posture, we intend to implement a Security Information and Event Management (SIEM) solution that will aggregate and analyze logs from all critical infrastructure, including network, cloud, and endpoint security platforms. We also intend to expand our vulnerability management process to ensure regular assessments of public-facing systems and network devices.

For the year ended December 31, 2025, we are not aware of any cybersecurity incidents that have materially affected or are reasonably likely to materially affect the Company, including our business strategy, results of operations, or financial condition. We describe whether and how risks from identified cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition, under the heading "Risks Related to Data Privacy and Cybersecurity" included as part of our risk factor disclosures at Item 1A of this Annual Report, which disclosures are incorporated by reference herein.

To date, we have not experienced a material cybersecurity incident and the expenses we have incurred from cybersecurity incidents were immaterial. This includes penalties and settlements, of which there were none.

Governance

Cybersecurity is an important part of our risk management processes and an area of increasing focus for our Board and management. Our Audit Committee of our Board of Directors is responsible for the oversight of risks from cybersecurity threats. At least annually, the Audit Committee receives an overview from management of our cybersecurity threat risk management and strategy processes covering topics such as data security posture, results from third-party assessments, progress towards pre-determined risk-mitigation-related goals, our incident response plan, and material cybersecurity threat risks or incidents and developments, as well as the steps management has taken to respond to such risks. In such sessions, the Audit Committee generally receives materials including a cybersecurity scorecard and other materials indicating current and emerging cybersecurity threat risks, and describing our ability to mitigate those risks, and discusses such matters with our Operations Administrator, who is supported by Compass MSP, a leading provider of technology managed services. Members of the Audit Committee are also encouraged to regularly engage in ad hoc conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs. Material cybersecurity threat risks may also be considered during separate Board meeting discussions.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Chief Executive Officer, who has founded and led several biotech companies for over 20 years, all of which have implemented systems and processes to protect sensitive clinical data and patient information. He is supported by our IT consultant, Compass MSP, a leading provider of technology managed services. Our consultant conducts a vulnerability assessment annually and tests our backup and recovery systems frequently.

These members of management are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including the operation of our incident response plan. If a cybersecurity incident is determined to be a material cybersecurity incident, our incident response plan and cybersecurity disclosure controls and procedures define the process to disclose such a material cybersecurity incident.

Item 2 Properties.

On August 15, 2022, we purchased a 36,000 square foot building located in Miramar, Florida, as our new headquarters. We intend to use the new facility for research and development laboratories and facilities for manufacturing, as well as offices for our employees, including clinical development, research, development, quality control, quality assurance, regulatory affairs, and administration. We have been in the process of refitting the building for our purposes. The property is under construction, and it is uncertain when the project will be completed. Until such time as the project is completed, we continue to occupy approximately 12,250 square feet of space in Miramar, Florida and currently lease this space under the terms of a lease that commenced on March 1, 2026 and terminates on February 28, 2027. Given our long relationship with the landlord of our leased location, we believe we will be able to negotiate an extension our lease, if required. We believe our existing location is sufficient to meet our current and near-term needs.

Item 3 Legal Proceedings.

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

Settlement and General Release: Arbitration

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

On July 18, 2024, we announced that , as of July 13, 2024, we and Dr. Hing C. Wong, our Founder and Chief Executive Officer, entered into a confidential Settlement Agreement and Release (the "Settlement Agreement") with Altor BioScience, LLC ("Altor"), NantCell, Inc. ("NantCell"), and ImmunityBio, Inc. (the parent of Altor and NantCell, together with Altor and NantCell, "ImmunityBio"), to resolve the previously disclosed Arbitration before JAMS brought by Altor and NantCell (the "Arbitration") as well as a complaint Altor filed against the Company in the Chancery Court of the State of Delaware for the contribution of legal fees and expenses advanced to Dr. Wong ("Complaint"). See Part I, Item 3. – "Legal Proceedings" for further information. The Settlement Agreement includes mutual general releases by and among the parties thereto. No party is required to make any monetary payments to any other party or person under the Settlement Agreement and each party will bear its own expenses incurred in connection with the matter. In accordance with the provisions of the Settlement Agreement, upon completion of remedial procedures, the parties stipulated that the Arbitration and Complaint should be dismissed. The Arbitration and related Complaint were dismissed with prejudice on or about December 24, 2024.

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

The Company retains ownership and control of the TOBI™ platform and TOBI-based molecules, with no restrictions under the Settlement Agreement on our ability to use the TOBI™ platform for protein-fusion molecules for non-oncology indications. We have rights to pursue oncology indications, in particular using HCW9302, HCW9206 and HCW9201. Further, the Company retains ownership of the Wugen license and shares of Wugen common stock transferred to the Company as the upfront licensing fee from Wugen for granting the Wugen license. For our molecule, HCW9218, we maintain the exclusive rights for clinical development and use of HCW9218 in the treatment of all non-oncological diseases. We retain ownership of our lead molecule, HCW9302, which expands T_{reg} cells and is designed to treat autoimmune diseases and other proinflammatory diseases, including cancer, and the ownership of HCW9206, a preclinical molecule which we are developing for the treatment of cancer and other age-related diseases. The Company agreed to provide ImmunityBio with a right of first refusal to enter a licensing agreement for oncology indications for HCW9206. We have no restrictions on the development of HCW9206 for our own clinical development activities, including oncology indications. Under the terms of the Settlement Agreement, ImmunityBio will own the cell line and supply for HCW9218, and the parties agreed that within six months from the date of the Settlement Agreement they will enter into a supply agreement providing the Company with a continuing supply of HCW9218 molecules. The Company also retains *in vivo* rights to HCW9201, a combination of IL-12, IL-15, and IL-18 in a single protein complex which is designed to stimulate activation and proliferation signals in human NK cells. The Company retains ownership of the cell lines for HCW9302, HCW9206 and HCW9201, and thus will retain independent control over manufacturing and supply for these compounds.

Other Matters

As the Company reported in a Form 8-K, on April 17, 2025, the Company received a summons and a copy of a complaint filed by BE&K in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "BE&K Complaint"). Other Defendants named in the BE&K Complaint who are subcontractors elected to filed counterclaims and cross-claims in response thereto. 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 Litigation) in the Circuit Court of the 17th Judicial Circuit in and for Broward County, Florida (the "Fisk Complaint") against the Company, BE&K, and the other defendants in the BE&K Complaint. On August 8, 2025, B&I Contractors, Inc. ("B&I"), one of the defendants in the BE&K Complaint, filed a motion for summary judgment (the "MSJ") as to the Count I (Foreclosure of Construction Lien). The Company has responded to the BE&K and Fisk Complaints and cross-claims as well as the B&I MSJ. The cases were consolidated, and a Case Management conference was held. On February 19, 2026, a stipulation was submitted to the Court for a settlement and release agreement between the Company and B&I calling for payment of a total of $860,000 in installments in settlement of amounts owed and an allowance for interest and other fees the last installment of which is payable on or before May 31, 2026. The remaining parties are engaged in discovery and the court set the case for trial in early December 2026.

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

Item 4 Mine Safety Disclosures.

Not applicable.

PART II

Item 5 Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information and Holders of our Common Stock

Our Common Stock is currently traded on The Nasdaq Global Select Market under the symbol "HCWB". As of March 25, 2026, 6,734,104 shares of the Company's Common Stock were issued and outstanding and were owned by approximately 4,500 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees.

Dividend Policy

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.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

Standby Equity Line of Credit

On February 20, 2025, the Company entered into an equity purchase agreement (the "ELOC Purchase Agreement") with Square Gate Capital Master Fund, LLC – Series 4 ("Square Gate") pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right to direct Square Gate to purchase up to an aggregate of $20,000,000 of shares of our Common Stock, plus, at the Company's option upon utilizing the initial $20,000,000, an additional amount equal to the lesser of 100% of the Company's market capitalization at the time of exercise of such option or $20,000,000, over the 36-month term of the ELOC Purchase Agreement. The Company issued 9,616 shares of our Common Stock to Square Gate on March 12, 2025, as its Commitment Fee under the ELOC Purchase Agreement (the "Commitment Shares"). On April 16, 2025, the U.S. Securities and Exchange Commission ("SEC") declared a registration statement effective to register the Commitment Shares and shares required to sell up to $40.0 million of the Company's shares to Square Gate, according to provisions of the Equity Purchase Agreement.

Sale of Common Stock and Warrants

On February 17, 2026, the Company entered into a securities purchase agreement with a single institutional investor (the "Investor") pursuant to which the Company agreed to offer and sell, in a follow-on public offering (the "2026 Offering"), 2,477,292 units (the "Units") consisting of (i) 2,477,292 shares (the "Common Shares") of the Company's Common Stock, $0.0001 par value per share or, in lieu thereof, up to 2,477,292 Pre-Funded Warrants (as defined below) to purchase up to 2,477,292 shares of Common Stock (the "Pre-Funded Warrant Shares"), and (ii) up to 2,477,292 Common Stock purchase warrants the exercise of which is conditioned on stockholder approval (the "Common Stock Warrants", and together with the Pre-Funded Warrants, the "Warrants") to purchase up to 2,477,292 shares of Common Stock.

On February 17, 2026, the Company also entered into a privately negotiated agreement with the Investor, which holds certain existing outstanding warrants to purchase up to 3,020,410 shares of Common Stock (the "Prior Warrants") to seek stockholder approval in accordance with applicable Nasdaq rules to reduce the exercise price of such Prior Warrants to the public offering price per Unit paid in the Offering (the "Existing Warrants Amendment Agreement"). There can be no assurance that we will obtain such stockholder approval or amend the Prior Warrants or as to the final terms of any amendments to the Prior Warrants.

The combined purchase price for each Unit consisting of one share of Common Stock or Pre-Funded Warrant in lieu thereof and accompanying Common Stock Warrant to purchase one share of Common Stock was $0.6055 per unit, and the combined purchase price for each unit consisting of one Pre-Funded Warrant that may be exercised for one share of Common Stock and accompanying Common Stock Warrant to purchase one share of Common Stock is $0.6054. The Common Stock Warrants have an exercise price of $0.6055 per share, will be exercisable only upon receipt of stockholder approval thereof in accordance with applicable Nasdaq rules, and expire on the five-year anniversary of such stockholder approval. The Pre-Funded Warrants have an exercise price of $0.0001, are exercisable immediately and will not expire until exercised in full.

The securities described above were offered pursuant to a registration statement on Form S-1, as amended (File No. 333-293396), which was declared effective by the SEC on February 17, 2026. The gross proceeds to the Company from the 2026 Offering are approximately $1.5 million before deducting the placement agent's fees and other offering expenses payable by the Company. The 2026 Offering closed on February 19, 2026.

On February 17, 2026, the Company entered into a placement agency agreement (the "Placement Agency Agreement") with Maxim Group LLC ("Maxim" or the "Placement Agent") pursuant to which the Company engaged the Placement Agent as the exclusive placement agent in connection with the Offering. The Company agreed to pay the Placement Agent a cash fee equal to 6.9% of gross proceeds from the sale of Common Shares, Pre-Funded Warrants and Common Stock Warrants to the Investor. The Company also agreed to reimburse the Placement Agent for out-of-pocket expenses, including the reasonable legal fees of its counsel not to exceed $65,000. The Placement Agency Agreement also contains representations, warranties, indemnification and other provisions customary for transactions of this nature.

The Common Stock Warrants and Prior Warrants require stockholder approval, per Nasdaq rules. The Company filed a definitive proxy statement on March 13, 2026 for a Special Stockholders' Meeting to be held on April 27, 2026, at this the stockholders will vote on a proposal to permit this transaction.

Conversion of Secured Notes

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 ("Conversion Shares"), warrants to purchase approximately $3.3 million of the Company's Common Stock at an exercise price of $26.00 per share ("Conversion Warrants"), and the right to their pro rata share of 49.11% of the proceeds of the Company's shares of Wugen common stock ("Wugen Shares"), if and when such shares are ever sold (the "Wugen Proceeds"). The conversion was approved at a Special Meeting of Stockholders held on March 31, 2025 and was effected pursuant to the terms of the Conversion Amendment. On May 7, 2025, pursuant to the Conversion Amendment, the Secured Notes held by the participating noteholders were cancelled, and the Company issued a total of 253,083 unregistered shares of Common Stock (which are subject to a 180-day lock-up) and warrants to purchase an additional 126,540 shares of Common Stock at an exercise price of $26.00 per share. 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.

Inducement Agreement

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

Sale of Common Stock and Warrants

On November 18, 2024, the Company entered into a securities purchase agreement with a single institutional investor (the "Investor") pursuant to which the Company agreed to offer and sell (i) in a registered direct offering (the "Registered Offering") (x) 104,000 shares (the "Shares") of the Company's Common Stock, par value $0.0001 per share, and (y) Pre-funded Warrants to purchase up to 63,925 shares of Common Stock (the "Pre-Funded Warrants") and (ii) in a concurrent private placement (the "Private Placement" and together with the Registered Offering, the "Offering"), unregistered warrants to purchase up to an aggregate of 154,275 shares of Common Stock ("Armistice Warrants"). The combined purchase price for each Share and accompanying Armistice Warrant to purchase one share of Common Stock was $41.20 per Share and the combined purchase price for each Pre-Funded Warrant and accompanying Common Stock Warrant to purchase one share of Common Stock was $40.196.

The Common Stock and Pre-Funded Warrants were each sold with an accompanying Armistice Warrant to purchase one share of Common Stock, and the Common Stock and Pre-Funded Warrants were immediately separated from the Armistice Warrants and were issued separately. The Armistice Warrants have an exercise price of $41.20 per share, are exercisable immediately, and expire on the five year anniversary of the date of issuance. The Pre-Funded Warrants have an exercise price of $0.0001, are exercisable immediately and will not expire until exercised in full.

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

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

Sale of Common Stock in Private Placement

On February 20, 2024, we entered into subscription agreements (the "Subscription Agreements") with certain officers and directors of the Company, including our Founder and Chief Executive Officer, our Chief Financial Officer and the Chairman of the Company's Board of Directors, pursuant to which the Company sold an aggregate of 44,643 shares of our Common Stock, at a purchase price of $56.00 per share for an aggregate purchase price of $2.5 million. The per share purchase price represents a 25% premium to the per share closing price of the Common Stock as reported on the Nasdaq Global Market on the February 20, 2024 and a 19% premium to the 5-day volume weighted average closing price per share of the Common Stock as reported on the Nasdaq Global Market for the period ending on the February 20, 2024.

The shares of Common Stock issued pursuant to the Subscription Agreements were not registered under the Securities Act of 1933, as amended, in reliance upon exemptions under Section 4(a)(2) of the Securities Act of 1933, as amended.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6 [Reserved].

Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes thereto included elsewhere in this Annual Report. This discussion contains forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, and intentions, which are based on the beliefs of our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Annual Report.

Company Overview

HCW Biologics Inc. ("HCW Biologics" or the "Company") is a clinical-stage biopharmaceutical company developing transformative fusion immunotherapeutics to support or treat diseases promoted by chronic inflammation. We have created novel compounds that represent a new class of drugs that we believe have the potential to fundamentally change the treatment of autoimmune disorders and other proinflammatory diseases, cancer and senescence-associated dysplasia. Among other things, we have begun commercialization of certain commercial-ready proprietary compounds for use as reagents in the production of immunotherapeutics for the treatment of infectious diseases and cancer. We want our products to improve patients' healthspan as well as their quality of life, and possibly extend longevity.

By leveraging our extensive immunology expertise, we have developed fusion immunotherapeutics representing a new class of drug that we believe has the potential to fundamentally change the treatments for autoimmune diseases, cancer, senescence-associated dysplasia, and many other diseases promoted by chronic inflammation — and in doing so, improve patients' quality of life and possibly extend longevity.

HCW Biologics 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 receptor agonist) through pivotal trials. This blockbuster immunotherapeutic treatment for cancer was sold to ImmunityBio, Inc. in 2017 in a $1.0 billion acquisition. In April 2024, Anktiva® was approved by the U.S. Food and Drug Administration for its first indication, the treatment of BCG-Unresponsive Non-Muscle Invasive Bladder Cancer.

The Company utilized its proprietary drug discovery and development platforms to create novel fusion immunotherapeutics, including multi-specific cytokines, targeted second- generation immune checkpoint inhibitors, and immune-cell engagers, which have the capabilities to rebalance immune cells to reestablish immune tolerance or rejuvenate subsets of immune cells that specifically target cancerous and infected cells, and accumulated, nonfunctional senescent cells. Our specialty is to develop treatments administered by subcutaneous injection, with an eye toward cost containment and cost savings as well as quality-of-life for patients.

Advancing our programs may be accomplished through Company-sponsored programs or with a corporate partner. Business development transactions are considered a key aspect of our financing strategy. We continually assess our programs to determine the optimal path to successfully complete clinical development and launch commercialization.

The Company has selected the following compounds for our clinical development programs, which are currently being developed in Company-sponsored programs:

- HCW9302 is a clinical-stage compound that is an injectable, first-in-kind interleukin 2 ("IL-2") fusion protein complex constructed using the Company's proprietary TOBI platform technology. Its mechanism of action involves binding to IL-2αβγ receptors predominantly expressed on regulatory T ("T_{reg}") cells, thereby activating and expanding Treg cells that can suppress unwanted immune and inflammatory responses. Beijing Trimmune Biotech Co., Ltd. ("Trimmune") has an option to license the rights to the China market for HCW9302.
- HCW11-018b is a preclinical molecule that is a novel, tetra-valent T-Cell engager we call the Big BiTE, since it consists of a BiTE (common for all T-Cell Engagers) and an Enhancer (which makes the HCWB T-Cell Engager the "BIG BiTE"). HCW11-018b is designed to address key challenges for first generation T-Cell Engagers: manufacturability, preclinical safety profile, and ability to treat solid tumors.
- HCW11-040 is a preclinical molecule that is a unique combination of cytokines and pembrolizumab, a generic form of Keytruda®, in a multi-functional fusion molecule. This lead product candidate exhibits the ability to expand Tpex cells without a cytokine storm in preclinical studies. In addition, it exhibits superior immune-cell activation, expansion, and cytotoxicity against cancer cells and tumors when compared to pembrolizumab in in-vitro and in-vivo studies.

Business Highlights

Clinical Development

- HCW9302: On November 17, 2025, the first patient was dosed at The Ohio State University Wexner Medical Center for the Company-sponsored, multi-center first-in-human clinical trial to evaluate HCW9302 in patients with alopecia areata (NCT07049328). This marks a major milestone in the Company's clinical development program in autoimmune diseases. A preliminary human data read out for this study is expected in the first half of 2026.
- HCW11-018b: IND-enabling activities are expected to be completed in the first half of 2027. The Company intends to file an IND application shortly thereafter, for authorization to evaluate HCW11-018b, our second-generation T-Cell engager, in patients with pancreatic cancer.
- HCW11-040: IND-enabling activities are expected to be completed in second half of 2027. The Company intends to file an IND application shortly thereafter, for authorization to evaluate HCW11-040, our second-generation immune checkpoint inhibitor, in neonatal infants with a chronic lung condition called BPD.

Business Development Transactions

Beijing Trimmune Biotech Co., Ltd. License

The Company is developing HCW11-006 through a corporate partnership with Beijing Trimmune Biotech Co., Ltd. ("Trimmune"). Trimmune is a new operating entity formed for the purpose of development and commercialization of HCW11-006, by WY Biotech Co., Ltd. ("WY Biotech"), a China-based company specializing in the early-stage development of recombinant protein drugs and gene/cell therapies, and the Company. Trimmune investors include CITIC Medical Fund, a multi-billion-dollar investment fund focused on innovative companies primarily targeting pharmaceuticals, biotechnology, medical devices, and diagnostics, and TigerYeah Capital Fund of TigerMed, a global leading Contract Research Organization. Trimmune is led by a team with an impressive track record for success in the development and commercialization of innovative drugs that treat diseases with large, unmet medical needs for the Chinese market. HCW11-006 is a preclinical molecule that combines several different immune functional domains as part of a group of compounds characterized as multi-functional immune cell stimulators.

As of March 16, 2026, we received the full payment of the upfront licensing fee for the exclusive worldwide license for HCW11-006, a preclinical molecule, from Trimmune. The Company received $3.5 million in gross proceeds, or $2.9 million net of taxes. In addition to the cash portion of the upfront license fee, before taxes, the Company also received a minority co-founder equity interest in Trimmune. In addition, for additional compensation, Trimmune has a option to license the China rights to HCW9302.

HCW Biologics is eligible to receive additional payments under the license, including development milestone payments and double-digit royalties on future product sales, as well as a portion of the proceeds from certain future transaction(s) involving the licensed molecule, if and when such transaction(s) occur. Upon completion of Phase 1 by the licensee, the Company may exercise its Opt-In Rights to reclaim the rights to the Americas market. For an additional fee, Trimmune may exercise an option to license the China rights to HCW9302, the Company's clinical-stage molecule, currently being evaluated in a Phase 1 trial in an autoimmune disorder.

Commercial-Ready Molecules Used as Reagents

During the year ended December 31, 2025, the Company launched two of its proprietary fusion protein molecules as commercial-ready molecules used as reagents to be used to support the production of immunotherapeutics to treat infectious diseases and cancer. While the Company's focus remains on the development of fusion immunotherapeutics for the treatment of diseases promoted by chronic inflammation, the Company intends to market these reagents directly or through a corporate partnership to generate revenue which could offset development costs for its immunotherapeutic treatments. On March 13, 2026, Science Advances, a peer-reviewed, high-impact journal, released a publication with the Company's data that showed the Company's proprietary, commercial-ready compound, HCW9206, could fundamentally change how CAR-T cell therapies are manufactured and potentially improve how they perform against diseases such as cancer and HIV. These findings support the Company's belief that HCW9206 is a leap forward in both clinical potential and manufacturing efficiency.

Financing

During the second half of 2025, the Company sold 600,000 shares of Common Stock through its Standby Equity Purchase Agreement ("SEPA") with Square Gate Capital for an aggregate of approximately $2.5 million in gross proceeds. As of November 20, 2025, the Company will be restricted from using the SEPA for a standstill period of 6 months, in accordance with terms of the November 2025 Inducement Transaction.

On May 15, 2025, the Company raised $5.0 million before commissions and transaction costs payable by us through the sale of 671,150 Units for $7.45 per Unit, each consisting of one share of Common Stock (or Pre-funded Warrant that may be exercised to purchase one share of Common Stock) plus two Common Stock Warrants each of which can be exercised to purchase one share of Common Stock. The Common Stock Warrants had an exercise price of $7.45 per share, were exercisable immediately upon issuance, and will expire on the five-year anniversary of the original issuance date.

On November 20, 2025, the Company raised $4.0 million before commissions and transaction costs payable by us through an inducement to exercise warrants to purchase 1,510,205 shares of Common Stock at $2.66 per share. These warrants were issued in November 2024 and May 2025, and immediately before the transaction had an exercise price of $7.45 per share. In addition, the Company agreed to issue to the investor unregistered warrants to purchase an aggregate of 3,020,410 shares of the Company's Common Stock with an exercise price of $2.41 per share (the "New Warrants"). The New Warrants will be immediately exercisable and will expire on the five and one-half year anniversary of the original issuance date. On January 29, 2026, the SEC declared effective a resale registration statement on Form S-1 (File Number 333-292652) covering the New Warrants.

On February 19, 2026, the Company raised $1.5 million before commission and transaction costs payable by us through the sale of 2,477,292 Units for $0.6055 per Unit, each consisting of one share of Common Stock (or Pre-funded Warrant that may be exercised to purchase one share of Common Stock) plus one Common Stock Warrant each of which can be exercised to purchase one share of Common Stock. In a private transaction, the Company agreed to reprice the 3,020,410 warrants that were issued in November 2025 from $2.41 per share to $0.0655 per share. The investor's ability to exercise the Common Stock Warrants issued in this transaction and the reduction of the exercise price for the warrants issued in November 2024 are both subject to stockholder approval. The Company filed a definitive proxy on March 13, 2026 for a Special Stockholders' Meeting to be held on April 27, 2026.

Compliance with Nasdaq Listing Rules

An important part of the Company's future financing plans is the ability to access the public markets for the sale of securities. This requires that the Company remain in compliance with all Nasdaq Listing Rules. As of the date of issuance of these financial audited statements, the Company is compliant with all listing rules of the Nasdaq Capital Market tier.

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

On February 26, 2026, the Nasdaq Hearings Panel found that the Company regained compliance with all continued listing rules of The Nasdaq Capital Market. Pursuant to Listing Rule 5815(d)(4)(B), the Company will be subject to a Mandatory Panel Monitor. 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, 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.

Contract Development and Manufacturing Facility for Biologics

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

For the year ended December 31, 2025, the Company recognized an impairment of $1.5 million related to its Property. In its assessment of potential indicators of impairment of the asset, the Company concluded that during the year, legal procedures were initiated by holders of mechanics liens against the Company's Property with claims for nonpayment on April 17, 2025, and the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure the mechanics liens on October 24, 2025. See See Part I, Item 3. – "Legal Proceedings." The Company has continued to pursue financing alternatives to provide the funding needed to come current in past amounts due and complete the construction and renovation of the Property.

Trends and Uncertainties

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

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

For discussion of risks related to potential impacts of supply chain, inflation, geopolitical and macroeconomic challenges on our operations, business results and financial condition, see Part I, Item 1A. "Risk Factors" in this Annual Report.

Components of Results of Operations

Revenues

We have no products approved for commercial sale and have not generated any revenue from commercial product sales of internally-developed immunotherapeutic products for the treatment of autoimmune disorders, cancer and senescence-associated dysplasia. Since inception, our sole source of revenue is from license and a clinical development supply agreement.

Wugen License

The Company entered the Wugen License with Wugen at the end of 2020, and we entered a development supply agreement with Wugen to provide it with clinical development materials needed for research and clinical development in Q1 2021. During the year ended December 31, 2025, the Company agreed to a request from Wugen to suspend the Wugen License, which will run for a period of one year from the effective date of the suspension, or until May 29, 2026. The Company expects to generate revenue for ancillary services provided to Wugen during this time, as provided for under the amended Wugen license. During the suspension, the Company is free to enter licenses with other parties for the molecules that are subject of the Wugen license.

Consideration under our contract included a nonrefundable upfront payment, development, regulatory and commercial milestones, and royalties based on net sales of approved products. In addition, the Company earned revenue from supplying Wugen with clinical and research grade materials for clinical development and commercialization of licensed products under a separate development supply agreement. For the recognition of revenue, we assessed which activities in the Wugen License should be considered distinct performance obligations that should be accounted for separately. We develop assumptions that require judgement to determine whether the license to our intellectual property is distinct from the research and development services or participation in activities under the Wugen License.

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

Trimmune License

We expect to derive revenue from a license agreement granting rights for development and commercialization of *in vivo* applications using HCW11-006. Consideration under our contract included a nonrefundable upfront payment, development, regulatory and commercial milestones, as well as royalties based on net sales of approved products. This closing occurred in the first quarter of 2026.

Operating Expenses

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

Research and Development

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

- Employee-related expenses, including salaries, benefits, and stock-based compensation expense;
- Expenses related to manufacturing and materials, consisting primarily of expenses incurred in connection with CMOs, which produce cGMP materials for clinical trials on our behalf;
- Expenses associated with preclinical activities, including research and development and other IND-enabling activities;
- Expenses incurred in connection with clinical trials; and
- Other expenses, such as facilities-related expenses, direct depreciation costs for capitalized scientific equipment, and allocation for overhead.

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

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

General and administrative expenses consist primarily of employee-related expenses for executive, legal, finance, accounting, human resources and other administrative personnel, as well as professional fees (including legal, audit and tax services), insurance costs, facilities expenses, and other public company compliance costs.

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

Legal Expenses (Recoveries), Net

Legal expenses (recoveries), net consist of legal fees incurred in connection with the Arbitration and related proceedings involving the Company and Dr. Hing C. Wong, net of insurance reimbursements received.

Nonoperating Loss

On May 1, 2024 with the SEC, the Company became aware that it was the victim of a criminal scheme involving the impersonation of a purchaser upon the default on a legally binding commitment to purchase $8.0 million of secured notes from the Company. The scheme resulted in the misdirection of approximately $1.3 million held in Company accounts to a fraudulent account controlled by a third party. The Company is pursuing all available remedies to recover this loss. Given the limited success that these efforts have had to date for the recovery of funds, the Company recognized a nonoperating loss of $1.3 million in for the year ended December 31, 2024 in the accompanying audited statement of operations.

Impairment of Long-Lived Asset

For the year ended December 31, 2025, the Company recognized an impairment of $1.5 million related to its building. In its assessment of potential indicators of impairment of the asset, the Company concluded that during the year, legal procedures were initiated by holders of mechanics liens against the Company's property with claims for nonpayment on April 17, 2025, and the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure the mechanics liens on October 24, 2025.

Interest Expense

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

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

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

On May 8, 2025, the Company issued a $150,000 promissory note with a personal guarantee from the Company's Founder and Chief Executive Officer, which has an original issue discount of $75,000 which is accreted on a straight-line basis from the date of issuance to the Maturity Date of February 7, 2026 (the "Secured Promissory Note"). The Company repaid $225,000 on February 6, 2026.

Change in Fair Value of Investment and Contingent Liability

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

Gain (Loss) on Sale of Put Shares

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

Gain on Extinguishment of Liability

The Company executed a settlement agreement relating to approximately $7.5 million of outstanding legal fees included in the Company's outstanding trade payables. The term of the settlement include $2.0 million of cash settlement payments and a $5.5 million contingent promissory note providing for certain potential payments if the Company achieves certain defined milestones in the future that are considered remote. As such, the Company recognized a $5.5 million gain on extinguishment of liability.

Other Income, Net

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

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2024 and 2025:

	Years Ended December 31,	
	2024	2025
Revenues:		
Revenues	$ 2,566,792	$ 54,232
Cost of revenues	(1,607,389)	(43,386)
Net revenues	959,403	10,846
Operating expenses:		
Research and development	6,388,994	5,442,884
General and administrative	6,816,449	7,701,281
Legal expenses (recoveries), net	15,910,480	(1,470,809)
Impairment of long-lived asset	—	1,500,000
Nonoperating loss	1,300,000	—
Total operating expenses	30,415,923	13,173,356
Loss from operations	(29,456,520)	(13,162,510)
Interest expense	(654,284)	(845,051)
Change in fair value of investment	—	(273,422)
Change in fair value of contingent liability	—	1,055,826
Loss on sale of put shares	—	(263,974)
Gain on extinguishment of liability	—	5,461,046
Other income, net	86,990	68,376
Net loss	$ (30,023,814)	$ (7,959,709)

Revenue

For the year ended December 31, 2024, we recognized $2.6 million of revenue and cost of revenues of $1.6 million. Revenues were derived exclusively from the sale of licensed molecules to Wugen. There is currently one ongoing Phase 1 clinical study evaluating WU-NK-101, the Wugen product candidate created using the licensed molecules, in solid tumors.

For the year ended December 31, 2025, we recognized $54,232 of revenue and cost of revenues of $43,386. Revenues were derived exclusively from the sale of licensed molecules to Wugen. The drop in revenue is attributed to a strategic decision made by Wugen to focus its resources on its CAR-T program, WU-CART-007, which was recently granted a Breakthrough Therapy Designation (Soficabtagene Geleucel "Sofi-cel"), an allogeneic CAR-T therapy for the treatment of T-cell malignancies. There is an ongoing pivotal study of Sofi-cel for Relapsed or Refractory T-Cell ALL/LBL in Pediatric and Adult Patients. As part of the nonrefundable upfront license fee paid by Wugen, the Company received shares of Wugen common stock as non-cash consideration. The Company continues to hold these shares as of December 31, 2025.

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2024 and 2025:

	Years Ended December 31,			
	2024	2025	$ Change	% Change
Salaries, benefits and related expenses	$ 2,797,370	$ 3,069,364	$ 271,994	10%
Manufacturing and materials	1,425,734	354,705	(1,071,029)	(75)%
Preclinical expenses	859,701	930,899	71,198	8%
Clinical trials	558,215	470,592	(87,623)	(16)%
Other expenses	747,974	617,324	(130,650)	(17)%
Total research and development expenses	**$ 6,388,994**	**$ 5,442,884**	**$ (946,110)**	(15)%

Research and development expenses decreased by $1.0 million, or 15%, from $6.4 million for the year ended December 31, 2024 to $5.4 million for the year ended December 31, 2025. This decrease was primarily attributable to decreased expenses for manufacturing and materials.

Salaries, benefits and related expenses increased by $271,994, or 10%, from $2.8 million for the year ended December 31, 2024 to $3.1 million for the year ended December 31, 2025. This increase was primarily attributable to the suspension of the Wugen license in the second quarter of 2025, which included suspension of the $500,000 annual reimbursement of research and development expenses. As a result, the Company received $62,500 in reimbursements from Wugen for the year ended December 31, 2025. The increase in salaries and related taxes for the year ended December 31, 2025 was partially offset by decreases of $57,799 in employee benefits and $13,182 in expenses for stock-based compensation. The Company had a staff reduction in May 2024, and continues to operate with the reduced headcount.

Manufacturing and materials expenses decreased by $1.1 million, or 75%, from $1.4 million for the year ended December 31, 2024 to $354,705 for the year ended December 31, 2025. For the year ended December 31, 2024, costs were primarily attributable to the production of a high-expressing cell line of HCW9101, an internally-developed affinity ligand used in our manufacturing processes. For the year ended December 31, 2025, expenses for manufacturing and materials primarily attributable to the production of HCW9101 and ancillary costs, such as storage and insurance for drug supply that was already manufactured and ready for future use.

Expenses associated with preclinical activities increased by $71,198, or 8%, from $859,701 for the year ended December 31, 2024 to $930,899 for the year ended December 31, 2025. For the year ended December 31, 2024, we launched our new TRBC drug discovery and development platform in the fourth quarter. In the second half of the end ended December 31, 2024, we completed IND-enabling studies for the IND application for HCW9302, to seek authorization for a clinical study to evaluation HCW9302 in patient with an autoimmune disease. For the year ended December 31, 2025, preclinical studies were performed to develop the data to base the selection of lead product candidates for our TRBC-based clinical development programs. The increase was primarily attributable to increases of $159,645 for additional studies conducted with our collaborators and $107,383 in the cost of experimental material for those studies, partially offset by a decline of $195,830 for drug testing costs.

Expenses associated with clinical trials, including patient fees, ancillary studies, clinical site operating expenses, professional fees related to regulatory filings and outside collaborations, decreased by $87,623, or 16%, from $558,215 for the year ended December 31, 2024 to $470,592 for the year ended December 31, 2025. For the year ended December 31, 2024, the Company completed two clinical studies to evaluate HCW9218 in cancer indications. These rights were transferred to ImmunityBio and its affiliates as a result of the Settlement and General Release reached in the third quarter of 2024. See Part I, Item 3. – "Legal Proceedings." For the year ended December 31, 2025, the Company was cleared to begin its clinical trial to evaluate HCW9302 in patients with an autoimmune disease in the first quarter and we dosed the first patient in the third quarter. There are currently two active sites enrolling patients for this study, including The Ohio State University and James A. Haley Veterans' Hospital.

Other expenses, which include overhead allocations, decreased by $130,650, or 17%, from $747,974 for the year ended December 31, 2024 to $617,324 for the year ended December 31, 2025. This decrease is primarily attributable to decreases of $120,193 in allocation for depreciation, $10,593 in general office and facilities related expenses and $5,513 in travel and travel-related expenses, which were partially offset by an increase of $8,198 in rent and occupancy costs.

General and Administrative Expenses

The following table summarizes our general and administrative expense for the years ended December 31, 2024 and 2025:

	Years Ended December 31,			
	2024	2025	$ Change	% Change
Salaries, benefits and related expenses	$ 2,563,936	$ 2,784,753	$ 220,817	9%
Professional services	1,171,885	1,995,446	823,561	70%
Facilities and office expenses	654,996	433,288	(221,708)	(34)%
Accretion of fixed bonus upon maturity of Secured Notes	527,304	405,222	(122,082)	NM
Depreciation	254,407	237,005	(17,402)	(7)%
Rent expense	205,511	191,598	(13,913)	(7)%
Other expenses	1,438,410	1,653,969	215,559	15%
Total general and administrative expenses	**$ 6,816,449**	**$ 7,701,281**	**$ 884,832**	13%

General and administrative expenses increased by $884,832, or 13%, from $6.8 million for the year ended December 31, 2024 to $7.7 million for the year ended December 31, 2025. The increase is primarily attributable to the change in the activities at the Company for the year ended December 31, 2025, compared with the prior period. As of July 13, 2024, the Company, Dr. Wong, and ImmunityBio and its affiliates entered into a Settlement Agreement that is described in Part I, Item 3. – "Legal Proceedings." 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. After the Settlement Agreement, there was marked increase in activities related to regaining compliance for Nasdaq listing rules, strengthening internal controls over financing reporting and raising capital for the relaunch of the Company's clinical development and business development programs. Thus, professional fees increased for the year ended December 31, 2025 when compared to the prior year.

Salaries, benefits and related expenses increased by $220,817, or 9%, from $2.6 million for the year ended December 31, 2024 to $2.8 million for the year ended December 31, 2025. The increase is primarily attributable to an increases of $186,337 in salaries and related taxes and $298,159 due to the waiver of a performance-based bonus by officers in the second quarter of 2024, partially offset by decreases of $227,207 in expense for stock-based compensation and $15,028 in employee benefits. There were no bonus payments to officers for the year ended December 31, 2025.

Professional fees increased by $823,561, or 70%, from $1.2 million for the year ended December 31, 2024 to $2.0 million for the year ended December 31, 2025. These expenses were incurred during the normal course of business, and include legal fees for corporate activities, fees incurred in prosecuting patents, as well as audit, tax and advisory fees. The increase is primarily attributed to an increase of $143,701 in corporate legal fees and $656,798 for other professional services. The increases in other professional services include increases of $188,979 for services and fees related to regaining compliance with Nasdaq listing rules; $171,380 for audit fees, reflecting change in auditors on September 20, 2024 and the complexity of financial transactions for the year ended December 31, 2025; $149,955 for technical advisors needed to bolster our resources and address weaknesses in internal controls over financial reporting; and $60,480 for the services of an interim controller.

Facilities and office expenses decreased by $221,708, or 34%, from $654,996 for the year ended December 31, 2024 to $433,288 for the year ended December 31, 2025, primarily due to decreases of $240,138 for software licenses and services needed for active clinical trials and $9,880 for janitorial and disposal services.

For the year ended December 31, 2024, there was $527,304 in accretion for the fixed bonus payment for Senior Notes issued during 2024. As of October 31, 2024, the Company received approximately $6.9 million from the issuance of Secured Notes. The terms of the Senior Notes were amended in the third quarter of 2024, adding the provision for the fixed bonus payment if the Senior Notes are held to Maturity.

For the year ended December 31, 2025, there was $405,222 in accretion for the fixed bonus payment for Senior Notes. In May 2025, as part of the Nasdaq Compliance Plan, the Company entered into the Second Amendment to its Secured Note in which certain Secured Note noteholders agreed to restructure their Secured Notes. At the time of the restructuring, the net carrying amount of the restructured Secured Notes was $7.4 million including principal of $6.6 million and accumulated accretion of a fixed bonus payable upon Maturity Date of $860,462. On May 7, 2025, the Company extinguished $7.4 million of debt through the issuance of 253,083 shares of Common Stock, warrants to purchase 126,540 shares of Common Stock, and rights to receive a pro rata share of 49.11% of the proceeds or shares from the Company's investment in Wugen. 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.

Other expenses increased by $215,559, or 15%, from $1.4 million for the year ended December 31, 2024 to $1.7 million for the year ended December 31, 2025. The increase is primarily due to increases of $190,361 for financing costs which includes expenses related to registering the shares underlying the SEPA, as required by the terms of our agreement, and commissions earned on sale of shares of Common Stock under the SEPA and $134,744 increase in property and casualty insurance, partially offset by decreases of $77,737 in other insurance costs and $23,592 in travel-related expenses.

Legal Expenses (Recoveries), Net

For the year ended December 31, 2024, the Company incurred $15.9 million in legal expenses in connection with the Arbitration. The Arbitration was settled on July 13, 2024, and the Arbitration and related Complaint were dismissed with prejudice as of December 31, 2024. For the year ended December 31, 2025, the Company received a $2.0 million insurance reimbursement for fees incurred in connection with the defense of Dr. Hing C. Wong, and incurred $529,191 in legal expenses in connection with the Arbitration. Prospectively, we anticipate we will incur some expenses for costs of remaining in compliance with the terms of the Settlement Agreement.

Interest Expense

The Company paid $280,794 and $366,358 in cash for interest for the years ended December 31, 2024 and 2025, respectively, related to the 2022 Loan. Interest was expensed in both periods.

For the years ended December 31, 2024 and 2025, the Company recognized an interest expense of $350,343 and $235,303, respectively, related to the Secured Notes.

For the year ended December 31, 2025, Company recognized $64,722 of accretion expense for the Secured Promissory Note and $86,516 of interest expense related to the EirGenix settlement agreement.

For the years ended December 31, 2024 and 2025, the Company recognized $10,367, for the amortization of debt issuance costs related to the 2022 Loan included within Interest expense on the audited statements of operations.

For the years ended December 31, 2024 and 2025, the Company recognized other costs of $12,780 and $81,785, respectively.

Change in Fair Value of Investment

The Company recognized a $273,422 loss due to the change in fair value of the investment in Wugen shares for year ended December 31, 2025. The decrease in fair value resulted from dilution of the Company's ownership interest following Wugen's issuance of preferred stock in a capital raise during the year ended December 31, 2025. There was no change in fair value of the investment in Wugen shares in the comparable period in 2024. The net change in fair value was recognized through earnings on the accompanying audited statement of operations for the year ended December 31, 2025.

Change in Fair Value of Investment and Contingent Liability

The Company recognized a $1.1 million gain due to the change in fair value of the contingent liability for year ended December 31, 2025. There was no change in fair value of the contingent liability in the comparable period in 2024. The net change in fair value was recognized through additional paid in capital during conversion on the accompanying audited statement of equity (deficit) and earnings on the accompanying audited statement of operations for the year ended December 31, 2025.

Loss on Sale of Put Shares

For the year ended December 31, 2025, the Company recognized $263,974 for a loss on the sale of put shares, related to the 600,000 shares sold using the Company's SEPA. The Company entered the SEPA agreement in the first quarter of 2025.

Other Income, Net

Other income, net had a de minimis decrease of $18,614, from $86,990 for the year ended December 31, 2024 to $68,376 for the year ended December 31, 2025.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2025, the Company had $2.0 million in cash and cash equivalents, including money market investments, and as a result, there was substantial doubt over whether the Company had sufficient capital to operate for the next twelve months from the issuance date of this Annual Report. We considered elements of our financing plan that were probable and likely to be implemented within the next year. While we have already begun to successfully execute our financing plan, including raising $16.3 million for the year ended December 31, 2024 and $11.5 million for the year ended December 31, 2025. In addition, during year ended December 31, 2025, the Company strengthened our balance sheet by extinguishing $7.7 million of debt through restructuring and conversion to equity, including restructuring $7.4 million of Secured Notes and accumulated accretion of a fixed bonus payable upon Maturity Date and converting $270,000 of unsecured promissory notes according to the terms in the agreement, as well as entering settlement agreements with vendors regarding past due amounts owed which resulted in reducing accounts payable by $5.5 million as of December 31, 2025.

In addition to equity financings, we also use business development transactions as a key strategy in our financing plan. We continuously assess our product portfolio, especially when milestones are achieved, to determine the optimal approach to continuing with clinical development. Since the inception of the Wugen License in December 2020, the Company has recognized cumulative revenues of $16.2 million. During the year ended December 31, 2025, the Company agreed to a request from Wugen to suspend the Wugen License, including Wugen's clinical trial due diligence obligations and its obligation to pay $500,000 annually to reimburse the Company for certain research and development expenses. The suspension will run for a period of one year from the effective date and will end on May 29, 2026. During the suspension, the Company has the exclusive right to seek alternate licensees and terminate the license in order to enter other business development transactions related to the ex vivo rights of licensed molecules. We are actively engaged in discussions with several large biologics manufacturing companies with interest in a license for these molecules.

For the year ended December 31, 2025, the Company raised $11.5 million in gross proceeds in the following transactions:

- On May 15, 2025, the Company closed on a $5.0 million financing with single institutional investor, who is an existing stockholder of the Company, the Company sold units consisting of Common Stock and Pre-funded Warrants with an accompanying two Common Stock Warrants, each of which could purchase one share of Common Stock. Each unit was valued at $7.45 per unit. The Company issued 158,000 shares of the Company's Common Stock and (ii) Pre-funded Warrants to purchase up to 513,140 shares of the Company's Common Stock in a follow-on public offering. The Company also issued warrants to purchase up to an aggregate of 1,342,280 shares of Common Stock for $7.45 per share. The Pre-funded Warrants issued in this transaction have all been exercised as of December 31, 2025. See Note 7. Sale of Common Stock and Warrants.
- On November 20, 2025, the Company entered into a warrant inducement agreement with a single institutional investor, who is an existing stockholder of the Company, for the immediate exercise of certain outstanding warrants that the Company issued on November 20, 2024 (the "November 2024 Warrants") and May 15, 2025 (the "May 2025 Warrants"), respectively. The gross proceeds from the exercise of the warrants were approximately $4.0 million. Pursuant to a warrant inducement agreement, the Investor agreed to a reduced exercise price of the outstanding November 2024 Warrants and May 2025 Warrants to an amended exercise price of $2.66, and to exercise the outstanding November 2024

Warrants to purchase an aggregate of 167,925 shares of the Company's Common Stock and the outstanding May 2025 Warrants to purchase an aggregate of 1,342,280 shares of the Company's Common Stock, at the amended exercise price of $2.66. In consideration for the immediate exercise of the existing warrants, the Company also agreed to issue to the investor unregistered warrants to purchase an aggregate of 3,020,410 shares of the Company's Common Stock with an exercise price of $2.41 per share (the "New Warrants"). The New Warrants will be immediately exercisable and will expire on the five and one-half year anniversary of the original issuance date. On January 29, 2026, the SEC declared effective a resale registration statement on Form S-1 (File Number 333-292652) covering the New Warrants. See Note 7. Sale of Common Stock and Warrants.

- Under the Standby Equity Purchase Agreement ("SEPA"), the Company issued 600,000 shares of Common Stock and raised $2.5 million in gross proceeds during the year ended December 31, 2025. On February 20, 2025, the Company entered into an Equity Purchase Agreement, which qualified as a SEPA, and a related Registration Rights Agreement with Square Gate Capital Master Fund, LLC - Series 4 ("Square Gate"), pursuant to which the Company will have the right, but not the obligation, to sell to Square Gate, and Square Gate will have the obligation to purchase from the Company, up to $20.0 million (the "Maximum Commitment Amount") worth of the Company's shares of Common Stock, at the Company's sole discretion, over the next 36 months (the "Put Shares"), subject to certain conditions precedent and other limitations. On April 16, 2025, the SEC declared a registration statement effective to register shares required to sell up to $40.0 million of the Company's shares to Square Gate, according to provisions of the Equity Purchase Agreement. On August 14, 2025, the parties agreed to amend the SEPA to allow for intraday trading. See Note 8. Standby Equity Purchase Agreement.

Subsequent to the year ended December 31, 2025, the Company raised $5.0 million in gross cash proceeds in the following transactions:

- On February 19, 2026, the Company completed a $1.5 million follow-on public offering, before offering costs, in which it issued 2,477,292 Units, which consisted of one share of Common Stock or Pre-funded Warrants that may be exercised for one shares of Common Stock in lieu thereof, and one Common Stock Warrant that may be exercised for one share of Common Stock, to a single, existing institutional investor. See Note 7. Sale of Common Stock and Warrants.
- As of March 16, 2026, we received the full payment of the upfront licensing fee for the exclusive worldwide license for HCW11-006, a preclinical molecule, from Trimmune. The Company received $3.5 million in gross proceeds, or $2.9 million net of taxes. In addition to the cash portion of the upfront license fee, before taxes, the Company also received a minority co-founder equity interest in Trimmune. For additional consideration, Trimmune has an option to license the exclusive China rights for HCW9302, the Company's clinical-stage molecule currently being evaluated for the treatment of an autoimmune disorder.

An important part of the Company's future financing plans is the ability to access the public markets for the sale of securities. This requires that the Company remain in compliance with all Nasdaq Listing Rules. The Company was granted hearings with the Nasdaq Hearing Panel to present its Nasdaq Compliance Plan ("Compliance Plan").

On March 3, 2025, the Nasdaq Hearings Panel (the "Panel") of The Nasdaq Stock Market LLC ("Nasdaq" or the "Exchange") granted the Company an extension in which to regain compliance with all Nasdaq continued listing rules. The Panel's determination follows a hearing on February 13, 2025, at which the Panel considered the Company's plan to regain compliance with Listing Rules 5450(a)(1), 5450(b)(2)(A) and 5450(b)(2&3)(C), the minimum bid price ("Bid Price"), the market value of publicly held securities ("MVPHS") and the market value of listed securities ("MVLS") rules, respectively. As a result of the extension, the Panel granted the Company's request for continued listing on the Exchange, provided that the Company demonstrates compliance with the Bid Price Rule by April 28, 2025, and all other Exchange continued listing rules by June 15, 2025.

On January 7, 2026, the Company received written notice from the Listing Qualifications Staff that as of December 31, 2025, the Company was compliant with all listing rules, in particular, Listing Rule 5550(b)(1), or the Equity Rule, to achieve and maintain a minimum balance of $2.5 million in stockholders' equity. 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. On March 26, 2026, the Company received a written notice from the Staff which notified the Company that, for the 30 consecutive business days, the Company's security did not maintain a minimum bid price of $1 per share, in accordance with Nasdaq Listing Rule 5810(c)(3)(A) ("Bid Price Rule"). Due to the fact that the Company effected a 1-for-40 reverse stock split on April 11, 2025, the Company was not afforded a 180-calendar day period to demonstrate compliance. The Company plans to request an appeal of this determination in a timely manner.

As reported in the Company's Form 8-K filed on July 18, 2024 and further described in Part I, Item 3. – "Legal Proceedings" below, as of July 13, 2024, the Company and Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, entered into a confidential Settlement Agreement and Release (the "Settlement Agreement") with ImmunityBio and its affiliates. The Settlement Agreement includes mutual general releases by and among the parties thereto. No party is required to make any monetary payments to any other party or person under the Settlement Agreement and each party will bear its own expenses incurred in connection with the matter. In accordance with the provisions of the Settlement Agreement, upon completion of remedial procedures, the parties stipulated that the Arbitration and Complaint should be dismissed. The Arbitration and related Complaint were dismissed on December 24, 2024.

The Company entered into the Settlement Agreement to avoid the costs, disruption and distraction of further litigation. In the accompanying audited balance sheet, as of December 31, 2024, the Company had a balance of $13.5 million due for legal fees incurred as a result of mounting a defense for the Company and Dr. Hing C. Wong, our Founder and Chief Executive Officer. In January 2025, the Company received a $2.0 million insurance payment which was used to offset obligations for Dr. Wong's legal fees. On December 30, 2025, the Company entered a settlement agreement with Cooley LLP ("Cooley") related to the remaining balance of $7.5 million still outstanding for the payment of legal fees incurred in connection the defense of Dr. Wong. As a result of that agreement, the Company, Dr. Wong and Cooley agreed to settle a $7.5 million obligation for $2.0 million in cash and contingent payments up to $5.5 million upon achievement of certain triggering events, all of which were deemed to be remote as of December 31, 2025. In accordance with the terms of the settlement agreement, $500,000 was paid on December 31, 2025. Based on an amendment to the settlement agreement, the Company paid $750,000 on March 20, 2026, and will pay the remaining $750,000 upon the earlier of the completion of a financing for at least $6.0 million in gross proceeds or August 31, 2026. After this settlement, as of December 31, 2025, the Company has a liability of $6.2 million for remaining amounts owed for legal fees related to the Arbitration which continue to remain outstanding.

On December 9, 2025, the Company entered into a settlement agreement with its contract development and manufacturing organization, EirGenix, Inc. ("EirGenix"). Outstanding obligations owed to EirGenix Inc. related to manufacturing costs were $1.7 million. The parties agreed to reduce this amount to $1.2 million, of which the Company paid $620,000 on March 3, 2026 and will pay an additional $620,000 on or before April 30, 2026.

The Company owns a property which we are renovating to create offices, laboratories, and a biologics manufacturing facility to produce clinical trial quantities of material to serve our needs, the needs of our licensees, and other small clinical-stage immunotherapeutic companies. We are actively seeking financing to complete this project. On August 15, 2022, the Company entered into a loan and security agreement (the "2022 Loan Agreement") with Cogent Bank, pursuant to which it received $6.5 million in proceeds to purchase our property at which the Company planned to build a facility to manufacture biologics and upgrade its research laboratory facilities. The loan is secured by a first priority lien on the property. As of December 31, 2025, certain subcontractors had filed mechanics liens related to unpaid invoices issued in connection with construction. The 2022 Loan Agreement contains a provision for a discretionary default in the event that the Company fails to pay sums due in connection with construction of any improvements; however, as of the reporting date, the lender has not elected to do so. As of December 31, 2025, the Company has reported the balance $6.2 million for this loan as Short-term debt, net. As discussed below, on October 24, 2025, the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure mechanics liens.

As of December 31, 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. ("B&I"), 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 responded in a timely manner. The cases have been consolidated, and a Case Management conference was held. On February 19, 2026, a stipulation was submitted to the Court for a settlement and release agreement between the Company and B&I calling for payment of a total of $860,000 in installments in settlement of amounts owed and an allowance for interest and other fees the last installment of which is payable on or before May 31, 2026. There was no gain or loss on the settlement with B&I.

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

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

Because of the numerous risks and uncertainties associated with the clinical development and commercialization of immunotherapeutics, we are unable to estimate the exact amount of capital requirements to pursue these activities. Our funding requirements will depend on many factors, including, but not limited to:

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

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

Summary of Statements of Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2024 and 2025:

	Years Ended December 31,	
	2024	2025
Cash used in operating activities	$ (14,227,428)	$ (13,391,617)
Cash (used in) provided by investing activities	(261,617)	—
Cash provided by financing activities	15,568,516	10,669,509
Net decrease in cash and cash equivalents	**$ 1,079,471**	**$ (2,722,108)**

Operating Activities

Net cash used in operating activities was $14.2 million for the year ended December 31, 2024 and $13.4 million for the year ended December 31, 2025.

Cash used in operating activities for the year ended December 31, 2024 consisted primarily of a net loss of $30.0 million, which includes $15.9 million of legal expenses related to legal proceedings and a $1.3 million loss related to a misdirection of funds resulting from the Company being a victim of criminal activity. Cash provided by operating activities included an $11.9 million increase resulting from the increase of accounts payable and other liabilities; a $1.0 million increase resulting from a decrease in accounts receivable; and an $831,622 increase related to a decrease in prepaid expenses and other assets. Adjustments for noncash changes also gave rise to an increase in cash from operating activities, including increases of $1.2 million for depreciation, amortization and accretion and a $1.0 million from unrealized losses.

Cash used in operating activities for the year ended December 31, 2025 consisted primarily of net loss for the period of $8.0 million, including a $1.5 million impairment on a long-lived assets, a gain on the extinguishment of liability related to arbitration legal fees of $5.5 million, a decrease in accounts payable of $3.5 million and an adjustment for the change in fair value of a contingent liability in the amount of $1.1 million. Cash provided by operating activities include $1.0 million in depreciation and accretion expense, $768,623 for stock-based compensation, $150,000 for a Commitment Fee paid in shares of the Company's Common Stock, $273,422 for the change in fair value of investments, $263,974 for a loss on the sale of Put Shares issued under the provisions of the SEPA and $692,015 net decrease in accounts receivable, prepaid expenses and other assets.

Investing Activities

For the year ended December 31, 2024, cash used in investing activities was $261,617, consisting of cash used for construction of our new headquarters and manufacturing facility. There was no cash used in or provided by investing activities for the year ended December 31, 2025.

Financing Activities

For the year ended December 31, 2024, cash provided by financing activities was $15.6 million, consisting of $6.5 million of cash provided through the issuance of Common Stock, $6.9 million of cash provided through the issuance of Secured Notes, $2.9 million of cash provided through the issuance of Common Stock Warrants, partially offset by $119,398 of cash used for debt repayment and $638,045 of cash used for issuance costs for Common Stock and Common Stock Warrants.

For the year ended December 31, 2025, cash provided by financing activities was $10.7 million, consisting of gross proceeds of $5.5 million of cash provided through the issuance of Common Stock, $2.5 million from the sale of Common Stock under the Company's Standby Equity Purchase Agreement, $3.8 million of cash provided through the issuance of Pre-funded Warrants and $150,000 in gross proceeds upon the issuance of a promissory note, partially offset by $127,623 of cash used for debt repayment and $1.2 million of cash used for issuance costs for Common Stock and Pre-funded Warrants.

Noncash Transactions

During the year ended December 31, 2025, there were significant noncash transactions. The Company restructured and extinguished $7.4 million of Secured Notes and accumulated accretion for a fixed bonus payable upon Maturity Date, in exchange for shares of Common Stock, warrants to exercise for Common Stock, and the right to receive proceeds upon the liquidation or sale of a portion of the Company's shares of Wugen common stock. Because this was a transaction with related parties, the $3.5 million gain from restructuring was recorded to additional paid-in capital for the year ended December 31, 2025.

Also during this period, the Company closed on financing transactions with an existing investor, giving rise to a dividend to an investor as a result of the difference between gross proceeds from the transactions and the fair value of securities issued. These transactions consisted of a $5.0 million equity financing, which included the repricing of previously issued warrants, and a $4.0 million warrant inducement transaction, which involved repricing existing warrants and exercise of those warrants at the new price, as well as issuance of additional warrants to purchase the Company's Common Stock. The Company estimated the fair value of the securities issued and repriced warrants was $23.3 million for both transactions. The difference between the gross proceeds and fair value was recognized as an equity dividend to investor of $14.3 million, which the Company recorded in additional paid-in capital as of December 31, 2025.

Contractual Obligations and Commitments

The Company has a non-cancellable operating lease agreements related to our facilities in Miramar, Florida. Effective on March 1, 2022, we entered into a lease extension for our current location for a period of two years, ending February 29, 2024. On January 30, 2024, we entered into a new one-year lease for the same location, effective on March 1, 2024. On January 27, 2025, we entered into a Lease Modification and Extension Agreement for a one-year lease for the same location, effective on March 1, 2025. On February 2, 2026, we entered a Lease Modification and Extension Agreement for a one-year lease, effective on March 1, 2026.

We have commitments with a third-party manufacturing organization to supply us with clinical grade materials. As of December 31, 2025, we are under contract for obligations of $396,100 that we expect to pay during the year ending December 31, 2026. In the normal course of business, we enter into contracts for non-clinical studies, preclinical testing, and other services and products. These contracts generally provide for termination following a certain period after notice and therefore we believe that our non-cancellable obligations under these agreements are not material.

Cogent Loan Agreement

On August 15, 2022, we entered into a loan and security agreement with Cogent Bank to partially fund our purchase of the property that will become our new headquarters. The agreement provides for a term loan of up to $6.5 million. Amounts outstanding on the term loan will accrue interest at a fixed rate per annum equal to 5.75%. We were obligated to make interest-only payments on the term loan from September 2022 through August 2023 and principal and interest payments in 47 equal monthly installments, based on a 25-year amortization schedule, commencing September 15, 2023 followed by one final balloon payment of all remaining principal, interest and fees due on the maturity date of August 15, 2027. Our obligations under the agreement are secured by, among other things, a mortgage on our new corporate headquarters and related real property. As of December 31, 2025, $6.2 million was outstanding under the term loan and we were in current in our interest and principal payments. In accordance with the terms of our loan and security agreement, the Company maintains an account at Cogent Bank as security, with a balance sufficient for the payment of interest, principal and insurance costs for a period of 90 - 120 days.

On October 24, 2025, Cogent Bank notified the Company in written demand pursuant to Section 7.2(3) of the Loan Agreement requiring the Company cure the mechanics liens no later than thirty (30) days. The demand required the Company to (i) satisfy and discharge all the Claims of Lien and record appropriate satisfactions to be recorded in the Public Records of Broward County, Florida for all of the Claims of Lien, and (ii) resolve all pending litigation against the Borrower and the mortgaged property described in the Mortgage and causing such claims in the Foreclosure Actions to be dismissed and all related notices of lis pendens to be released. The Company and Cogent Bank have had negotiations to come to terms on a forbearance agreement to provide additional time for the Company to comply with the demands Cogent Bank made in the demand letter.

Settlement Agreements for Payment of Past Due Amounts

The Company entered into the Settlement Agreement to avoid the costs, disruption and distraction of further litigation. As of December 31, 2024, the Company had a balance of $13.5 million due for legal fees incurred as a result of mounting a defense for the Company and our Chief Executive Officer. In January 2025, the Company received a $2.0 million insurance payment which was used to offset obligations for legal fees for Dr. Hing C. Wong, our Chief Executive Officer. On December 30, 2025, the Company and Dr. Wong entered a settlement agreement with Cooley LLP ("Cooley") related to a past due obligation arising from legal fees incurred in connection the defense of Dr. Wong. As a result of that agreement, the Company, Dr. Wong and Cooley agreed to settle a $7.5 million obligation for $2.0 million in cash and contingent payments up to $5.5 million upon achievement of certain triggering events, all of which were deemed to be remote as of December 31, 2025. In accordance with the terms of the settlement agreement, $500,000 was paid on December 31, 2025. Based on an amendment to the settlement agreement, the Company paid $750,000 on March 20, 2026, and will pay the remaining $750,000 upon the earlier of the completion of a financing for at least $4.0 million in gross proceeds or August 31, 2026.

On December 9, 2025, the Company entered into a settlement agreement with its contract development and manufacturing organization, EirGenix, Inc. ("EirGenix"). Outstanding obligations owed to EirGenix Inc. related to manufacturing costs were $1.7 million. The parties agreed to reduce this amount to $1.2 million if the amount was paid in full by April 30, 2026. The Company paid $620,000 on March 3, 2026.

On February 19, 2026, a stipulation was submitted to the Court for a settlement and release agreement between the Company and B&I calling for payment of a total of $860,000 in installments in settlement of amounts owed and an allowance for interest and other fees the last installment of which is payable on or before May 31, 2026.

Critical Accounting Policies, Significant Judgements and Use of Estimates

The audited financial statements included elsewhere in this Annual Report are prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP"), which requires the use of estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses in the periods presented. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgements about the carrying value of assets and liabilities that are not readily apparent from other sources. We believe the accounting estimates employed are appropriate and the resulting balances are reasonable; however, due to the inherent uncertainties in developing estimates, actual results could differ from the original estimates, requiring adjustments to these balances in future periods. Refer to Note 1 to our audited financial statements included elsewhere in this Annual Report for our significant accounting policies related to our critical accounting estimates.

We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgements and estimates.

Revenue Recognition

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

If all conditions are not met for revenue recognition, the Company recognizes deferred revenue. The Company's policy is to recognize deferred revenue only to the extent product release occurred after meeting specification required, product is shipped, and cash payment is received.

Fair Value Measurements

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

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

Investments

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

When consideration is an equity interest in a private entity whose equity has limited marketability with no readily determinable fair value and for which the Company does not have significant influence over the investee, the Company measures the equity interest using the measurement alternative, at cost less impairment, adjusted for observable price changes in orderly transactions for the identical or similar investment of the same issuer (ASC Topic 321, Investments - Equity Securities), unless the fair value method is otherwise elected. If the Company elects to measure an equity security at fair value, the entity shall measure all identical or similar investments of the same issuer, including future purchases of identical or similar investments of the same issuer, at fair value. The election to measure those securities at fair value shall be irrevocable. Any resulting gains or losses on the securities for which that election is made shall be recorded in earnings at the time of the election. See Note 3. Fair Value of Financial Instruments.

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

During the year ended December 31, 2025, Wugen has its first closing for a Series C Preferred Stock equity offering. While this closing was completed with only existing investors and was not widely marketed, we considered that these parties invested nearly $100.0 million through the purchase of shares in cash to through conversion of debt. In addition, they are sophisticated investors who are market participants with knowledge of the life sciences industry as well as Wugen. Therefore, we considered this first closing of the Series C Preferred Stock equity offering to be an orderly transaction. Wugen may have subsequent closings for this offering in the future, at which time the Company will assess the impact on our investment in Wugen common shares. During the period, the Company utilized a combination of valuation techniques, consisting of adjusted enterprise valuation method and the backsolve method (based on the capital raise described above) to estimate the fair value. Wugen is a private company, and we have a limited amount of information available to us. We are aware of the sensitivity of the backsolve method to the quality of inputs, which can sometimes be subjective, especially when relying on a single recent funding event. To mitigate the risks of using a backsolve valuation approach, the Company used the adjusted enterprise valuation method in combination with the backsolve method.

The Company concluded that the fair value of the Wugen investment is $1.3 million and recognized an unrealized net loss of $273,422 as of December 31, 2025. The Company also concluded the fair value of the related contingent liability for the rights to proceeds from the sale or liquidation of Wugen shares is $692,531 and recognized an unrealized net gain of $1.1 million as of December 31, 2025. A portion of the change in fair value of the contingent liability was recorded in additional paid-in capital upon conversion of the Secured Notes.

Standby Equity Purchase Agreement

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

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

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

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

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

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

- The gain (loss) for the excess (deficit) of (a) the carrying amount of the asset or liability for the financial instrument plus the proceeds received and (b) the fair value of the common shares.
- Any discount, issuance or transaction costs incurred in conjunction with the settlement of the put shares.

Other than the above, there have been no material changes to our critical accounting policies and estimates from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies, Significant Judgements and Use of Estimates" in our Annual Report. For all of the significant accounting policies see Note 1 to our Annual Report.

Stock-based Compensation

As described in Note 1 and Note 11 to our audited financial statements included elsewhere in this Annual Report, we maintain a stock-based compensation plan as a long-term incentive for employees, non-employees, and directors. The plan allows for grants of incentive stock options, non-qualified stock options, and other forms of equity awards. We have granted options with service-based and performance-based vesting conditions.

We measure our stock-based awards granted to employees and directors based on the estimated fair value of the option on the date of grant (grant date fair value) and recognize compensation expense over the vesting period. Compensation expense is recorded as either research and development or general and administrative expenses in the statements of operations based on the function to which the related services are provided. Forfeitures are accounted for as they occur. We estimate grant date fair value using the Black-Scholes option-pricing model.

For stock option grants with service-based vesting, stock-based compensation expense represents the portion of the grant date fair value of employee stock option grants recognized over the requisite service period of the awards on a straight-line basis, net of estimated forfeitures. For options that vest upon the achievement of performance milestones, the Company estimates fair value at the date of grant and compensation expense is recognized using the accelerated attribution method when it is determined that the performance criteria are probable of being met.

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

- *Fair Value of Common Stock*—Prior to our initial public offering, the estimated fair value of our Common Stock was determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuation of our Common Stock as well as our Board's assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation to the date of the grant. Since the completion of our initial public offering on July 19, 2021, the fair value of each share of Common Stock underlying stock option grants is based the quoted market price on the primary stock exchange on which our Common Stock is traded on the day the stock award or option is granted.
- *Expected term*—The expected term of stock options is determined using the "simplified" method, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data.
- *Expected volatility*—Since there is no trading history for our Common Stock, the expected volatility was estimated based on the historical equity volatility for comparable publicly traded biotechnology companies. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty.
- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury Bond in effect at the time of grant for periods corresponding with the expected term of the exit event.
- *Dividend yield*—The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on our Common Stock.

Income Taxes

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

As of December 31, 2024 and 2025, we had available federal net operating loss ("NOL") carryforwards of $62.2 million and $70.0 million, respectively. We also had available state NOLs carryforwards of approximately $62.3 million and $70.2 million, as of December 31, 2024 and 2025, respectively. The federal and state NOLs will carryforward indefinitely. The federal NOLs are available to offset 80% of taxable income for state taxes for tax years starting after 2020. In addition, we had federal research and development credits carryforwards of $1.5 million and $1.7 million, as of December 31, 2024 and 2025, respectively. These credits are available to reduce future federal income taxes, if any, and carryforwards expire from 2038 through 2045 and are subject to review and possible adjustment.

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

We record unrecognized tax benefits as liabilities or reduce the underlying tax attribute, as applicable, and adjust them when our judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from our current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available.

Recent Accounting Pronouncements

See Note 1 to our audited financial statements included elsewhere in this Annual Report for more information about recent accounting pronouncements.

Emerging Growth Company and Smaller Company Reporting Status

As an emerging growth company, or EGC, under the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited financial statements in a registration statement for an initial public offering, or IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements.

We may remain classified as an EGC until the December 31, 2026, although if the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $1 billion of non-convertible debt over a three-year period.

We are also a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act. Similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations, such as an ability to provide simplified executive compensation information and only two years of audited financial statements in an annual report on Form 10-K, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure.

Item 7A Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 under the Exchange Act and are not required to provide the information under this item.

Item 8 Financial Statements and Supplementary Data.

HCW Biologics Inc.
Index to Financial Statements

Years ended December 31, 2024 and 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and the Board of Directors of HCW Biologics Inc.
Miramar, Florida

Opinion on the Financial Statements

We have audited the accompanying balance sheet of HCW Biologics Inc (the "Company") as of December 31, 2025 and 2024, the related statements of operations, stockholders' equity (deficit), and cash flows for the year ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the year ended December 31, 2025 and 2024, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, negative cash flows from operations, negative working capital and the need for funding to support its operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provide a reasonable basis for our opinion.

/s/ Crowe LLP

We have served as the Company's auditor since September 2024.

Indianapolis, Indiana

March 31, 2026

HCW Biologics Inc.
Balance Sheets

	December 31, 2024	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,674,572	$ 1,952,464
Accounts receivable, net	582,201	32,175
Prepaid expenses	328,181	222,156
Other current assets	113,528	77,564
Total current assets	5,698,482	2,284,359
Investments	1,599,751	1,326,329
Property, plant and equipment, net	22,909,869	20,880,849
Other assets	28,476	28,476
Total assets	$ 30,236,578	$ 24,520,013
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Liabilities		
Current liabilities:		
Accounts payable	$ 22,332,261	$ 13,143,394
Accrued liabilities and other current liabilities	981,940	1,110,104
Short-term debt, net	6,314,684	6,809,215
Total current liabilities	29,628,885	21,062,713
Debt, net	7,377,865	—
Contingent liability - related party	—	692,531
Total liabilities	37,006,750	21,755,244
Commitments and contingencies (Note 17)		
Stockholders' equity (deficit):		
Common stock:		
Common, $0.0001 par value; 250,000,000 shares authorized and 1,113,532 shares issued at December 31, 2024; 250,000,000 shares authorized and 3,279,812 shares issued at December 31, 2025	111	328
Additional paid-in capital	93,785,854	111,280,287
Accumulated deficit	(100,556,137)	(108,515,846)
Total stockholders' equity (deficit)	(6,770,172)	2,764,769
Total liabilities and stockholders' equity (deficit)	$ 30,236,578	$ 24,520,013

The accompanying notes are an integral part of these financial statements.

HCW Biologics Inc.
Statements of Operations

	Years Ended December 31,	
	2024	2025
Revenues:		
Revenues	$ 2,566,792	$ 54,232
Cost of revenues	(1,607,389)	(43,386)
Net revenues	959,403	10,846
Operating expenses:		
Research and development	6,388,994	5,442,884
General and administrative	6,816,449	7,701,281
Legal expenses (recoveries), net	15,910,480	(1,470,809)
Impairment of long-lived asset	—	1,500,000
Nonoperating loss	1,300,000	—
Total operating expenses	30,415,923	13,173,356
Loss from operations	(29,456,520)	(13,162,510)
Interest expense	(654,284)	(845,051)
Change in fair value of investment	—	(273,422)
Change in fair value of contingent liability	—	1,055,826
Loss on sale of put shares	—	(263,974)
Gain on extinguishment of liability	—	5,461,046
Other income, net	86,990	68,376
Net loss	$ (30,023,814)	$ (7,959,709)
Equity dividend to investor	—	(14,338,993)
Net loss attributable to Common Stockholders	$ (30,023,814)	$ (22,298,702)
Net loss per share, basic and diluted	$ (30.96)	$ (10.63)
Weighted average shares outstanding, basic and diluted	969,825	2,097,701

The accompanying notes are an integral part of these financial statements.

HCW Biologics Inc.
Statements of Changes in Stockholders' Equity (Deficit)

	Stockholders' Equity (Deficit)				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	(Deficit)
Balance, January 1, 2024	900,628	$ 90	$ 83,993,950	$ (70,532,323)	$ 13,461,717
Issuance of Common Stock upon exercise of stock options	336	—	2,444	—	2,444
Issuance of Common Stock upon equity subscription	44,643	5	2,500,001	—	2,500,006
Issuance of Common Stock	104,000	10	2,452,655	—	2,452,665
Issuance of warrants	—	—	4,465,588	—	4,465,588
Exercise of pre-funded warrants	63,925	6	250	—	256
Issuance cost of Common Stock	—	—	(226,201)	—	(226,201)
Issuance costs of Common Stock warrants	—	—	(411,844)	—	(411,844)
Stock-based compensation	—	—	1,009,011	—	1,009,011
Net loss	—	—	—	(30,023,814)	(30,023,814)
Balance, December 31, 2024	**1,113,532**	**$ 111**	**$ 93,785,854**	**$ (100,556,137)**	**$ (6,770,172)**
Issuance of Common Stock (1)	727,447	73	4,496,855	—	4,496,928
Issuance of pre-funded warrants	—	-	4,207,718	—	4,207,718
Issuance of Common Stock warrants	—	-	14,948,620	—	14,948,620
Exercise of pre-funded warrants	513,140	51	-	—	51
Issuance cost of Common Stock	—	-	(269,680)	—	(269,680)
Issuance cost of Common Stock warrants	—	-	(712,453)	—	(712,453)
Issuance cost of pre-funded warrants	—	-	(227,646)	—	(227,646)
Equity dividend to investor	—	-	(14,338,993)	—	(14,338,993)
Issuance of Common Stock upon exercise of stock options	205	-	1,654	—	1,654
Issuance of Common Stock to Square Gate	9,616	1	149,999	—	150,000
Issuance of Common Stock under Standby Equity Purchase Agreement	600,000	60	2,804,845	—	2,804,905
Issuance of Common Stock to extinguish restructured debt	253,083	25	1,774,087	—	1,774,112
Issuance of Common Stock warrants to extinguish restructured debt	—	-	544,249	—	544,249
Gain on conversion of debt with related parties	—	-	3,346,562	—	3,346,562
Stock-based compensation	—	-	768,623	—	768,623
Adjustment for reverse stock split	62,789	7	(7)	—	—
Net loss	—	-	-	(7,959,709)	(7,959,709)
Balance, December 31, 2025	**3,279,812**	**$ 328**	**$ 111,280,287**	**$ (108,515,846)**	**$ 2,764,769**

(1) Represents the aggregate fair value of 1,704,447 shares of common stock, which includes 727,447 shares that have been issued and 977,000 shares held in abeyance (See Note 7 - Sale of Common Stock Warrants).

The accompanying notes are an integral part of these financial statements.

HCW Biologics Inc.
Statements of Cash Flows

	Years Ended December 31,	
	2024	**2025**
Cash flows from operating activities:		
Net loss	$ (30,023,814)	$ (7,959,709)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and accretion	1,184,389	1,041,771
Stock-based compensation	1,009,011	768,623
Commitment fee	—	150,000
Change in fair value of investment	—	273,422
Change in fair value of contingent liability	—	(1,055,826)
Gain on extinguishment of liability	—	(5,461,046)
Loss on sale of put shares	—	263,974
Loss on conversion of debt with related parties	—	(131,135)
Impairment of long-lived asset	—	1,500,000
Changes in the carrying amount of right-of-use asset	(418)	—
Changes in operating assets and liabilities:		
Accounts receivable	953,556	550,026
Prepaid expenses and other assets	831,622	141,989
Accounts payable and other liabilities	11,874,767	(3,473,706)
Operating lease liability	(56,541)	—
Net cash used in operating activities	(14,227,428)	(13,391,617)
Cash flows from investing activities:		
Purchases of property and equipment	(261,617)	—
Net cash used in investing activities	(261,617)	—
Cash flows from financing activities:		
Proceeds from issuance of Common Stock, net	6,462,834	5,493,086
Proceeds from issuance of Common Stock under SEPA, net	—	2,540,931
Proceeds from issuance of pre-funded warrants, net	—	3,822,894
Proceeds from Common Stock warrants	2,958,125	-
Proceeds from issuance of debt	6,905,000	150,000
Issuance costs for Common Stock, pre-funded warrants, and Common Stock warrants	(638,045)	(1,209,779)
Debt repayment	(119,398)	(127,623)
Net cash provided by financing activities	15,568,516	10,669,509
Net increase (decrease) in cash and cash equivalents	1,079,471	(2,722,108)
Cash and cash equivalents at the beginning of the period	3,595,101	4,674,572
Cash and cash equivalents at the end of the period	$ 4,674,572	$ 1,952,464
Supplemental disclosure of cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 569,770	$ 601,661
Noncash investing activities:		
Capital expenditures accrued, but not yet paid	$ 2,010,478	$ —
Purchases of property and equipment included in accounts payable	$ 829,207	$ 22,000
Noncash financing activities:		
Extinguishment of restructured debt with related parties	$ —	$ 7,440,462
Issuance of Common Stock, warrants and other rights upon extinguishment of restructured debt with related parties	$ —	$ 3,962,766
Gain on extinguishment of debt with related parties	$ —	$ 3,477,696
Equity dividend to investor	$ —	$ 14,338,993

The accompanying notes are an integral part of these financial statements.

HCW Biologics Inc.
Notes to the Financial Statements
December 31, 2024 and 2025

1. Organization and Summary of Significant Accounting Policies

Organization

HCW Biologics Inc. ("HCW Biologics" or the "Company") is a clinical-stage biopharmaceutical company developing transformative fusion immunotherapeutics to support or treat diseases promoted by chronic inflammation. Our assets include both clinical-stage immunotherapeutics as well as commercial-ready proprietary compounds for use as reagents in the production of immunotherapeutics for the treatment of infectious diseases and cancer. The Company believes low-grade chronic inflammation is a significant contributing factor to several diseases and conditions, such as autoimmune disorders and other proinflammatory diseases such as neurodegenerative disease, cancer, and senescence-associated dysplasia. The Company is located in Miramar, Florida and was incorporated in the state of Delaware in April 2018.

Reverse Stock Split

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

In addition to the Reverse Stock Split, the stockholders approved two other proposals at the Special Meeting: (1) use of the Company's equity line of credit to raise up to $40.0 million through sales of shares of the Company's Common Stock thereunder and (2) execution of the principal terms for the conversion of up to approximately $6.9 million of the outstanding principal of Secured Notes into shares of Common Stock. See Note 5. Debt -- Troubled Debt Restructuring of Secured Notes.

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

Liquidity and Going Concern

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

As of December 31, 2025, the Company had not generated any revenue from commercial product sales of its internally developed immunotherapeutic products. During its development activities, the Company has sustained operating losses experienced negative operating cash flows and negative working capital position and expects to continue to incur operating losses for the foreseeable future. Since inception to December 31, 2025, the Company incurred cumulative net losses of $105.8 million.

For the year ended December 31, 2025, the Company has funded operations primarily through the sale of stock; issuance of Senior Notes; and revenues generated from the Company's exclusive worldwide license with Wugen, Inc. ("Wugen"), pursuant to which Wugen licensed limited rights to develop, manufacture, and commercialize cell therapy treatments for cancer based on two of the Company's internally-developed multi-cytokine fusion protein molecules, and its manufacturing and supply arrangement with Wugen. For the years ended December 31, 2024 and 2025, the Company recognized revenues generated from the supply of clinical and research grade material to Wugen of $2.6 million and $54,232, respectively. From inception on December 24, 2020 to December 31, 2025, the Company recognized over $16.2 million in revenue as a result of the Wugen license.

For the year ended December 31, 2025, the Company agreed to Wugen's request to suspend the Wugen License for a period of one year, ending on May 29, 2026. Until the end of the term, the Company has the right to seek another licensee for the molecules HCW9206 and HCW9201, which were the subject of the Wugen license. During the period of suspension, Wugen plans to focus its ongoing pivotal clinical trials for its CAR-T clinical program. In January 2026, Wugen received a Breakthrough Therapy Designation from the U.S. Food and Drug Administration ("FDA") for its investigational CAR-T cell therapy, Sofi-cel. Sofi-cel is an investigational, potential first-in-class, allogeneic, anti-CD7 CAR-T cell therapy currently under evaluation in a pivotal trial (T-RRex) for patients with relapsed or refractory (R/R) T cell acute lymphoblastic leukemia or T cell lymphoblastic lymphoma (T-ALL/LBL). Breakthrough Therapy Designation is intended to expedite the development and review of medicines for serious or life-threatening conditions with evidence of a substantial clinical improvement. Wugen plans to file a BLA in 2027. This therapy holds the potential to be the first approved "off-the-shelf" CART-T for T-cell malignancies. The Company continues to hold a significant number of shares of Wugen common stock.

On November 17, 2025, the Company and Trimmune entered into an Amended and Restated License, Research and Co-Development Agreement ("Trimmune License") following the assignment of the original WY Biotech License to Trimmune. In accordance with the terms of the Trimmune License, the deal closing took place upon receipt of the upfront payment. On March 16, 2026, the Company received the full upfront license fee, which consisted of $3.5 million in gross proceeds, or $2.9 million net of taxes, and a transferable minority equity interest in Trimmune. See Note 18. Subsequent Events.

Pursuant to the terms of the Trimmune License, the Company retains a 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 (the "Opt-in Territory") following completion of the Phase 1 clinical trial. Trimmune is responsible for funding all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization activities for the licensed molecule in its territory.

On December 30, 2025, the Company entered a settlement agreement with Cooley LLP ("Cooley") related to legal fees incurred in connection the defense of Dr. Wong. As a result of that agreement, the Company, Dr. Wong and Cooley agreed to settle a $7.5 million obligation for $2.0 million in cash and contingent payments up to $5.5 million upon achievement of certain triggering events, all of which were deemed to be remote as of December 31, 2025. In accordance with the terms of the settlement agreement, $500,000 was paid on December 31, 2025. Based on an amendment to the settlement agreement, the Company paid $750,000 on March 20, 2026, and will pay the remaining $750,000 upon the earlier of the completion of a financing for at least $4.0 million in gross proceeds or August 31, 2026. After this settlement, as of December 31, 2025, the Company has a liability of $6.2 million for remaining amounts owed for legal fees related to the Arbitration which continue to remain outstanding.

On December 9, 2025, the Company entered into a settlement agreement with its contract development and manufacturing organization, EirGenix, Inc. ("EirGenix"). Outstanding obligations owed to EirGenix related to manufacturing costs were $1.7 million. The parties agreed to reduce this amount to $1.2 million if the amount was paid in full by April 30, 2026, but if the Company fails to do so, the entire $1.7 million plus interest and penalties will be due. The Company paid $620,000 on March 3, 2026. See Note 18. Subsequent Events.

Subsequent to the year ended December 31, 2025, the Company raised $5.0 million in gross cash proceeds. See Note 18. Subsequent Events. Proceeds were derived from the following transactions:

- On February 19, 2026, the Company completed a $1.5 million follow-on public offering, before offering costs with an existing institutional investor.
- As of March 16, 2026, we received the the upfront license fee from Trimmune, including $3.5 million before taxes.

As of December 31, 2025, the conclusion of a going concern assessment, before consideration of the Company's financing plans, was that there is substantial doubt about the Company's ability to continue as a going concern. The Company considered future elements of its financing plan that were probable and likely to be implemented within the next year to determine if financing activities currently underway are sufficient mitigate the substantial doubt in the going concern analysis, in addition to considering continued operating losses and the burden of obligations for expenses incurred in connection with past legal proceedings. The Company expects to complete other capital-raising transactions in 2026, with an emphasis on strategic investors and business development transactions. Management concluded that there were no mitigating circumstances which alleviated the substantial doubt over its ability to continue as a going concern. If the Company is not successful in raising additional capital through these activities, management intends to revise its business plan and reduce costs. If such revisions are insufficient, the Company may have to curtail or cease operations.

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

Summary of Significant Accounting Policies

Basis of Presentation

The accompanying audited financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Reclassification of Prior Period Presentation of Legal Expenses

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

Use of Estimates

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

Segment Reporting

The Company operates and manages its business as one reportable and operating segment, which is the business of developing and commercializing novel immunotherapies for diseases promoted by chronic inflammation. The Company's chief executive officer, who is the chief operating decision maker ("CODM"), reviews financial information on an aggregate basis for allocating and evaluating financial performance. In addition, our CODM is regularly provided with detailed results of preclinical and clinical data which is considered in his decision for the allocation of resources. See Note 16. Segment Reporting for further details. The single operating segment constitutes all of the Company activity, the CODM regularly reviews the entity-wide operating results and performance. All long-lived assets are maintained in the United States of America.

Cash and Cash Equivalents

Cash and cash equivalents consist of demand deposits at financial institutions, money market funds, and highly liquid investments with original maturities of three months or less.

Fair Value Measurements

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

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

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

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

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values, as disclosed in Note 3, takes into account the market for the Company's financial assets and liabilities, the associated credit risk, and other factors as required. The Company considers active markets as those in which transactions for the assets or liabilities occur in sufficient frequency and volume to provide pricing information on an ongoing basis.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash, cash equivalents, accounts receivable, and investments. The Company's cash and cash equivalents are deposited in accounts with financial institutions that management believes are of high credit quality. Such deposits may, at times, exceed federally insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

For the year ended December 31, 2025, the Company recognized revenues of $54,232. All of the Company's revenues were derived from the supply of clinical grade material to Wugen under the supply agreement between Wugen and the Company, as contemplated in the Wugen License. As of December 31, 2025, there was a balance of $32,175 in accounts receivable related to sales to Wugen on the accompanying audited balance sheets, which was collected as of the date of issuance of the Annual Report. Since December 24, 2020, the Company holds 2,174,311 shares of Wugen common stock, which were received as consideration for the Wugen License on December 24, 2020. Currently, these shares represent 1.61% equity ownership interest of Wugen, based on fully diluted, issued and outstanding shares as of December 31, 2025. The Company has not been able to realize any benefit from the sale of these shares, as they are not currently traded on any public market and thus have limited marketability. A portion of these shares have been pledged to certain noteholders as part of the terms for restructure debt or conversion. See Note 5. Debt - Troubled Debt Restructuring of Secured Notes.

The Company is highly dependent on a third-party manufacturer to supply drug products for its research and development activities of its programs, including clinical and non-clinical studies. To mitigate this risk, the Company endeavors to use multiple organizations for third-party manufacturing. These programs could be adversely affected by a significant interruption in the supply of such drug products. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Property, Plant and Equipment, Net

Property, plant and equipment are stated at cost less accumulated depreciation. The Company has elected to use component depreciation for property, plant and equipment, which is permitted but not required under US GAAP. A long-lived asset may consist of several different and significant physical components.

A component is a tangible part or portion of property, plant and equipment that (a) can be separately identified as an asset and depreciated or amortized over its own separate expected useful life and (b) is expected to provide economic benefit for more than one year. If a component has an expected useful life that differs from the expected useful life of the asset to which it relates, the cost should be accounted for separately and depreciated or amortized over its separate expected useful life. The Company identifies the components at the time of the acquisition or construction of the long-lived asset. The total capitalized costs of the long-lived asset is allocated to components either on a specific identification basis or based on relative fair value.

Depreciation expense for each component is calculated using the straight-line method over the estimated useful lives of the assets within the component, which range from 3 to 39 years. Land is not subjected to the recording of depreciation expense because it has an infinite life. Leasehold improvements are amortized on a straight-line method over the shorter of the useful life of the leasehold improvement or the term of the lease.

Construction-in-progress represents property and buildings under construction and consists of construction expenditures, equipment procurement, and other direct costs attributable to the construction. Construction-in-progress is not depreciated. Upon completion and becoming ready for intended use, construction-in-progress is reclassified to the appropriate component within property, plant and equipment. If a component that is separately identified and depreciated is replaced, the replacement should be capitalized at the time of its installation if the capitalization criteria have been met. The net book value of the component that was replaced, if any, should be charged to depreciation expense in the period it is replaced. If not separately identifiable in the accounting records, the estimated net book value of an item to be replaced should be calculated by estimating the previously capitalized costs of the replaced component and subtracting an estimate of accumulated depreciation. The estimate of accumulated depreciation is calculated using the same depreciation method and expected useful life previously used to depreciate the total asset to which the component relates.

The following table sets forth the estimated useful lives for property, plant and equipment:

	Estimated Useful Lives
Building	39 years
Property	5 - 15 years
Laboratory equipment	5 years
Office equipment	3 years
Furniture and fixtures	7 years
Leasehold improvements	The lesser of the lease term or life of the asset

Costs, such as repairs and maintenance, associated with replacing items not identified as a component are expensed as incurred.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for indications of possible impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amounts to the future undiscounted cash flows attributable to these assets. An impairment is recognized to the extent an asset group is not recoverable, and the carrying amount exceeds the projected discounted future cash flows arising from these assets. Impairments, if any, are recognized in earnings. There was a $1.5 million impairment to the group of assets that comprise the building project the Company has undertaken to build a manufacturing facility, upgraded laboratories, a vivarium and common areas. There was no impairment for the years ended December 31, 2024.

Collaborative Arrangements

When the Company enters into collaboration arrangements, it assesses whether the arrangements fall within the scope of FASB issued ASC 808, Collaborative Arrangements, based on whether the arrangements involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. If the payments from the collaboration partner to the Company represent consideration from a customer, such as license fees and contract research and development activities, the Company accounts for those payments within the scope of FASB issued ASC 606, Revenue from Contracts with Customers ("Topic 606"). However, if the Company concludes that the payments are not from a customer, for certain activities and associated payments, such as for certain collaborative research, development, manufacturing, and commercial activities, these payments are presented as a reduction of research and development expense or general and administrative expense, based on where the Company presents the underlying expense.

Revenue Recognition

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

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

License Grants

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

Milestone and Contingent Payments

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

Materials Supply:

The Company provides clinical and research grade materials so that licensees may develop products based on the licensed molecules. The amounts billed are recognized as revenue as the performance obligations are satisfied by the Company, once the Company determines that a contract exists.

On June 18, 2021, the Company entered into a master services agreement ("MSA") with Wugen for the supply of materials for clinical development of licensed products. Each of these transactions represents a single performance obligation that is satisfied over time. The Company recognizes revenue using an input method based on the costs incurred relative to the total expected cost, which determines the extent of the Company's progress toward completion. As part of the accounting for these arrangements, the Company must develop estimates and assumptions that require judgement to determine the progress towards completion. The Company reviews its estimate of the progress toward completion based on the best information available to recognize the cumulative progress toward completion as of the end of each reporting period, and makes revisions to such estimates, if facts and circumstances change during each reporting period. Any such revisions are recorded on a cumulative catch-up basis, noting no material revisions during the years ended December 31, 2024 and 2025. For each in process SOW, amounts are billed in the same quarter the costs are incurred.

For the years ended December 31, 2024 and 2025, the Company recognized revenues related to sale of development supply materials to Wugen of $2.6 million and $54,232, respectively.

Accounts Receivable, Net

Accounts receivable is presented in accordance the current expected credit losses ("CECL") impairment model as required under FASB ASC 326, Financial Instrument - Credit Losses ("Topic 326"). The Company estimates a reserve for expected credit losses based on existing contractual payment terms, actual payment patterns of its customers, current and future economic and market conditions and individual customer circumstances. As of December 31, 2024 and 2025, the Company determined that a reserve for expected credit losses was not required. No accounts were written off during the periods presented.

Deferred Revenue

Deferred revenue represents amounts billed, or in certain cases, yet to be billed to the Company's customer for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The current portion of deferred revenue represents the amount to be recognized within one year from the balance sheet date based on the estimated performance period of the underlying performance obligations. There were no deferred revenue balances as of December 31, 2024 and 2025.

Investments

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

When consideration is an equity interest in a private entity whose equity has limited marketability with no readily determinable fair value and for which the Company does not have significant influence over the investee, the Company measures the equity interest using the measurement alternative, at cost less impairment, adjusted for observable price changes in orderly transactions for the identical or similar investment of the same issuer (ASC Topic 321, Investments - Equity Securities), unless the fair value method is otherwise elected. If the Company elects to measure an equity security at fair value, the entity shall measure all identical or similar investments of the same issuer, including future purchases of identical or similar investments of the same issuer, at fair value. The election to measure those securities at fair value shall be irrevocable. Any resulting gains or losses on the securities for which that election is made shall be recorded in earnings at the time of the election. See Note 3. Fair Value of Financial Instruments.

For the year ended December 31, 2025, the Company elected to account for its Wugen shares, previously accounted for under the measurement alternative, at fair value as determined using financial valuation techniques and market information available. Further, the Company will remeasure the change in fair value of the Wugen shares, and related contingent liability, in subsequent reporting periods and recognize the change in earnings.

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

Operating Leases

The Company determines if an arrangement is a lease at inception. Unless the Company elects to use the practical expedient available under US GAAP lease accounting guidance, operating leases are included in Other assets, Accrued liabilities and Other current liabilities, and Other liabilities in the Company's balance sheets. Operating lease Right of Use ("ROU") assets and Operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. The operating lease ROU asset also includes any lease payments made and excludes lease incentives and initial direct costs incurred. The Company has a lease agreement with lease and non-lease components, which are accounted for separately. For short-term leases with a term of one year or less, the Company adopts the practical expedient and does not record an ROU asset or lease liability for such short-term leases.

Research and Development Expenses

Research and development costs are expensed as incurred and include salaries, benefits, and other operating costs such as outside services, supplies and allocated overhead expenses. The Company may perform research and development for its own proprietary drug candidates and technology development or for certain third parties under collaborative arrangements. For its proprietary drug candidates and its own internal technology development programs, the Company invests its own funds without reimbursement from a third party. Where the Company performs research and development activities under a clinical joint development collaboration, it records the partner's share of collaboration expenses as a reduction to research and development expense when reimbursement amounts are due under the agreement.

The Company records an accrued expense for the estimated costs of its contract manufacturing activities performed by third parties if there is no invoice. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to vendors. Payments under the contracts include upfront payments and milestone payments, which depend on factors such as the achievement of the completion of certain stages of the manufacturing process. For purposes of recognizing expense, the Company assesses whether the production process is sufficiently defined to be considered the delivery of a good, as evidenced by predictive or contractually required yields in the production process, or the delivery of a service, where processes and yields are developing and less certain. If the Company considers the process to be the delivery of a good, the Company recognizes the expense when the drug product is delivered, or otherwise bears risk of loss. If the Company considers the process to be the delivery of a service, the expense is recognized based on its best estimates of the contract manufacturer's progress towards completion of the stages in the contracts. The Company recognizes and amortizes upfront payments and accrues for liabilities based on the specific terms of each arrangement. Arrangements may provide upfront payments for certain stages of the arrangement and milestone payments for the completion of certain stages, and, accordingly, may result in advance payments for services that have not been completed or goods not delivered and liabilities for stages where the contract manufacturer is entitled to a milestone payment.

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

Accrued Research and Development Expenses

In order to properly record services that have been rendered but not yet billed to the Company, the Company reviews open contracts and purchase orders, communicates with personnel and estimates the level of service performed and the associated cost incurred for the service when has not yet been invoiced or otherwise notified of the Company of the actual cost. The majority of the Company's service providers invoice monthly or quarterly in arrears for services performed or when contractual milestones are met. The Company makes estimates of accrued expenses as of each balance sheet date in financial statements based on facts and circumstances known at that time. The Company periodically confirms the accuracy of its estimates with the service providers and adjusts if necessary. Examples of accrued research and development expenses include amounts owed to clinical sites for clinical trial expenses, collaborators, toxicology testing, and other service providers in connection with research and development activities.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses in the statements of operations and expensed as incurred, since recoverability of such expenditures is uncertain.

Stock-based Compensation

The Company measures its stock-based awards granted to employees and directors based on the estimated fair value of the option on the date of grant (grant date fair value) and recognizes compensation expense over the vesting period. Compensation expense is recorded as either research and development or general and administrative expenses in the statements of operations based on the function to which the related services are provided. The Company has granted options with service-based and performance-based vesting conditions.

The Company uses the Black-Scholes option pricing model for the respective grant to determine the grant date fair value. The Black-Scholes option pricing model requires the input of highly subjective assumptions. These variables include, but are not limited to, its stock price volatility over the term of the awards and actual and projected employee stock option exercise behaviors. Management will continue to assess the assumptions and methodologies used to calculate the estimated grant date fair value of stock-based compensation. Circumstances may change and additional data may become available over time, which could result in changes to these assumptions and methodologies and materially impact the Company's grant date fair value determination.

For stock option grants with service-based vesting, stock-based compensation expense represents the portion of the grant date fair value of employee stock option grants recognized over the requisite service period of the awards on a straight-line basis, net of estimated forfeitures. For options that vest upon the achievement of performance milestones, the Company estimates fair value at the date of grant and compensation expense is recognized using the accelerated attribution method when it is determined that the performance criteria are probable of being met.

Debt Issuance Costs

Debt issuance costs are presented in the balance sheets as a direct deduction from the carrying amount of the related debt and are amortized, using the effective interest method, as interest expense over the contractual life of the related debt.

Deferred Offering Costs

The Company defers offering costs consisting of legal, accounting and other fees and costs directly attributable to offering costs. For offerings expected to occur within 90 days, the deferred offering costs will be offset against the proceeds received upon the completion of the offering. Deferred offering costs will be recorded under Other noncurrent assets on the balance sheets. In the event an offering is terminated or the timing for completing the offering is uncertain, all of the deferred offering costs will be expensed within the Company's statements of operations in the reporting period in which the determination is made.

Income Taxes

The Company accounts for income taxes using an asset and liability approach in accordance with applicable guidance prescribed by FASB issued ASC 740, Income Taxes ("Topic 740"). Topic 740 requires that the deferred tax consequences of temporary differences between the amounts recorded in the financial statements and the amounts included in the federal and state income tax returns to be recognized in the balance sheets.

The Company makes judgments regarding the realizability of its deferred tax assets. The balance sheet carrying value of its deferred tax assets is based on whether the Company believes it is more likely than not that the Company will generate sufficient future taxable income to realize these deferred tax assets after consideration of all available evidence. The Company regularly reviews its deferred tax assets for recoverability considering historical profitability, projected future taxable income, the expected timing of the reversals of existing temporary differences and tax planning strategies. In assessing the need for a valuation allowance, the Company considers both positive and negative evidence related to the likelihood of realization of the deferred tax assets. The weight given to the positive and negative evidence is commensurate with the extent to which the evidence may be objectively verified. As such, it is generally difficult for positive evidence regarding projected future taxable income exclusive of reversing taxable temporary differences to outweigh objective negative evidence of recent financial reporting losses. Generally, cumulative losses in recent years is a significant piece of negative evidence that is difficult to overcome in determining that a valuation allowance is not needed.

The Company's tax positions may be subject to income tax audits. The Company recognizes the tax benefit of an uncertain tax position only if it is more likely than not that the position is sustainable upon examination by the taxing authority, based on the technical merits. The tax benefit recognized is measured as the largest amount of benefit which is more likely than not to be realized upon settlement with the taxing authority. The Company recognizes interest accrued and penalties related to unrecognized tax benefits in its tax provision. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for income taxes includes the effects of any accruals that the Company believes are appropriate, as well as the related net interest and penalties. The Company had no accrual for interest or penalties on its balance sheets as of December 31, 2024 and 2025, and has not recognized interest or penalties in its statements of operations for the years ended December 31, 2024 and 2025.

Tax Credit Receivable

The Company may be eligible for research and development credits for its research and development activities, in accordance with Internal Revenue Code ("I.R.C.") § 41(c). The credits are generally available to offset income tax liabilities. As of December 31, 2024 and 2025, the outstanding payroll tax receivables is included in Other current assets in the accompanying balance sheets.

Net Loss Per Share

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

Standby Equity Purchase Agreement

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

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

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

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

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

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

- The gain (loss) for the excess (deficit) of (a) the carrying amount of the asset or liability for the financial instrument plus the proceeds received and (b) the fair value of the common shares.
- Any discount, issuance or transaction costs incurred in conjunction with the settlement of the put shares.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (ASU 2024-03) which requires public business entities to provide enhanced disaggregation of expenses in financial statements, including detailed disclosures on inventory purchases, employee compensation, depreciation, and amortization. The new guidance is effective for the Company for fiscal periods beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027. The Company is evaluating the impact of the standard on the Company's financial statements.

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," which requires enhanced disclosures regarding the rate reconciliation and income taxes paid, among other items. The standard is effective for annual periods beginning after December 15, 2024. The Company adopted this standard as required. The adoption of this ASU did not have a significant impact on the Company's financial statements.

In September 2025, the FASB issued Accounting Standards Update (ASU) 2025-06, Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40): Accounting for and Disclosure of Software Costs to update the accounting for internal use software costs. The guidance requires entities to start capitalizing eligible costs when (1) management has authorized and committed to funding the software project, and (2) it is probable that the project will be completed and the software will be used to perform the function intended. The guidance, which applies to all entities, is effective for fiscal years beginning after December 15, 2027, and interim periods within those fiscal years. Entities may apply the guidance using a prospective, retrospective or modified transition approach. Early adoption is permitted. The Company is evaluating the impact of the standard on the Company's financial statements.

In September 2025, the FASB issued Accounting Standards Update (ASU) 2025-07—Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-based Noncash Consideration from a Customer in a Revenue Contract to expand the scope of contracts that are excluded from derivative accounting (i.e., measured at fair value through earnings). ASU 2025-07 addresses stakeholders' concerns about (1) the application of derivative accounting to contracts with features based on the operations or activities of one of the parties to the contract and (2) the diversity in accounting for share-based noncash consideration from a customer that is consideration for the transfer of goods or services. The guidance is effective for annual reporting periods beginning after 15 December 2026, and interim periods within those annual periods. Entities may apply the guidance either on a modified retrospective or prospective basis. Early adoption is permitted. The Company is evaluating the impact of the standard on the Company's financial statements.

2. Property, Plant and Equipment, Net

Property, plant and equipment, net consists of the following:

	December 31,	
	2024	2025
Land	$ 2,150,038	$ 2,150,038
Building	6,105,570	6,105,570
Property	1,767,231	1,767,231
Laboratory equipment	2,146,637	2,146,637
Office equipment	225,369	225,369
Furniture and fixtures	292,045	292,045
Leasehold improvements	354,276	354,276
Construction in progress	13,545,161	12,023,161
	$ 26,586,327	$ 25,064,327
Less: Accumulated depreciation and amortization	(3,676,458)	(4,183,478)
Property, plant and equipment, net	$ 22,909,869	$ 20,880,849

Construction in progress of $13.5 million represents direct costs of construction and equipment incurred for the Company's new research lab and manufacturing facilities, which are not ready for their intended use. Depreciation and amortization expense for the year ended December 31, 2024 was $644,616, of which $390,209 is included in research and development expenses in the accompanying audited statements of operations. Depreciation and amortization expense for the year ended December 31, 2025 was $507,021, of which $270,016 is included in research and development expenses in the accompanying audited statements of operations.

During the years ended December 31, 2024 and 2025, the Company capitalized interest expense of $189,416 and $0, respectively, which is presented within Construction in progress in the accompanying audited balance sheets.

For the year ended December 31, 2025, the Company recognized an impairment of $1.5 million related to the group of assets related to the property it is refurbishing to create a biologics manufacturing facility, upgraded laboratory space, vivarium and common areas. As a result a result of the impairment, the net book value of this asset group is $16.6 million. In its assessment of potential indicators of impairment of the asset, the Company concluded that during the year, legal procedures were initiated by holders of mechanics liens against the Company's property with claims for nonpayment on April 17, 2025, and the Company was notified by Cogent Bank that it exercised its discretion to make a demand that the Company cure the mechanics liens on October 24, 2025. See Note 17. Commitment and Contingencies - Other Matters.

3. Fair Value of Financial Instruments

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

Money market funds included in cash and cash equivalents and U.S. government-backed securities are measured at fair value based on quoted prices in active markets, which are considered Level 1 inputs.

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

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

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

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 1,607,009	$ —	$ —	$ 1,607,009
Investment	—	—	1,326,329	1,326,329
Liabilities:				
Contingent liability	—	—	(692,531)	(692,531)
Total	$ 1,607,009	$ —	$ 633,798	$ 2,240,807

4. Accrued Liabilities and Other Current Liabilities

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

As of December 31, 2025, the Company had a balance of $1.1 million included in Accrued liabilities and other current liabilities in the accompanying audited balance sheet, consisting of $422,000 for construction expenses, $87,000 for accrued interest expense, $49,000 for manufacturing expenses, $159,000 for legal fees, $186,000 for clinical expenses, $79,000 for salary expenses and $118,000 for other accrued expenses or current liabilities.

5. Debt

Cogent Bank Loan

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

As of December 31, 2025, the Company had $6.2 million in principal outstanding under the 2022 Loan Agreement. The interest-only period was one year followed by 48 months of equal payments of principal and interest beginning on September 15, 2023 based on a 25-year amortization rate. The unamortized balance is due on August 15, 2027 (the "2022 Loan Agreement Maturity Date"), and bears interest at a fixed per annum rate equal to 5.75%. Upon the 2022 Loan Agreement Maturity Date, a final payment of unamortized principal will be due. The Company is in compliance with covenants related to current payment of principal and interest as of December 31, 2025. The Company has the option to prepay the outstanding balance of the loan prior to the 2022 Loan Agreement Maturity Date without penalty.

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

Secured Notes

As of December 31, 2024, the Company received $6.9 million in funding from the issuance of Secured Notes, which is included within Debt, net on the accompanying audited balance sheet. Investors included Dr. Hing C. Wong, Founder and Chief Executive Officer, who invested $2.4 million; Rebecca Byam, Chief Financial Officer, who invested $220,000; Lee Flowers, Senior Vice President of Business Development, who invested $25,000; Scott T. Garrett, the Chairman of the Company's board of directors, who invested $140,000; Gary M. Winer, a member of the Company's board of directors at the time of his investment, who invested $60,000; Rick S. Greene, a member of the board of directors, who invested $25,000, and other significant investors. In July and October 2024, the terms of the Secured Notes were amended, including but not limited to a fixed bonus payable on Maturity.

As of December 31, 2025, there was $325,000 of outstanding principal amount of Secured Notes reported in Short-term debt, net in the accompanying audited balance sheet. As of December 31, 2025, the Company restructured $6.6 million outstanding principal of Secured Notes by conversion to equity. The Company pledged a portion of the proceeds of the sale or liquidation of its shares of Wugen common stock ("Pledged Collateral"). The Pledged Collateral will be held and released according to the terms of the Escrow Agreement, as security for the Secured Notes.

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

If the Secured Notes are repaid on the Maturity Date, holders will receive their pro rata share of a fixed bonus payment of $3.4 million in addition to payment of outstanding principal and accrued interest. If a bonus payment is paid, there is no prepayment penalty. For the years ended December 31, 2024 and 2025, the Company recognized $527,304 and $405,222, respectively, as an expense for accretion of the fixed bonus payment due in the event the Secured Notes are repaid on the Maturity Date, presented within General and administrative expenses in the accompanying audited statements of operations.

The Secured Notes were deemed to be a hybrid instrument, consisting of a debt host with embedded derivatives requiring bifurcation and accounting for separately. The embedded derivatives consist of the Mandatory Redemption, which depends on certain events occurring, and the fixed bonus payable upon the Maturity Date. The fair value of the embedded derivative, which incorporated the likelihood of certain events occurring, was immaterial. Thus, as of December 31, 2024 and 2025, the Company did not recognize the embedded derivative in the accompanying audited balance sheets. The Company accounts for the fixed bonus payment to be paid if the Secured Notes are repaid on the Maturity Date by accreting the bonus payment to the full amount due on the Maturity Date, utilizing the effective interest rate method.

On May 1, 2025, the noteholders holding $6.6 million of the principal of the outstanding Secured Notes elected to convert their outstanding indebtedness to equity and entered the Second Amendment to the Amended and Restated Note Purchase Agreement (the "Conversion Agreement"). On May 7, 2025, $6.6 million of outstanding principal amount of Secured Notes and an obligation of $860,462 of accumulated accretion as of the conversion date of a fixed bonus to be paid on the Maturity Date to these noteholders were extinguished upon conversion. For those noteholders who converted to equity, the right to a fixed bonus payable on the Maturity Date was terminated and previously accumulated fixed bonus was waived. See section "Troubled Debt Restructuring of Secured Notes" below.

For those Secured Notes which remain outstanding, as of December 31, 2025, the Company reported $397,065 for the outstanding principal and accumulated accretion of a fixed bonus payment due upon maturity as a current liability in Short-term debt, net in the accompanying audited balance sheet.

Troubled Debt Restructuring of Secured Notes

The Company entered into the Second Amendment to its Secured Note in which certain Secured Note noteholders and the Company agreed to the terms to effectively extinguished $7.4 million of debt through the issuance of 253,083 shares of Common Stock, warrants to purchase 126,540 shares of Common Stock, and rights to receive a pro rata share of 49.11% of the proceeds or shares from the Company's investment in Wugen. The transaction was accounted for under ASC Subtopic 470-50, Debt Modifications and Extinguishments, and ASC Subtopic 470-60, Troubled Debt Restructurings by Debtors as a troubled debt extinguishment, as the Company was experiencing financial difficulty and it was granted a concession by Secured Note noteholders whereby the fair value of consideration transferred was less than the carrying amount of the Secured Notes.

The net carrying amount of the restructured Secured Notes was $7.4 million, including principal of $6.6 million and accumulated accretion of a fixed bonus payable upon Maturity Date of $860,462. The fair value of consideration transferred including Common Stock, warrants to purchase Common Stock, and rights to proceeds of a portion of the Company's shares of Wugen common stock was $4.0 million, with the difference of $3.5 million being recognized as a troubled debt restructuring gain. Due to the related party nature of the converting noteholders, the gain was recorded to additional paid-in capital as of December 31, 2025 in the accompanying audited statements of stockholders' equity (deficit).

Unsecured Promissory Notes

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

As of May 15, 2025, the outstanding principal of Convertible Bridge Notes were converted. The fair value of consideration transferred including 36,242 shares of Common Stock and rights to proceeds of a portion of the Company's shares of Wugen common stock was $401,134, with the difference of $131,135 being recognized as a loss on conversion. Due to the related party nature of the converting noteholders, the loss was recorded to additional paid-in capital in the accompanying audited statements of stockholders' equity (deficit).

Promissory Note with Personal Guarantee

On May 8, 2025, the Company issued a promissory note for $150,000, secured by a personal guaranty and pledge given by the Company's Founder and CEO, Dr. Hing C. Wong ("Guarantor") in accordance with the provisions of that certain Guaranty and Pledge Agreement of even date herewith between the Company and the Holder. The promissory note was issued with an original issue discount of $75,000. On the Maturity Date of February 7, 2026, the Company will repay $225,000. There are provisions which allow the Company to prepay the promissory note before the Maturity Date. The proceeds of this promissory note were used to pay the expenses required to be paid prior to the equity financing which closed on May 15, 2025. The Company is accreting the original issue discount on a straight-line basis over the seven-month term. There is no current interest due on the promissory note with personal guarantee. As of December 31, 2025, the Company reported a balance of $214,722 in the audited balance sheet. For the year ended December 31, 2025, the Company recognized accretion of original issue discount of $64,722 in Interest expense in the accompanying audited statement of operations. The Company repaid the Promissory Note in full on February 6, 2026.

Contingent Liabilities

In connection with the Trouble Debt Restructuring and the conversion of the Unsecured Promissory Note discussed above, the converting noteholders have a right to receive proceeds of a portion of the Company' shares of Wugen common stock in the event of a liquidation or sale of these shares. The Company retained ownership of all of its Wugen shares which is presented in Investments on the accompanying audited balance sheets. The Company recognized a contingent liability for the rights transferred to the converting noteholders presented in Contingent liability - related party on the accompanying audited balance sheets. As of December 31, 2025, the carrying value of the Company's Wugen shares was $1.3 million, and carrying value for the Contingent liability - related party was $692,531 in the accompanying audited balance sheet. See Note 3. Fair Value of Financial Instruments.

Five-Year Maturities

The Company classifies the total undiscounted contractual payments that are due in the next 12 months as current. The loan was initially measured on a present value basis. An amortization schedule is used to determine how much of each payment is applied to interest and principal each period. The payment is first applied to interest, and the remainder reduces the principal balance. The table below shows the amount of maturities for each of the five years following the date of the latest balance sheet:

Cogent Bank Loan

	Maturities per Year
2026	$ 135,266
2027	6,079,440
Total Debt	$ 6,214,706

Senior Secured Notes

	Maturities per Year
2026	$ 435,500
Total Debt	$ 435,500

Promissory Note

	Maturities per Year
2026	$ 225,000
Total Debt	$ 225,000

Note that the total debt in the table above includes the full accretion of debt issuance costs for the Cogent Bank Loan and the full accretion of the fixed bonus payment for the Secured Notes.

6. License Agreements

Wugen License

On December 24, 2020, the Company entered into the Wugen License transferring rights to Wugen to develop, manufacture, and commercialize certain cellular therapy products based on two of the Company's fusion protein molecules. The term of the agreement will expire on a product-by-product and country-by-country basis, upon the later of (i) ten years from the first commercial sale of the product or (ii) the expiration of the last-to-expire valid patent claim of such product. The Company concluded that Wugen is a customer and the Wugen License is a functional license under the provisions of Topic 606.

During the year ended December 31, 2025, the Company agreed to a request from Wugen to suspend the Wugen License, which will run for a period of one year from the effective date of the suspension, or until May 29, 2026. The Company expects to generate revenue for ancillary services provided to Wugen during this time, as provided for under the amended Wugen License. During the suspension, the Company is free to enter licenses with other parties for the molecules that are subject of the Wugen license. We are seeking a large biologics manufacturer who has a use for a reagent based on HCW9206 and like molecules to improve the efficacy of their manufacturing process of CAR-T products.

Trimmune License

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 ("Trimmune License") following the assignment of the original License, Research and Co-Development Agreement, which includes an exclusive license to HCW11-006 for in vivo applications ("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 and an option to license HCW9302 for in vivo applications in China or Asia. In the Trimmune License, the parties agreed to restructure the upfront license fee to consist of a $3.5 million cash payment from which the government of China would withhold taxes which are refundable, and a transferable minority equity ownership interest in Trimmune. In addition, the parties agreed that for additional consideration, Trimmune has an option to license the exclusive China rights to clinical development and commercialization for in vivo applications of HCW9302, the Company's clinical-stage molecule currently being evaluated for the treatment of an autoimmune disorder.

In addition to the upfront license fee, the Company is eligible to receive additional development milestone payments and double-digit royalties on future product sales. The Company will receive a substantial portion of the proceeds from certain future transaction(s) involving the molecule, if such a transaction(s) occur. We also have a payment-free, milestone-free, and royalty-free option to recapture the development and commercialization rights for this molecule for the United States, Canada, Central America, and South America (Opt-in Territory) after the conclusion of the Phase 1 clinical trial in China. Trimmune is financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the molecule. Each party will be financially responsible for all costs associated with research and development, manufacturing, clinical development, regulatory approval, and commercialization for the licensed molecule in its territory. Therefore, expenses to complete the first Phase 1 clinical trial in China will be paid by Trimmune. This arrangement allows HCW Biologics to have direct access to the Phase 1 results without financial responsibility for the costs incurred prior to the time a decision must be made regarding the Opt-In Right.

In accordance with the terms of the Trimmune License, the deal closing took place upon receipt of the upfront payment. On March 16, 2026, the Company received the full upfront license fee, which consisted of $3.5 million in gross proceeds, or $2.9 million net of taxes, and a transferable minority equity interest in Trimmune. See Note 18. Subsequent Events.

Milestones and Royalties

In addition to upfront fees and revenues from other transactions that took place upon entering the these licenses, the licenses includes milestone payments and royalties. The Company uses judgment to determine whether milestones or other variable consideration should be included in the transaction price. For revenue-based royalties, including milestone payments based on the level of sales, the Company will include royalties in the transaction price at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalties are allocated has been satisfied (or partially satisfied). As part of management's evaluation of the transaction price, the Company considers numerous factors, including whether the achievement of the milestones is outside of its control, contingent upon the efforts of others or subject to scientific risks of success. If the Company concludes it is probable that a significant revenue reversal would not occur, the associated milestone payment is included in the transaction price. Milestone payments that are not within its control, such as regulatory approvals, are generally not considered probable until those milestones are achieved. The Company reevaluates the transaction price, including estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

7. Sale of Common Stock and Warrants

Sale of Shares of Common Stock through SEPA

During the year ended December 31, 2025, the Company submitted Put Shares to Square Gate which were accepted and resulted in the sale of 600,000 shares of Common Stock. See Note 8. Standby Equity Purchase Agreement.

November 2025 Inducement Transaction

On November 19, 2025, the Company entered into a warrant inducement agreement with an investor ("Investor") for the immediate exercise of certain outstanding warrants that the Company issued on November 20, 2024 (the "November 2024 Warrants") and May 15, 2025 (the "May 2025 Warrants"), respectively. Pursuant to a warrant inducement agreement, the Investor agreed to a reduced exercise price of the outstanding November 2024 Warrants and May 2025 Warrants to an amended exercise price of $2.66,

and to exercise the outstanding November 2024 Warrants to purchase an aggregate of 167,925 shares of the Company's Common Stock and the outstanding May 2025 Warrants to purchase an aggregate of 1,342,280 shares of the Company's Common Stock, at the amended exercise price of $2.66. Investor exercised the November 2024 and May 2025 for an aggregate of 1,510,205 shares of the Company's Common Stock. 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 November 2024 and May 2025 Warrants. As of December 31, 2025, of the shares purchased in the Inducement transaction, 533,205 shares were issued and outstanding and 977,000 shares were held in abeyance. On March 16, 2026, the Investor requested the Company to issue the remaining shares held in abeyance.

In consideration for the immediate exercise of the November 2024 and May 2025 Warrants, the Company also agreed to issue to the Investor unregistered warrants to purchase an aggregate of 3,020,410 shares of the Company's Common Stock with an exercise price of $2.41 per share (the "New Warrants" or "Common Stock Warrants"). The New Warrants will be immediately exercisable and will expire on the five and one-half year anniversary of the original issuance date. The Company agreed to file a registration statement with the SEC covering the resale of the shares of Common Stock issuable upon exercise of the New Warrants. 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 underlying the New Warrants.

The gross proceeds to the Company from the Offering were approximately $4.0 million before deducting the placement agent's fees and other offering expenses of $321,379 payable by the Company. The fair value of the securities issued and the modification of the warrant in this transaction was $8.2 million. This included a fair value of $2.9 million for the shares of Common Stock issued based on the number of shares purchased (including shares held in abeyance) times the closing price on November 20, 2025, or $1.92 per share. In addition, the fair value of the Common Stock Warrants issued in this transaction was estimated at $4.9 million using the Black-Scholes option pricing model with assumptions including a term of 5.5 years, volatility of 121.4% and a risk-free rate of 3.68%. As this was a transaction with an existing stockholder, the difference between the gross proceeds and the fair value of securities issued and the modification of the warrant, or $4.2 million, was deemed to be an equity dividend to the Investor which was recorded in additional-paid-in capital as of December 31, 2025.

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

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

May 2025 Equity Financing

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

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

The gross proceeds to the Company from this financing were approximately $5.0 million before deducting the placement agent's fees and other offering expenses of $802,602 payable by the Company. This transaction closed on May 15, 2025, at which time the closing stock price was $8.20 per share. In this financing, the Company issued shares of Common Stock of Pre-Funded Warrants that may be exercised to purchase Common Stock in lieu thereof, and Warrants that may be exercised to purchase Common Stock. In a contemporaneous private agreement entered into with the investor, the Company agreed to reprice warrants to purchase up to 167,925 shares of Common Stock that were issued to the investor in a financing that closed on November 20, 2024 to an exercise price of $7.45 per share. The fair value of the Common Stock was determined based on the shares issued and the closing price on the date the transaction closed. The Company estimated the fair value of the Warrants issued, using the Black Scholes valuation model to estimate the fair value of the warrants with assumptions including a term of 5 - 0 years, volatility of 120.6% and a risk-free rate of 4.07% - 4.45%. The fair value of securities issued was $15.2 million. As this was a transaction with an existing stockholder, the Company recognized a $10.2 million deemed equity dividend to the Investor which was recorded in additional-paid-in capital for the year ended December 31, 2025.

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

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

As of December 31, 2025, the Investor exercised all of the Pre-Funded Warrants by delivering a notice of exercise to the Company and paying the exercise price for 513,140 shares of registered Common Stock.

The Common Stock Warrants issued on May 15, 2025 were all exercised on November 20, 2025, in connection with the Inducement Transaction described above.

November 2024 Equity Financing

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

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

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

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

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

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

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

The Common Stock Warrants issued on November 20, 2024 were all exercised on November 20, 2025, in connection with the Inducement Transaction described above.

8. Standby Equity Purchase Agreement

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

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

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

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

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

As of December 31, 2025, the Company concluded that the Equity Purchase Agreement for Standard Put Shares does not qualify for equity classification. On the effective date, the Company concluded that the fair value of the Equity Purchase Agreement at inception was zero and no asset or liability was recorded. As a result, fees paid to Square Gate in excess of the fair value of the Equity Purchase Agreement were expensed as incurred. Any issuance costs or other transaction costs attributable to a freestanding equity-linked financial instrument that is classified as an asset or liability should be recognized in earnings in the period incurred. The Commitment Fee and issuance costs for the registration statement to register the underlying shares of Common Stock issued under the Equity Purchase Agreement were expensed for the year ended December 31, 2025.

For the year ended December 31, 2025, the Company expensed the $150,000 Commitment Fee which was incurred in the period ended March 31, 2025. The Commitment Fee was paid in-kind with an equivalent value of shares of the Company's Common Stock. For the year ended December 31, 2025, the Company recorded commission expenses of $76,216 payable to the Company's exclusive Placement Agent.

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

Standard Put Shares

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

Intraday Put Shares

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

Put Shares Accepted by Square Gate

During the year ended December 31, 2025, the Company issued 600,000 shares of Common Stock through issuance of shares under the SEPA which resulted in net proceeds of $2.5 million. Loss on the sale of put shares was $263,974 and was presented in Loss on sale of put shares in the accompanying audited statement of operations for the year ended December 31, 2025.

9. Preferred Stock

At December 31, 2024 and December 31, 2025, the Company had 10,000,000 shares of preferred stock authorized and no such shares issued.

10. Net Loss Per Share

The following table summarizes the computation of the basic and diluted net loss per share. The 977,000 of shares held in abeyance as of December 31, 2025 were included in the weighted-average common shares outstanding since all necessary conditions for issuance have been met.

	Years Ended December 31,	
	2024	2025
Numerator:		
Net loss	$ (30,023,814)	$ (7,959,709)
Equity dividend to investor	—	(14,338,993)
Net loss attributable to Common Stockholders	$ (30,023,814)	$ (22,298,702)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	969,825	2,097,701
Net loss per share, basic and diluted	$ (30.96)	$ (10.63)

The following table summarizes the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive:

	December 31,	
	2024	2025
Common stock options	44,601	44,193
Common stock warrants	—	3,146,950
Potentially dilutive securities	44,601	3,191,143

11. Stock-based Compensation

On June 21, 2021, the 2021 Plan was adopted by the Company's board of directors and approved by the Company's stockholders. As of the adoption date, the 2019 Plan was terminated. No terms were changed for grants previously awarded under the 2019 Plan, and the Company concluded a modification did not occur. Under the 2019 Plan, the Company primarily granted employees incentive stock options, which had a maximum term of ten years from the date of the grant. Generally, the incentive stock options granted under the 2019 Plan have a four-year, service-based vesting period. All of the options granted under the 2019 Plan had an exercise price equal to the fair value of a share of Common Stock on the date of the grant, according to Company policy.

The 2021 Plan permits the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units, and stock bonus awards. The 2021 Plan initially reserved 86,109 shares of Common Stock, including the transfer of remaining shares reserved under the 2019 Plan. In addition, the number of shares reserved for issuance under the 2021 Plan will increase automatically on the first day of each fiscal year beginning with the 2022 fiscal year.

Under the 2021 Plan, the term of each stock option must be stated in the stock award agreement. In the case of an incentive stock option, the term will be ten years from the date of grant, or such shorter term as may be provided in the stock award agreement. Moreover, in the case of an incentive stock option granted to a participant who owns stock representing more than 10% of the total combined voting power of all classes of our stock or the stock of any of our affiliates, the term of the incentive stock option will be five years from the date of grant or such shorter term as may be provided in the stock award agreement. Under the 2021 Plan, the Company continues to have a policy to grant options with an exercise price equal to the fair value of a share of Common Stock, as determined by the closing price on Nasdaq on the grant date.

The following summarizes the Company's stock option activity for the years ended December 31, 2024 and 2025:

	Shares Issuable under Options	Weighted Average Exercise Price	Weighted Average Remaining Contract Term	Aggregate Intrinsic Value
Outstanding at January 1, 2024	44,483	$ 132.4	7.7 years	$ 238,210
Granted	1,250	44.8		
Exercised	(337)	7.2		
Forfeited or cancelled	(548)	67.6		
Expired	(248)	76.4		
Outstanding at December 31, 2024	44,601	$ 131.9	6.8 years	$ 56,352
Exercisable at December 31, 2024	33,422	$ 127.2	6.7 years	$ 56,352
Outstanding at December 31, 2024	44,601	$ 131.9	6.8 years	$ 56,352
Granted	400	3.6		
Exercised	(200)	8.0		
Forfeited or cancelled	(95)	82.8		
Expired	(160)	35.8		
Adjustment for reverse stock split	(353)			
Outstanding at December 31, 2025	44,193	$ 131.8	5.8 years	$ —
Exercisable at December 31, 2025	42,965	$ 134.0	5.8 years	$ —

The exercise price of the underlying stock options and the fair value of the Company's Common Stock for stock options as of the reporting date. The intrinsic value of stock options exercised during the years ended December 31, 2024 and 2025 was $14,484 and $1,654, respectively. The weighted-average fair value of options granted during the years ended December 31, 2024 and 2025 was $33.77 and $2.44 per share, respectively.

For stock option grants with service-based vesting, stock-based compensation expense represents the portion of the grant date fair value of employee stock option grants recognized over the requisite service period of the awards on a straight-line basis, net of estimated forfeitures. For options that vest upon the achievement of performance milestones, the Company estimates fair value at the date of grant and compensation expense is recognized using the accelerated attribution method when it is determined that the performance criteria are probable of being met.

In determining the grant date fair value of the stock-based awards, the Company uses the Black-Scholes option-pricing model and assumptions discussed below. Each of these inputs is subjective and its determination generally requires significant judgment.

Fair Value of Common Stock—Since the completion of our initial public offering on July 19, 2021, the fair value of each share of Common Stock underlying stock option grants is based the quoted market price on the primary stock exchange on which our Common Stock is traded on the day the stock award or option is granted.

Expected term—The expected term of stock options is determined using the "simplified" method, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data.

Expected volatility—The expected volatility was derived from the historical stock volatilities of comparable peer public companies within our industry.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury Bond in effect at the time of grant for periods corresponding with the expected term.

Dividend yield—The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its Common Stock.

For the years ended December 31, 2024 and 2025, the fair value of employee and director stock option awards was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Years Ended December 31,	
	2024	2025
Expected term (years)	5.5	4.15
Expected volatility	92.93%	94.52%
Risk-free interest rate	4.22%	3.55%
Dividend yield	—	—
Fair value underlying common stock	$33.77	$2.44

For the year ended December 31, 2024, for options with service-based vesting conditions, the Company recognized $61,250 of employee stock-based compensation expense in research and development expenses and $947,762 of employee stock-based compensation in general and administrative expenses in the accompanying audited statement of operations.

For the year ended December 31, 2025, for options with service-based vesting conditions, the Company recognized $48,069 of employee stock-based compensation expense in research and development expenses and $720,555 of employee stock-based compensation in general and administrative expenses in the accompanying audited statement of operations. As of December 31, 2025, the Company had an aggregate of $23,697 of unrecognized employee stock-based compensation cost for options with service-based vesting, which is expected to be recognized over a weighted average vesting period of 1.14 years.

12. Employee Benefit Plan

The Company offers a defined contribution savings plan (the "Benefit Plan") under Section 401 of the Internal Revenue Code for all eligible employees. The Benefit Plan allows for discretionary contributions which are limited to the maximum allowable for federal tax purposes. The total expense related to the discretionary payments made by the Company to the Benefit Plan for the years ended December 31, 2024 and 2025 was $160,851 and $127,295, respectively.

13. Collaborative Arrangements

The Company has certain contract research agreements with contractors and research institutions that were entered during the two years ended December 31, 2025 for the (i) hybridoma development, (ii) cell line manufacturing productivity improvement, and (iii) research to support pre-clinical studies. Under the hybridoma development and cell line manufacturing productivity improvement agreements, we own all rights to the resulting intellectual property, including the antibodies, sequences, and data. For certain contractors, the Company is obligated to pay one future milestone payment upon filing and acceptance of an IND for each respective human antibody or protein from cell line; however no additional future development or financial obligations are due under these contract research agreements as of December 31, 2024 or 2025. For certain research collaborations agreements, the research intellectual property may be jointly owned or ownership may be based upon inventorship. In those circumstances, the Company has obtained the exclusive option to an exclusive license for the research intellectual property.

14. Income Taxes

The Company did not have a provision for income taxes (current or deferred tax expense) for tax years ended December 31, 2024 and 2025.

In accordance with ASU 2023-09, the following table summarizes differences between income tax expense (benefit) at the statutory federal income tax rate and as presented on the statements of operations:

Rate Reconciliation	**2024**		**2025**	
Net Loss Before Taxes	$ (30,023,814)		$ (7,959,709)	
Tax at U.S. federal statutory tax rate	(6,305,001)	21.00%	(1,671,539)	21.00%
Tax Credits				
Research and development tax credit	(324,035)	1.08%	(187,192)	2.35%
Change in valuation allowance	6,540,349	(21.78%)	1,017,795	(12.79%)
Nontaxable and nondeductible items				
Gain on Conversion of Sr. Secured Notes	—	0.00%	702,778	(8.83%)
Other	34,362	(0.11%)	144,120	(1.81%)
Other Adjustments				
Other	54,325	(0.18%)	(5,962)	0.07%
Income tax expense/(benefit)	$ —	0.00%	$ —	0.00%

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2024 and 2025 are presented below:

	2024	**2025**
Deferred tax assets:		
Federal net operating loss carryforward	$ 13,058,574	$ 14,691,145
State net operating loss carryforward	2,707,319	3,051,100
Capitalized section 174 R&D expenses	4,113,266	2,958,575
Reserve for credit losses	1,330,613	1,330,613
R&D Tax Credit	1,530,652	1,709,745
Depreciable assets	-	454,612
Accrued expenses	37,786	64,758
Capitalized legal fees for patents	2,698,931	2,197,457
Stock-based compensation	792,057	959,388
Charitable contributions	65	65
Unrealized loss on investment	—	33,115
Total deferred tax assets	26,269,263	27,450,573
Deferred tax Liabilities:		
Unrealized gain/loss	$ (5,238)	$ (5,238)
Depreciable assets	(27,054)	-
Deferred revenue/costs	(8,617)	(19,659)
Total deferred tax liability	(40,909)	(24,897)
Net deferred tax asset	26,228,354	27,425,676
Less: valuation allowance	(26,228,354)	(27,425,676)
Net deferred tax asset (after valuation allowance)	$ —	$ —

A valuation allowance is recorded to reduce the deferred tax asset if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of December 31, 2025, after consideration of all the evidence, both positive and negative, management has determined that a valuation allowance of $27.4 million is necessary to reduce the deferred tax asset to the amount that will more likely than not be realized. During the year ended December 31, 2025, the valuation allowance increased by $1.2 million.

As of December 31, 2024 and 2025, the Company had available federal NOL carryforwards of $62.2 million and $70.0 million, respectively. The Company also has available state NOLs carryforwards of approximately $62.3 million and $70.2 million, as of December 31, 2024 and 2025, respectively. The federal and state NOLs will carryforward indefinitely. The Federal NOLs are available to offset 80% of taxable income. In addition, the Company had federal research and development credits carryforwards of $1.5 million and $1.7 million, as of December 31, 2024 and 2025, respectively, to reduce future federal income taxes, if any. These carryforwards expire from 2038 through 2045 and are subject to review and possible adjustment.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, (the Code), substantial changes in the Company's ownership may limit the amount of net operating loss and research and development credit carryforwards that could be used annually in the future to offset taxable income. A formal Section 382 study has not been completed to determine if an ownership change has occurred and if its net operating losses are subject to an annual limitation. Such annual limitations could affect the utilization of NOL and tax credit carryforwards in the future.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act of 2017, modifications to the international tax framework, and the restoration of favorable tax treatment for certain business provisions. The provisions in the OBBBA have multiple effective dates, with certain provisions effective in 2025 and others implemented through future years.

One of the most significant provisions for the Company is the repeal of the requirement to capitalize and amortize domestic research and experimental (R&E) expenditures under Section 174 of the Internal Revenue Code. Effective for tax years beginning after December 31, 2024, the Company is permitted to immediately deduct domestic R&E expenditures as incurred for federal income tax purposes. The requirement to amortize foreign R&E expenditures over 15 years remains unchanged. The Company has included the impact of the provisions effective in 2025, including the Section 174 change, in its Consolidated Financial Statements. The impact of these provisions was not material to the Company's results of operations and financial condition for the year ended December 31, 2025.

The Company's tax returns remain subject to examination by tax authorities beginning with the tax year ended December 31, 2021. However, due to NOLs and credits carried forward from prior tax years, substantially all tax years may also be subject to examination. The Company recognizes the tax benefit of an uncertain tax position only if it is more likely than not that the position is sustainable upon review by the taxing authorities based on the technical merits. The Company recognizes interest accrued and penalties for unrecognized tax benefits in its tax provision. As of December 31, 2024 and 2025, the Company had not recognized any expense related to uncertain tax position in its statements of operations.

15. Related Party Transactions

On February 20, 2024, the Company completed a $2.5 million private placement of shares of Common Stock with certain of its officers and directors at a price of $1.40 per share. The Company issued 1,785,718 shares of Common Stock in connection with the offering. The shares have not been registered and will not be sold or transferred except as permitted under law and pursuant to registration or exemption therefrom. The Board of Directors and Audit Committee of the Board of Directors reviewed the transaction under the Company's policy for Related Party Transactions (the "Policy") and determined that the transaction was in compliance with the Policy.

As of October 31, 2024, the Company issued an aggregate of $6.9 million of Secured Notes, with $2.9 million from the Company's officers and members of the board of directors, including $2.4 million purchased by Dr. Hing C. Wong, Founder and 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, who was a member of the board of directors at the time of his investment, $25,000 purchased by Lee Flowers, Senior Vice President for Business Development, and $25,000 purchased by Rick S. Greene, member of the board of directors. In addition, other significant stockholders invested in Secured Notes totally $3.7 million.

In May 2025, as part of the Nasdaq Compliance Plan, the Company entered into the Second Amendment to its Secured Note in which certain Secured Note noteholders agreed to restructure their Secured Notes. At the time of the restructuring, the net carrying amount of the restructured Secured Notes was $7.4 million including principal of $6.6 million and accumulated accretion of a fixed bonus payable upon Maturity Date of $860,462. On May 7, 2025, the Company extinguished $7.4 million of debt through the issuance of 253,083 shares of Common Stock, warrants to purchase 126,540 shares of Common Stock, and rights to receive a pro rata share of 49.11% of the proceeds or shares from the Company's investment in Wugen. The fair value of consideration transferred including Common Stock, warrants to purchase Common Stock, and rights to proceeds of a portion of the Company's shares of Wugen common stock was $4.0 million, with the difference of $3.5 million being recognized as a troubled debt restructuring gain. Due to the related party nature of the converting noteholders, the gain was recorded to additional paid-in capital as of December 31, 2025 in the accompanying audited statements of stockholders' equity (deficit).

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

On May 15, 2025, the Company completed an offering (the "Offering") with an existing stockholder of the Company in which the Company issued (i) 158,000 shares of the Company's Common Stock and (ii) Pre-funded Warrants to purchase up to 513,140 shares of Common Stock in a follow-on public offering. The Company also issued Warrants to purchase up to an aggregate of 1,342,280 shares of Common Stock. The gross proceeds to the Company from the Offering were approximately $5.0 million before deducting the placement agent's fees and other offering expenses of $802,602 payable by the Company. The Company estimated the fair value of the securities issued, using the Black Scholes valuation model to estimate the fair value of the warrants, and determined the fair value of securities issued was $15.2 million. As this was a transaction with an existing stockholder of the Company, the Company recognized a $10.2 million deemed equity dividend to the Investor which was recorded in additional-paid-in capital for the year ended December 31, 2025. See Note 7. Sale of Common Stock and Warrants - May Equity Financing.

On November 20, 2025, the Company completed an inducement transaction (the "Inducement Transaction") with an existing stockholder of the Company. Pursuant to a warrant inducement agreement, the related-party stockholder agreed to a reduced exercise price of the outstanding Warrants issued in previous transactions in November 2024 and May 2025. In consideration for the immediate exercise of the Warrants, the Company also agreed to issue to the related-party stockholder unregistered warrants to purchase an aggregate of 3,020,410 shares of the Company's Common Stock. The gross proceeds to the Company from the Offering were approximately $4.0 million before deducting the placement agent's fees and other offering expenses of $321,379 payable by the Company. The fair value of the securities issued, using the Black Scholes valuation model to estimate the fair value of securities issued and the modification of the warrant, was $8.2 million. As this was a transaction with an existing stockholder of the Company, the Company recognized $4.2 million deemed equity dividend to investor which was recorded in additional-paid-in-capital for the year ended December 31, 2025. See Note 7. Sale of Common Stock and Warrants - November 2025 Inducement Transaction.

16. Segment Reporting

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

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

The Company has not generated any product revenue from commercial product sales of internally-developed immunotherapeutic products for the treatment of diseases, as no products have been approved for commercial sale as of December 31, 2025. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances molecules through all stages of development and clinical trials and, ultimately, seek approval for commercial sale.

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

The tables below summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2024 and 202**5:**

	Years Ended December 31,	
	2024	**2025**
Revenues:		
Revenues	$ 2,566,792	$ 54,232
Cost of revenues	(1,607,389)	(43,386)
Net revenues	959,403	10,846
Operating expenses:		
Research and development expenses		
Salaries, benefits and related expenses	2,797,370	3,069,364
Manufacturing and materials	1,425,734	354,705
Preclinical expenses	859,701	930,899
Clinical trials	558,215	470,592
Overhead allocations	747,974	617,324
Total research and development expenses	6,388,994	5,442,884
General and administrative		
Salaries, benefits and related expenses	2,563,936	2,784,753
Professional services[(a)]	1,171,885	1,995,446
Facilities and office expenses	654,996	433,288
Depreciation expenses	254,407	237,005
Rent and occupancy expenses	205,511	191,598
Insurance	952,199	1,011,034
Taxes	196,804	174,398
Other expenses	289,407	468,537
Total general and administrative expenses	6,289,145	7,296,059
Other segment items[(b)]	18,305,078	(4,768,388)
Total operating expenses	30,983,217	7,970,555
Net segment loss	**$ (30,023,814)**	**$ (7,959,709)**

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

(b) Other segment items include the following unusual or nonrecurring items:

	Years Ended December 31,	
	2024	2025
Arbitration legal fees (recoveries), net	$ 15,910,480	$ (1,470,809)
Accretion of fixed bonus upon maturity of Secured Notes	527,304	405,222
Interest expense	654,284	845,051
Change in fair value of investment	—	273,422
Change in fair value of contingent liability	—	(1,055,826)
Nonoperating loss	1,300,000	—
Loss on sale of put shares	—	263,974
Gain on extinguishment of liability	—	(5,461,046)
Impairment of long-lived asset		1,500,000
Other income, net	(86,990)	(68,376)
Other segment items	**$ 18,305,078**	**$ (4,768,388)**

17. Commitments and Contingencies

Operating Leases

The Company has operating leases for approximately 12,250 square feet of space located in Miramar, Florida. On January 27, 2025, the Company entered a new one-year lease for the same location which commenced on March 1, 2025 and terminated on February 28, 2026. On February 2, 2026, the Company entered a new one-year lease for the same location which commenced on March 1, 2026 and terminates on February 28, 2027. As a lease of 12 months or less in duration and qualifies for a short-term lease exemption under FASB ASC 842, Leases, for short-term leases, as provided for in ASC 842-20-25-2, which is the short-term lease exception whereby a lessee recognizes the lease payments in profit or loss on a straight-line basis over the lease term. The Company elected to account for this lease on a straight-line basis over the lease term and will not recognize a ROU asset and a lease liability as a result. The Company has no obligations under financing leases.

As of December 31, 2025, the remaining lease payments were as follows:

2026	$ 49,316
Total future minimum lease payments	$ 49,316

For the years ended December 31, 2024 and 2025, rent expense recognized by the Company was $196,000 and $208,413, respectively, of which $101,300 and $109,147, respectively, is included in Research and development in the statements of operations included in the audited financial statements.

Contractual Commitments

The Company has commitments with R&D outsourcing and development companies to supply us with clinical grade materials or other development services. As of December 31, 2025, it is under contract for future obligations of $396,100 it expects to pay during the year ending December 31, 2026.

Company Victim to Fraudulent Criminal Scheme

As reported in the Company's Form 8-K filed on May 1, 2024 with the SEC, the Company became aware that it was the victim of a criminal scheme involving the impersonation of a purchaser upon the default (the "Default") on a legally binding commitment to purchase $8.0 million of secured notes from the Company. The scheme resulted in the misdirection of approximately $1.3 million held in Company accounts to a fraudulent account controlled by a third party. The Company recognized a $1.3 million loss reported as a Nonoperating loss in the accompanying audited statements of operations for the year ended December 31, 2024. The Company has pursued all available remedies to recover this loss, including reporting it to law enforcement.

Legal Matters

Legal Proceedings

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

Arbitration, Settlement and General Release

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

As of July 13, 2024, the Company and Dr. Hing C. Wong, the Company's Founder and Chief Executive Officer, entered into a confidential Settlement Agreement with Altor BioScience, LLC ("Altor"), NantCell, Inc. ("NantCell"), and ImmunityBio, Inc. (the parent of Altor and NantCell, together with Altor and NantCell, "ImmunityBio"), to resolve the previously disclosed Arbitration before JAMS brought by Altor and NantCell as well as the Complaint Altor filed against the Company in the Chancery Court of the State of Delaware for the contribution of legal fees and expenses advanced to Dr. Wong. The Settlement Agreement includes mutual general releases by and among the parties thereto. No party is required to make any monetary payments to any other party or person under the Settlement Agreement and each party will bear its own expenses incurred in connection with the matter. The Arbitration and related Complaint were dismissed with prejudice as of December 31, 2024.

As of December 31, 2024, the Company owed $13.5 million in legal fees for costs incurred in connection with mounting a legal defense for the Company and Dr. Wong. In January 2025, the Company received a $2.0 million insurance reimbursement which was paid directly to Cooley LLP ("Cooley"), the law firm that represented Dr. Wong in his defense. On December 30, 2025, the Company and Dr. Wong entered into a settlement agreement with Cooley related to legal fees incurred in connection the defense of Dr. Wong. As a result of that agreement, the Company, Dr. Wong and Cooley agreed to settle an approximately $7.5 million obligation for $2.0 million in cash payments and a commitment to potential contingent payments up to approximately $5.5 million upon achievement of certain triggering events (including a sale of the Company above a certain threshold or receipts of substantial cash amounts for future business development transactions), all of which were deemed to be remote as of December 31, 2025. In accordance with the terms of the settlement agreement, $500,000 was paid on December 31, 2025. Based on an amendment to the settlement agreement, the Company paid $750,000 on March 20, 2026, and will pay the remaining $750,000 upon the earlier of the completion of a financing for at least $4.0 million in gross proceeds or August 31, 2026. After this settlement, as of December 31, 2025, the Company recognized a liability of $6.2 million for remaining amounts owed for legal fees related to the Arbitration which continue to remain outstanding.

Other Matters

As of December 31, 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. ("B&I), 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 were consolidated, and a Case Management conference was held. On February 19, 2026, a stipulation was submitted to the Court for a settlement and release agreement between the Company and B&I calling for payment of a total of $860,000 installments in settlement of amounts owed and an allowance for interest and other fees, the last installment of which is payable on or before May 31, 2026.

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

Inflationary Cost Environment, Geopolitical Risks and Other Macroeconomic Factors

The Company's operations have been affected by many headwinds, including inflationary pressures, tariffs, rising interest rates, ongoing global supply chain disruptions resulting from increased geopolitical tensions such as the war in the Middle East, the conflict between Russia and Ukraine, China-Taiwan relations, financial market volatility and currency movements. The Company has been impacted by inflation, and may continue to be so, when procuring materials required for the buildout of our new headquarters, the costs for recruiting and retaining employees and other employee-related costs. Management employs a number of strategies to effectively navigate these issues, including product redesign, alternate sourcing, and establishing contingencies in budgeting and timelines. Future developments in these and other areas present material uncertainty and risk with respect to the Company's clinical trials, IND-enabling activities, buildout of the new headquarters, as well as the Company's financial condition and results of operations. The extent and duration of such events and conditions, and resulting disruptions to our operations, are highly unpredictable.

18. Subsequent Events

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

February 2026 Sale of Common Stock and Warrants

On February 17, 2026, the Company entered into a securities purchase agreement with an existing stockholder of the Company, a single institutional investor (the "Investor") pursuant to which the Company agreed to offer and sell, in a follow-on public offering (the "2026 Offering"), 2,477,292 units (the "Units") consisting of (i) 2,477,292 shares (the "Common Shares") of the Company's Common Stock, $0.0001 par value per share (the "Common Stock") or, in lieu thereof, up to 2,477,292 Pre-Funded Warrants (as defined below) to purchase up to 2,477,292 shares of Common Stock (the "Pre-Funded Warrant Shares"), and (ii) up to 2,477,292 Common Stock purchase warrants the exercise of which is conditioned on stockholder approval (the "Common Warrants", and together with the Pre-Funded Warrants, the "Warrants") to purchase up to 2,477,292 shares of Common Stock.

On February 17, 2026, the Company also entered into a privately negotiated agreement with the Investor, which holds certain existing outstanding warrants to purchase up to 3,020,410 shares of Common Stock (the "Prior Warrants") to seek stockholder approval in accordance with applicable Nasdaq rules to reduce the exercise price of such Prior Warrants to the public offering price per Unit paid in the Offering (the "Existing Warrants Amendment Agreement"). There can be no assurance that we will obtain such stockholder approval or amend the Prior Warrants or as to the final terms of any amendments to the Prior Warrants.

The combined purchase price for each Unit consisting of one share of Common Stock or Pre-Funded Warrant in lieu thereof and accompanying Common Stock Warrant to purchase one share of Common Stock was $0.6055 per unit, and the combined purchase price for each unit consisting of one Pre-Funded Warrant that may be exercised for one share of Common Stock and accompanying Common Stock Warrant to purchase one share of Common Stock is $0.6054. The Common Stock Warrants have an exercise price of $0.6055 per share, will be exercisable only upon receipt of stockholder approval thereof in accordance with applicable Nasdaq rules, and expire on the five-year anniversary of such stockholder approval. The Pre-Funded Warrants have an exercise price of $0.0001, are exercisable immediately and will not expire until exercised in full. The Company filed a definitive proxy statement for a Special Stockholders' Meeting to be held on April 27, 2026.

The securities described above were offered pursuant to a registration statement on Form S-1, as amended (File No. 333-293396), which was declared effective by the Securities and Exchange Commission on February 17, 2026. The gross proceeds to the Company from the 2026 Offering are approximately $1.5 million before deducting the placement agent's fees and other offering expenses payable by the Company. The 2026 Offering closed on February 19, 2026.

On March 16, 2026, the Investor exercised all of its Pre-Funded Warrants issued in the 2026 Offering, and the Company issued 2,477,292 shares of Common Stock. Also on February 25, 2026 and March 16, 2026, the Investor requested the Company issue 237,000 and 740,000, respectively, of the remaining shares in abeyance.

B&I Contractors Settlement Agreement and Release

On February 19, 2026, a stipulation was submitted to the Court for a settlement and release agreement between the Company and B&I calling for payment of a total of $860,000 in installments in settlement of amounts owed and an allowance for interest and other fees the last installment of which is payable on or before May 31, 2026. The Company did not recognize any gain or loss as a result of this settlement.

Compliance with Nasdaq Continued Listing Requirements

On February 26, 2026, the Nasdaq Hearings Panel found that the Company regained compliance with all continued listing rules of The Nasdaq Capital Market. Pursuant to Listing Rule 5815(d)(4)(B), the Company will be subject to a Mandatory Panel Monitor. 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, 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. On March 26, 2026, the Company received a written notice from the Staff which notified the Company that, for the 30 consecutive business days, the Company's security did not maintain a minimum bid price of $1 per share, in accordance with Nasdaq Listing Rule 5810(c)(3)(A) ("Bid Price Rule"). Due to the fact that the Company effected a 1-for-40 reverse stock split on April 11, 2025, the Company was not afforded a 180-calendar day period to demonstrate compliance. The Company plans to request an appeal of this determination in a timely manner.

Beijing Trimmune Biotech Co., Ltd. License

As of March 16, 2026, the Company received the full payment of the upfront licensing fee for the exclusive worldwide license for HCW11-006, a preclinical molecule, from Trimmune. In accordance with the terms of the Trimmune License, the deal closing took place upon receipt of the upfront payment. The upfront license fee consisted of a payment of $3.5 million in gross proceeds, or $2.9 million net of taxes, and a transferable minority equity interest in Trimmune.

Settlement Agreement with EirGenix, Inc.

On December 9, 2025, the Company and EirGenix entered into a settlement agreement. On March 3, 2026, the Company paid $620,000 to EirGenix for the first payment in the $1.2 million settlement agreement. On March 17, 2026, the parties agreed to amend the terms of the settlement agreement such that the settlement of $1.2 million must be paid in full by April 30, 2026, or the entire amount of $1.7 million in past due amounts plus interest and penalties thereon will be due.

Settlement Agreement with Cooley LLP

On March 23, 2026, the Company and Cooley LLP entered into an Amendment to Settlement Agreement and Mutual Release the parties entered on December 30, 2025. In accordance with the amended agreement, the Company paid Cooley $750,000 on March 24, 2026. The remaining $750,000 owed will be paid upon the earlier of the completion of a financing for at least $4.0 million in gross proceeds or August 31, 2026.

Engagement Letter with E.F. Hutton & Co.

On March 26, 2026, the Company entered into an engagement letter with the E.F. Hutton & Co. to act as the exclusive placement agent for a private placement.

Item 9 Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

As the Company reported in its Form 8-K filed on September 20, 2024, on September 19, 2024, the Audit Committee (the "Audit Committee") of the Board of Directors (the "Board") of HCW Biologics Inc. (the "Company") dismissed Grant Thornton LLP ("Grant Thornton") as the Company's auditing firm, effective immediately. This decision was not related to any disagreements with Grant Thornton on any matter of accounting principles, financial statements disclosures, auditing scope or auditing procedure. The Audit Committee appointed Crowe LLP ("Crowe"), as the successor independent registered public accounting firm beginning in the quarter ended September 30, 2024, and it was effective immediately.

Item 9A Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2025, our management, with participation of our principal executive officer and principal financial officer, performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a – 15(e) under the Exchange Act). Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level. A material weakness in the internal control over financial reporting (described below) was identified related to impairment assessment of long-lived assets.

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States.

As of December 31, 2025, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, a material weakness over financial reporting was identified (described below). A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or condensed interim financial statements would not be prevented or detected on a timely basis.

A material weakness was identified related to management's assessment of long-lived assets for impairment. This material weakness resulted in an adjustment of $1.5 million to the Company's consolidated financial statements for the year ended December 31, 2025. Additionally, this material weakness could result in misstatements of long-lived assets (property, plant and equipment) or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

Because of this material weakness, management concluded that the Company did not maintain effective internal control over financial reporting as of December 31, 2025.

Remediation Plans for Material Weakness in Internal Control over Financial Reporting

We are committed to establishing and maintaining a stronger internal control environment. In response to the identified material weakness above, the Company's Board of Directors and its Audit Committee are conducting an internal investigation to determine the root cause of the material weakness, with advice from outside advisors. Upon conclusion of this investigation, they will work with management to evaluate internal controls over financial reporting based on criteria set forth in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Remediation plan will include obtaining a current appraisal at least once a year in preparation for the Annual Report, and more often if the market appears to be weakening or other triggers for an indication of impairment have occurred. Management intends to establish procedures to ensure proper monitoring of indicators of impairment such as a significant market price decrease, adverse changes in physical condition/usage, legal factors, or current-period operating losses, for each reporting period.

Inherent Limitations of Internal Controls

Our internal control system was designed to, in general, provide reasonable assurance to our company's management and board regarding the preparation and fair presentation of published financial statements, but because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over the financial reporting during the fourth quarter of 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Independent Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm. For as long as we remain an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on the effectiveness of our internal control over financial reporting.

Item 9B Other Information.

10b5-1 Trading Plans

During the fiscal quarter ended December 31, 2025, none of our officers or directors adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Special Meeting of Stockholders

As required in the $1.5 million equity offering and repricing of existing warrants that closed on February 19, 2026, the Company will hold a Special Meeting of Stockholders on April 27, 2026 at 10:00 a.m. Eastern Time. At the Special Meeting the Company will submit the following two proposals to its stockholders for approval:

Proposal 1:

To approve, for purposes of complying with Nasdaq Listing Rule 5635(d), the issuance of shares of our Common Stock upon exercise of up to 2,477,292 Common Stock Purchase Warrants (the "Common Warrants") issued pursuant to that certain Securities Purchase Agreement, dated February 17, 2026 (the "SPA"), entered into in connection with the Company's follow-on public offering of Units (the "Offering"), which Offering was conducted pursuant to a registration statement (the "Registration Statement") declared effective by the SEC on February 17, 2026 and closed on February 19, 2026, as previously disclosed in the Company's Current Report on Form 8-K filed on February 19, 2026, each Unit consisting of (i) one share of Common Stock or one Pre-Funded Warrant to purchase one share of Common Stock and (ii) one Common Warrant, with such Common Warrants exercisable only upon receipt of stockholder approval and having an exercise price equal to 100% of the public offering price per Unit, and such additional terms and conditions of the Common Warrants not materially inconsistent with the foregoing as our Board may hereafter approve;

Proposal 2:

To approve, for purposes of complying with Nasdaq Listing Rule 5635(d), the repricing of certain warrants issued on November 20, 2025 to purchase up to 3,020,410 shares of our Common Stock (the "Prior Warrants") pursuant to that certain Existing Warrants Amendment Agreement, dated February 17, 2026, entered into in connection with the Offering conducted pursuant to the Registration Statement (as disclosed in the Company's Current Report on Form 8-K filed on February 19, 2026), to reduce the exercise price of the Prior Warrants from $2.41 per share to $0.6055 per share, and to approve the issuance of shares of our Common Stock upon exercise of the Prior Warrants as so amended, and such additional terms and conditions of such amendment not materially inconsistent with the foregoing as our Board may hereafter approve; and

Proposal 3:

To transact such other business as may properly come before the Special Meeting or any adjournments or postponements thereof.

Standby Equity Line of Credit

On February 20, 2025, the Company entered into an equity purchase agreement (the "ELOC Purchase Agreement") with Square Gate Capital Master Fund, LLC – Series 4 ("Square Gate") pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right to direct Square Gate to purchase up to an aggregate of $20,000,000 of shares of our Common Stock, plus, at the Company's option upon utilizing the initial $20,000,000, an additional amount equal to the lesser of 100% of the Company's market capitalization at the time of exercise of such option or $20,000,000, over the 36-month term of the ELOC Purchase Agreement. The Company issued 9,616 shares of our Common Stock to Square Gate on March 12, 2025, as its Commitment Fee under the ELOC Purchase Agreement (the "Commitment Shares"). On April 16, 2025, the SEC declared a registration statement effective to register the Commitment Shares and shares required to sell up to $40.0 million of the Company's shares to Square Gate, according to provisions of the Equity Purchase Agreement.

Sale of Common Stock and Warrants

February 2026 Financing

On February 17, 2026, the Company entered into a securities purchase agreement with a single institutional investor (the "Investor") pursuant to which the Company agreed to offer and sell, in a follow-on public offering (the "2026 Offering"), 2,477,292 units (the "Units") consisting of (i) 2,477,292 shares (the "Common Shares") of the Company's Common Stock, $0.0001 par value per share (the "Common Stock") or, in lieu thereof, up to 2,477,292 Pre-Funded Warrants (as defined below) to purchase up to 2,477,292 shares of Common Stock (the "Pre-Funded Warrant Shares"), and (ii) up to 2,477,292 Common Stock purchase warrants the exercise of which is conditioned on stockholder approval (the "Common Warrants", and together with the Pre-Funded Warrants, the "Warrants") to purchase up to 2,477,292 shares of Common Stock.

On February 17, 2026, the Company also entered into a privately negotiated agreement with the Investor, which holds certain existing outstanding warrants to purchase up to 3,020,410 shares of Common Stock (the "Prior Warrants") to seek stockholder approval in accordance with applicable Nasdaq rules to reduce the exercise price of such Prior Warrants to the public offering price per Unit paid in the Offering (the "Existing Warrants Amendment Agreement"). There can be no assurance that we will obtain such stockholder approval or amend the Prior Warrants or as to the final terms of any amendments to the Prior Warrants.

The combined purchase price for each Unit consisting of one share of Common Stock or Pre-Funded Warrant in lieu thereof and accompanying Common Stock Warrant to purchase one share of Common Stock was $0.6055 per unit, and the combined purchase price for each unit consisting of one Pre-Funded Warrant that may be exercised for one share of Common Stock and accompanying Common Stock Warrant to purchase one share of Common Stock is $0.6054. The Common Stock Warrants have an exercise price of $0.6055 per share, will be exercisable only upon receipt of stockholder approval thereof in accordance with applicable Nasdaq rules, and expire on the five-year anniversary of such stockholder approval. The Pre-Funded Warrants have an exercise price of $0.0001, are exercisable immediately and will not expire until exercised in full.

The securities described above were offered pursuant to a registration statement on Form S-1, as amended (File No. 333-293396), which was declared effective by the Securities and Exchange Commission (the "SEC") on February 17, 2026. The gross proceeds to the Company from the 2026 Offering are approximately $1.5 million before deducting the placement agent's fees and other offering expenses payable by the Company. The 2026 Offering closed on February 19, 2026.

On February 17, 2026, the Company entered into a placement agency agreement (the "Placement Agency Agreement") with Maxim Group LLC ("Maxim" or the "Placement Agent") pursuant to which the Company engaged the Placement Agent as the exclusive placement agent in connection with the Offering. The Company agreed to pay the Placement Agent a cash fee equal to 6.9% of gross proceeds from the sale of Common Shares, Pre-Funded Warrants and Common Stock Warrants to the Investor. The Company also agreed to reimburse the Placement Agent for out-of-pocket expenses, including the reasonable legal fees of its counsel not to exceed $65,000. The Placement Agency Agreement also contains representations, warranties, indemnification and other provisions customary for transactions of this nature.

On March 16, 2026, the Investor exercised all of the Pre-Funded Warrants purchased in this transaction, and the Company issued 2,477,292 shares of Common Stock.

May 2025 Financing

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

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

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

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

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

As of December 31, 2025, the Investor exercised all of the Pre-Funded Warrants by delivering a notice of exercise to the Company and paying the exercise price. As a result, the Company issued 513,140 shares of registered Common Stock to the Investor as of December 31, 2025.

The Common Stock Warrants issued in May 2025 were repriced and exercised in the Inducement Transaction on November 19, 2025 (see below).

November 2024 Financing

On November 18, 2024, the Company entered into a securities purchase agreement with a single institutional investor (the "Investor") pursuant to which the Company agreed to offer and sell (i) in a registered direct offering (the "Registered Offering") (x) 104,000 shares (the "Shares") of the Company's Common Stock, par value $0.0001 per share (the "Common Stock"), and (y) Pre-funded Warrants to purchase up to 63,925 shares of Common Stock (the "Pre-Funded Warrants") and (ii) in a concurrent private placement (the "Private Placement" and together with the Registered Offering, the "Offering"), unregistered warrants to purchase up to an aggregate of 154,275 shares of Common Stock ("Armistice Warrants"). The combined purchase price for each Share and accompanying Armistice Warrant to purchase one share of Common Stock was $41.20 per Share and the combined purchase price for each Pre-Funded Warrant and accompanying Common Stock Warrant to purchase one share of Common Stock was $40.196.

The Common Stock and Pre-Funded Warrants were each sold with an accompanying Armistice Warrant to purchase one share of Common Stock, and the Common Stock and Pre-Funded Warrants were immediately separated from the Armistice Warrants and were issued separately. The Armistice Warrants have an exercise price of $41.20 per share, are exercisable immediately, and expire on the five year anniversary of the date of issuance. The Pre-Funded Warrants have an exercise price of $0.0001, are exercisable immediately and will not expire until exercised in full.

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

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

The Common Stock Warrants issued in November 2024 were repriced and exercised in the Inducement Transaction on November 19, 2025 (see below).

Conversion of Unsecured Convertible Promissory Notes

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

As of May 15, 2025, the outstanding principal of unsecured convertible promissory notes were converted. The fair value of consideration transferred including 36,242 shares of Common Stock and rights to proceeds of a portion of the Company's shares of Wugen common stock was $401,134, with the difference of $131,135 being recognized as a loss on conversion. Due to the related party nature of the converting noteholders, the loss was recorded to additional paid-in capital in the accompanying audited financial statements as of and for the year ended December 31, 2025.

Conversion of Secured Notes

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 ("Conversion Shares"), warrants to purchase approximately $3.3 million of the Company's Common Stock at an exercise price of $26.00 per share ("Conversion Warrants"), and the right to their pro rata share of 49.11% of the proceeds of the Company's shares of Wugen common stock ("Wugen Shares"), if and when such shares are ever sold (the "Wugen Proceeds"). The conversion was approved at a Special Meeting of Stockholders held on March 31, 2025 and was effected pursuant to the terms of the Conversion Amendment. On May 7, 2025, pursuant to the Conversion Amendment, the Secured Notes held by the participating noteholders were cancelled, and the Company issued a total of 253,083 unregistered shares of Common Stock (which are subject to a 180-day lock-up) and warrants to purchase an additional 126,540 shares of Common Stock at an exercise price of $26.00 per share. 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.

Inducement Agreement

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

As of December 31, 2025, there were 977,000 shares held in abeyance. On February 25, 2026 and March 16, 2026, the Investor requested the Company issue 237,000 and 740,000, respectively, of the remaining shares in abeyance.

Sale of Common Stock in Private Placement

On February 20, 2024, we entered into subscription agreements (the "Subscription Agreements") with certain officers and directors of the Company, including our Founder and Chief Executive Officer, our Chief Financial Officer and the Chairman of the Company's Board of Directors, pursuant to which the Company sold an aggregate of 44,643 shares of our Common Stock, at a purchase price of $56.00 per share for an aggregate purchase price of $2.5 million. The per share purchase price represents a 25% premium to the per share closing price of the Common Stock as reported on the Nasdaq Global Market on the February 20, 2024 and a 19% premium to the 5-day volume weighted average closing price per share of the Common Stock as reported on the Nasdaq Global Market for the period ending on the February 20, 2024.

The shares of Common Stock issued pursuant to the Subscription Agreements were not registered under the Securities Act of 1933, as amended, in reliance upon exemptions under Section 4(a)(2) of the Securities Act of 1933, as amended.

Item 9C Disclosure Regarding Foreign Jurisdictions That Prevent Inspections.

Not applicable.

PART III

Item 10 Directors, Executive Officers and Corporate Governance.

The information required by this item is included under the captions "Board of Directors and Corporate Governance," "Proposal One: Director Election," "Executive Officers" and "Delinquent Section 16(a) Reports" included in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the year ended December 31, 2025, and is incorporated herein by reference.

Our board of directors has adopted a Code of Conduct and Ethics applicable to all officers, directors, and employees, which is available on our website (https://investors.hcwbiologics.com/) under "Governance." We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Conduct and Ethics by posting such information on the website address and location specified above.

Item 11 Executive Compensation.

The information required by this item is included under the captions "Board of Directors and Corporate Governance" and "Executive Compensation" in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the year ended December 31, 2025, and is incorporated herein by reference.

Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is included under the captions "Equity Compensation Plan Information" and "Security Ownership of Certain Beneficial Owners and Management" in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the year ended December 31, 2025, and is incorporated herein by reference.

Item 13 Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is included under the captions "Board of Directors and Corporate Governance" and "Certain Relationships and Related Party Transactions" in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the year ended December 31, 2025 and is incorporated herein by reference.

Item 14 Principal Accounting Fees and Services.

The information required by this item is included under the caption "Proposal Two: Ratification of Appointment of Independent Registered Public Accounting Firm" in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the year ended December 31, 2025, and is incorporated herein by reference.

PART IV

Item 15 Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

The information concerning HCW Biologics' audited financial statements and the Report of Independent Registered Public Accounting Firm required by this Item 15(a)(1) is incorporated by reference herein to the section of this Annual Report, Item 8, titled, "Financial Statements and Supplementary Data."

(a)(2) Financial Statement Schedules

All financial statement schedules have been omitted as the information is not required under the related instructions or is not applicable or because the information required is already included in the audited financial statements or the notes to those audited financial statements.

(a)(3) Exhibits

We have filed, or incorporated into this Annual Report by reference, the exhibits listed on the accompanying Exhibit Index immediately preceding the signature page of this Annual Report.

Exhibit Index

Exhibit No.	Exhibit title	Incorporated by reference				Filed or furnished herewith
		Form	File No.	Exhibit No.	Filing date	
3.1	Amended and Restated Certificate of Incorporation	8-K	001-40591	3.1	07/26/2021	
3.1a	Certificate of Amendment of Certificate of Incorporation, filed March 31, 2025	8-K	001-40591	3.1a	04/01/2025	
3.1b	Certificate of Correction of the Certificate of Amendment of Certificate of Incorporation, filed April 1, 2025	8-K	001-40591	3.1b	04/01/2025	
3.2	Amended and Restated Bylaws	8-K	001-40591	3.2	07/26/2021	
4.1	Specimen Stock Certificate	S-1/A	333-256510	4.1	07/09/2021	
4.2	Description of Securities	10-K	001-40591	4.2	03/29/2022	
4.3	Form of New Warrant	8-K	001-40591	4.1	11/20/2025	
4.4	Form of Common Stock Purchase Warrant	8-K	001-40591	4.1	02/19/2026	
4.5	Form of Pre-Funded Common Stock Purchase Warrant	8-K	001-40591	4.2	02/19/2026	
4.6	Form of Common Stock Warrant, dated May 7, 2025, between Company and Holder	10-Q	001-40591	10.13	08/18/2025	
10.1	Form of Inducement Agreement between the Company and Armistice Capital Management LLC	8-K	001-40591	10.1	11/20/2025	
10.2	Securities Purchase Agreement, dated February 17, 2026, between Company and Purchaser	8-K	001-40591	10.2	02/19/2026	
10.3	Amendment to Existing Warrants Agreement, dated February 17, 2026, between the Company and Purchaser	8-K	001-40591	10.3	02/19/2026	
10.4	Form of Lock-up Agreement	S-1	333-393396	10.42	02.11.2026	
10.5	Form of Indemnification Agreement between HCW Biologics Inc. and each of its officers and directors.	S-1/A	333-256510	10.1	07/09/2021	
10.6+	2019 Equity Incentive Plan, as amended, and forms of agreement thereunder.	S-1	333-256510	10.2	07/09/2021	
10.7+	First Amendment to 2019 Equity Incentive Plan.	S-1	333-256510	10.3	07/09/2021	
10.8+	2021 Equity Incentive Plan and forms of agreement thereunder	S-1	333-256510	10.4	07/09/2021	
10.9+	Employment Agreement, dated July 6, 2021, between Peter Rhode and HCW Biologics Inc.	S-1	333-256510	10.6	07/09/2021	
10.10+	Employment Agreement, dated October 9, 2019, between Rebecca Byam and HCW Biologics Inc.	S-1	333-256510	10.7	07/09/2021	
10.11+	Non-Employee Director Compensation Policy.	S-1	333-256510	10.8	07/09/2021	
10.12+	Employment Agreement, dated June 18, 2021, between Dr. Hing C. Wong and HCW Biologics Inc.	S-1	333-256510	10.13	07/09/2021	
10.13+	Executive Incentive Bonus Plan	S-1	333-256510	10.11	07/09/2021	
10.14†	Exclusive License Agreement, dated December 24, 2020, between HCW Biologics Inc. and Wugen, Inc.	S-1	333-256510	10.10	07/09/2021	
10.15†	Master Services Agreement, dated March 14, 2019, between HCW Biologics Inc. and EirGenix, Inc.	S-1	333-256510	10.12	07/09/2021	
10.16†#	Purchase and Sale Agreement, by and between HCW Biologics Inc. and Wai 3300 Corporate Way, LLC, dated May 27, 2022	10-Q	001-40591	10.1	08/12/2022	
10.17#	Loan Agreement by and between HCW Biologics Inc. and Cogent Bank, dated August 15, 2022	10-Q	001-40591	10.1	11/07/2022	
10.18#	Mortgage and Security Agreement by and between HCW Biologics Inc. and Cogent Bank, dated August 15, 2022	10-Q	001-40591	10.2	11/07/2022	
10.19	Form of Subscription Agreement, dated February 20, 2024, by and between the Company and the Subscribers party thereto	8-K	001-40591	10.1	02/22/2024	

10.20	Form of Amended and Restated Senior Secured Note Purchase Agreement, dated July 2, 2024, by and between the Company and the Purchase party thereto	10-Q	001-40591	10.1	08/14/2024	
10.21	Form of Amended and Restated Pledge Agreement, dated July 2, 2024, by and among the Company, Escrow Agent and Noteholder parties thereto	10-Q	001-40591	10.3	08/14/2024	
10.22	Form of Escrow Agreement, dated May 1, 2025, by and between the Company, Escrow Agent and Noteholder party thereto	10-Q	001-40591	10.4	08.14.2024	
10.23	Form of First Amendment to Amended and Restated Secured Note Purchase Agreement, dated September 30, 2024, by and between the Company and Purchaser party thereto	10-Q	001-40591	10.5	11/14/2024	
10.24	Form of Secured Promissory Note by and between the Company and the Holder party thereof	10-Q	001-40591	10.2	08/14/2024	
10.25	Second Amendment to Amended and Restated Senior Secured Note Purchase Agreement and Related Agreements, dated May 1, 2025, between Company and Holder	10-Q	001-40591	10.12	08/18/2025	
10.26	Equity Purchase Agreement, dated February 20, 2025, between the Company and Square Gate Master Fund - Series 4.	8-K	001-40591	10.1	2/21/2025	
10.27	Registration Rights Agreement, dated February 20, 2025, between the Company and Square Gate Master Fund - Series 4	8-K	001-40591	10.2	2/21/2025	
10.28	First Amendment to the Equity Purchase Agreement, dated August 14, 2025, between the Company and Square Gate Master Fund - Series 4.	8-K	001-40591	10.1	08/15/2025	
10.29	Amended and Restated Amended and Restated License, Research and Co-Development Agreement, dated November 17, 2025, between the Company and Beijing Trimmune Biotech Co., Ltd.	S-1	333-293396	10.40	02/11/2026	
10.30†#	Amendment 1 to Amended and Restated License, Research and Co-Development Agreement, dated January 27, 2026, between the Company and Beijing Trimmune Biotech Co., Ltd.	S-1	333-293396	10.43	02/11/2026	
10.31†#	Shareholder Purchase Agreement, dated October 10, 2025, between co-founders of Beijing Trimmune Biotech Co., Ltd., including the Company	S-1	333-293396	10.44	02/11/2026	
10.32	Exclusive License Agreement 12-Month Suspension, dated May 29, 2025, between the Company and Wugen, Inc.	10-Q	001-40591	10.17	08/18/2025	
10.33	Settlement Agreement and Release, dated July 13, 2024, by and between the Company and Altor BioScience, LLC, NantCell, Inc., and ImmunityBio, Inc.	10-Q	001-40591	10.6	11/14/2024	
10.34	Placement Agency Agreement, dated February 17, 2026, between the Company and Maxim Group LLC	8-K	001-40591	10.1	02/19/2026	
10.35	Preliminary Proxy Statement dated March 3, 2025, on Form 14A, including Appendices					X
10.36	Definitive Proxy Statement dated March 13, 2026, on Form 14A, including Appendices					X
19.1	HCW Biologics Inc. Insider Trading Policy					X
23.1	Consent of Independent Registered Public Accounting Firm					X
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and Rule 15d-14(a) of the Exchange Act					X

31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and Rule 15d-14(a) of the Exchange Act					X
32.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
99.1	HCW Biologics Inc. Compensation Recovery Policy	10-K	011-40591	97.1	04/01/2024	
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					X

+ Indicates a management contract or compensatory plan or arrangement.

†† Certain information in this document has been excluded pursuant to Item 601(b)(10) of Regulation S-K. Such excluded information is not material and is the type of information the Registrant treats as private and confidential. The Registrant agrees to furnish supplementally such information to the SEC upon request.

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

Item 16 Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

HCW Biologics Inc.

Date: March 31, 2026

By: /s/ Hing C. Wong, Ph.D.
Hing C. Wong, Ph.D.
Founder and Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Hing C. Wong and Rebecca Byam, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Hing C. Wong, Ph.D. **Hing C. Wong, Ph.D.**	Founder, Chief Executive Officer (Principal Executive Officer)	March 31, 2026
/s/ Rebecca Byam **Rebecca Byam**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2026
/s/ Scott T. Garrett **Scott T. Garrett**	Chairperson of the Board of Directors	March 31, 2026
/s/ Lisa M. Giles **Lisa M. Giles**	Director	March 31, 2026
/s/ Rick S. Greene **Rick S. Greene**	Director	March 31, 2026
/s/ Gary M. Winer **Gary M. Winer**	Director	March 31, 2026