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Filed Pursuant to Rule 424(b)(4)
Registration Nos. 333-256510 and 333-258025

PROSPECTUS

7,000,000 Shares

Common Stock

This is the initial public offering of common stock of HCW Biologics Inc. Prior to this offering, there has been no public market for our common stock. The initial public offering price is $8.00 per share.

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol "HCWB."

We are an "emerging growth company" as defined under the federal securities laws and, as such, we have elected to comply with reduced reporting requirements for this prospectus and may elect to do so in future filings.

Investing in the common stock involves a high degree of risk. See the section entitled "Risk Factors" beginning on page 12 to read about factors you should consider before buying shares of our common stock.

	Per Share	Total
Initial public offering price	$ 8.00	$56,000,000
Underwriting discounts and commissions(1)	$ 0.56	$ 3,920,000
Proceeds, before expenses, to HCW Biologics Inc.	$ 7.44	$52,080,000

(1) Does not include a non-accountable expense allowance equal to 0.35% of the gross proceeds of this offering and other accountable expenses payable to the representative of the underwriters. See "Underwriting" for additional disclosure regarding underwriting discounts, commissions and estimated offering expenses.

Certain of our directors and existing stockholders or their affiliates, including our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer and Vice President of Clinical Operations, have agreed to purchase an aggregate of approximately 1,480,625 shares of our common stock in this offering at the initial public offering price. The underwriter will receive the same underwriting discount on any shares purchased by these parties as they will on any other shares sold to the public in this offering.

To the extent the underwriters sell more than 7,000,000 shares of common stock, we have granted the underwriters a 45-day option to purchase up to 1,050,000 additional shares of common stock from us at the initial public offering price less the underwriting discounts and commissions.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on or about July 22, 2021.

Sole Book Running Manager

EF HUTTON
division of Benchmark Investments, LLC

Co-Manager

REVERE SECURITIES LLC

The date of this prospectus is July 19, 2021

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of its date regardless of the time of delivery of this prospectus or of any sale of securities.

For investors outside the United States, neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required. Persons outside the United States who come into possession of this prospectus and any free writing prospectus related to this offering are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any such free writing prospectus applicable to that jurisdiction.

Until, August 13, 2021, (25 days after the commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

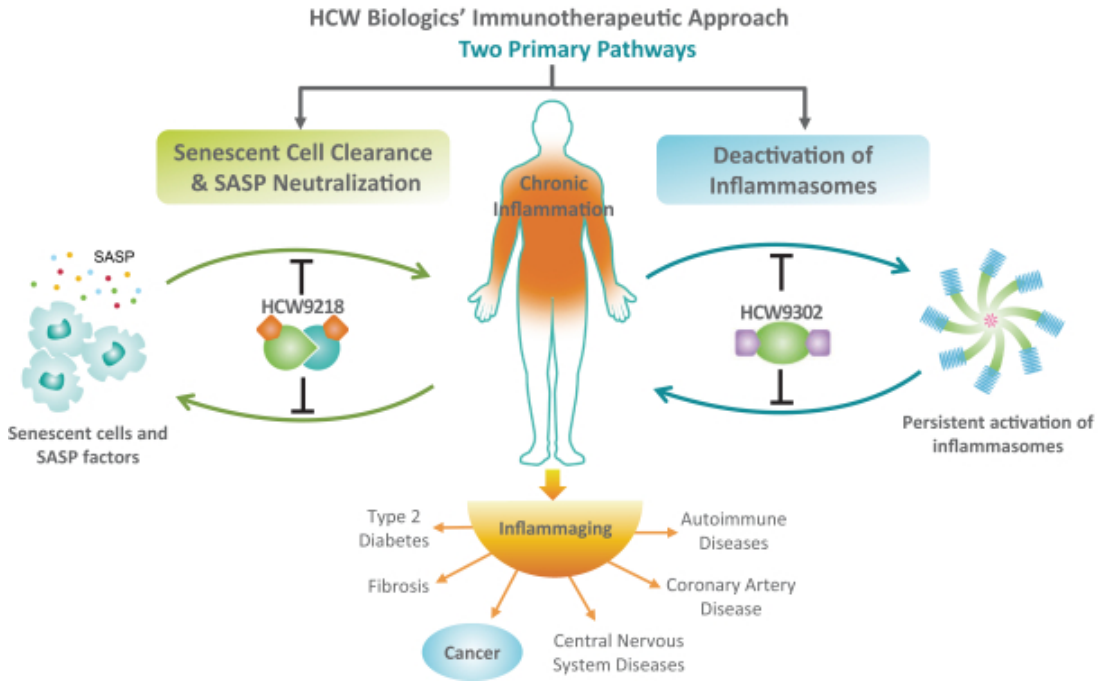
PROSPECTUS SUMMARY

This summary highlights information contained in greater detail elsewhere in this prospectus. Before making an investment in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto, and the information in the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business."

HCW Biologics Inc.

Overview

We are an innovative preclinical stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation and age-related diseases. We believe age-related low-grade chronic inflammation, or "inflammaging," is a significant contributing factor to several chronic diseases and conditions, such as cancer, cardiovascular disease, diabetes, neurodegenerative disease, and autoimmune disease. We believe our approach has the potential to provide an innovative treatment of these age-related diseases.



Our gateway indication is oncology. Advances in immuno-stimulatory and anti-immunosuppressive therapeutics have revolutionized cancer treatment. Our lead molecule, HCW9218, is designed with both of these functionalities – it rejuvenates the immune system to reduce senescence, and it captures transforming growth factor-ß ("TGF-ß") to neutralize its immunosuppressive activity. We are preparing to submit an investigational new drug application ("IND") for a Phase 1b/2 clinical trial in pancreatic cancer to evaluate HCW9218, which includes completing drug product testing and nonclinical animal toxicity/pharmacokinetic studies, as well as finalizing clinical protocol. Pending submission and the U.S. Food and Drug Administration's ("FDA")

acceptance of the IND to proceed, we expect to initiate this clinical trial by the end of 2021 after obtaining Institutional Review Board ("IRB") approval of our clinical research, completing clinical site initiation, and finalizing clinical trial agreements. However, we have not submitted the IND for the planned trial, and we cannot provide any assurance that the FDA will authorize us to initiate our planned clinical trials on a timely basis, or at all. In the event that the FDA does not accept our IND, we may also be required to seek feedback, and the feedback may be unfavorable. In the event we do not receive feedback on a timely basis, or we are required to change the design of our clinical protocol or address other feedback, clinical development of our products would be delayed and our costs may increase. Moreover, if the FDA does not accept the IND we file, we may be required to conduct additional preclinical testing or other IND-enabling activities, which would result in further delay and additional costs.

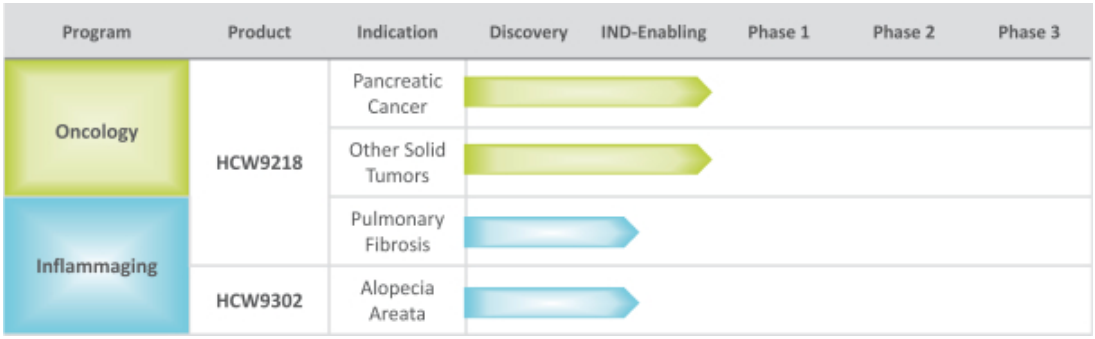
We are initially developing HCW9218 as an injectable immunotherapeutic for patients with solid tumors. Our initial goal is to evaluate HCW9218 in patients with cancer as we attempt to minimize the side effects of chemotherapy through stimulating anti-tumor effector immune cell responses, blocking TGF-ß immunosuppressive activity, eliminating chemotherapy-induced senescent cells in tumors and normal tissues (i.e., senolytic effect), and reducing senescence-associated secretory phenotype ("SASP") factor activity (i.e., senomorphic effect). We are leveraging extensive clinical expertise to structure clinical trials with clear, objective, and measurable endpoints. We expect to manage our clinical trials internally, relying on our in-house expertise in managing clinical trials conducted in collaboration with National Cancer Institute (NCI)-Designated Comprehensive Cancer Centers. Currently, we are engaged in preliminary discussions with seven leading institutions who have shown interest in participating in our clinical trials as clinical sites. We are presently working with the identified Principal Investigators from these institutions to establish clinical development strategies for our product candidates and to refine study protocols for pancreatic, ovarian, breast, prostate, and colorectal cancer trials. Because the discussions with these clinical sites and Principal Investigators are considered preliminary, we are not certain we will be successful in reaching an agreement with any or all of these institutions. The course of these discussions and whether we might need to identify alternative clinical sites could impact the start date for our clinical trials. Any delays in our clinical trials could increase our costs and slow down the development and approval process, which could harm our commercial prospects.

The aim of the Phase 1b/2 clinical trial in pancreatic cancer is to evaluate HCW9218 as an adjunct therapy to chemotherapy. The Phase 1b portion will be a dose escalation study of HCW9218 as monotherapy in refractory patients with advanced pancreatic cancer. The Phase 2 portion of this clinical trial will include a cohort of patients receiving HCW9218 as monotherapy and a cohort of patients receiving HCW9218 as an adjunct to chemotherapy. Pending submission and FDA acceptance of the IND to proceed with a company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in patients with pancreatic cancer, we plan to have an additional clinical trial to evaluate HCW9218 in solid tumors with an investigator-sponsored IND. Our ability to proceed with this trial depends on the submission and acceptance of both INDs for our company-sponsored pancreatic cancer clinical trial and the investigator-initiated solid tumor clinical trial as well as finalizing our agreement with the sponsor. We are currently engaged in preliminary discussions with an institution that has expressed interest to be a sponsor for an IND using HCW9218 as an adjunct to chemotherapy in patients with solid tumors (breast, ovarian, prostate, and colorectal cancers). However, these discussions are preliminary, and we may not succeed in reaching an agreement with this institution. Depending on the course of these discussions and whether we need to seek an alternative sponsor for an IND, there could be a delay in initiating a Phase 1b/2 clinical trial to evaluate HCW9218 in patients with solid tumors. Any delays in our clinical trials could increase our costs and slow down the development and approval process, which could harm our commercial prospects.

We have internally-developed over 30 molecules using our TOBI (Tissue factOr-Based fusIon) platform. Our core focus will be development of our lead product candidates, HCW9218 and HCW9302, as transformative immunotherapeutics, administered subcutaneously. We are actively seeking to out-license certain rights for molecules with great potential but outside of our focus area. We signed our first out-license agreement

at the end of 2020 when we entered into an exclusive worldwide license with Wugen, Inc. ("Wugen"), a company that specializes in cell-based therapies for cancer. Wugen licensed limited rights to develop cell therapy treatments for cancer based on two of our internally-developed multi-cytokine fusion protein molecules, one of which is our clinical-stage molecule, HCW9201. This molecule is currently being evaluated for generation of memory-like NK ("ML-NK") cell products in two Phase 2 studies in patients with relapse/refractory acute myeloid leukemia ("r/r AML") in trials that are initiated by Washington University and supported by Wugen. Patient enrollment and treatment have commenced, and preliminary data from these clinical trials are expected to begin to become available in the second half of 2021.

Pipeline



Our Approach

We have combined our deep understanding of disease-related immunology with our expertise in advanced protein engineering to internally develop our TOBI platform for the design of immunotherapeutic drugs. This modular and tunable technology has allowed us to generate a novel pipeline of internally-developed product candidates capable of activating and targeting desired immune responses and blocking unwanted immunosuppressive activities. Using our TOBI platform, we have successfully developed molecules that can be administered by subcutaneous injection as well as adoptive cell therapy approaches. We have selected two molecules as our lead product candidates: HCW9218 and HCW9302. We have chosen these product candidates because we believe they have the potential to become transformative immunotherapeutics, which can be administered by subcutaneous injection.

Our unique approach is to utilize our internally-developed TOBI platform to create novel multi-functional immunotherapeutics to rejuvenate our immune system to reduce the accumulation of senescent cells and to expand regulatory T ("Treg") cells to suppress the activity of inflammasomes. We believe this approach would eliminate the main drivers of inflammation and address the underlying development and sustainment of these factors as an innovative strategy to treat age-related diseases. We are also using our platform technology to generate product candidates to direct the immune system against solid and hematological cancers to be used as an adjunct to chemotherapies.

Our TOBI platform is a new approach to construct multi-functional fusion proteins and fusion protein complexes using a novel tissue factor ("TF") scaffold platform. The extracellular domain of human TF was selected as it has a rigid elongated structure comprised mainly of ß-sheets with its N- and C-termini located at distal ends of the polypeptide, permitting genetic fusions of other protein domains without anticipated steric interference. This TF domain does not interact with the cell membrane phospholipid bilayer and, as a result, does not exhibit procoagulant activity. This TF domain is expressed at high levels by most cell types and is not

expected to be immunogenic in humans. Consistent with these properties, we found that genetic fusion to the TF domain promoted increased production of difficult-to-express proteins, such as IL-15. Additionally, the TF fusion proteins could be readily purified by affinity chromatography using an anti-TF antibodies and low pH elution conditions, like those used in Protein A-based affinity purification of therapeutic antibodies.

Using the TOBI platform, we have constructed more than 30 fusion complexes comprised of various cytokines, ligands, receptors, and single-chain antibodies, including disease-targeting antibodies and immune checkpoint inhibitors. The modular fusion components are carefully selected to stimulate, inhibit, and/or target specific immune responses using a knowledge-based disease-relevant strategy and in many cases, are designed to provide synergistic and balanced activities for optimal therapeutic benefit. The resulting fusion proteins are rigorously tested in state-of-the-art cell culture systems and disease-specific animal models to verify their activity for the intended clinical use and targeted indications. TOBI also provides a scalable approach for generating large-scale current good manufacturing process ("cGMP")-grade of heteromeric fusion protein complexes to support clinical applications.

The Science of Chronic Inflammation

Senescence is a form of irreversible cell growth arrest accompanied by phenotypic changes, resistance to apoptosis, and activation of damage-sensing signaling pathways. Senescence is considered a stress response that can be induced by a wide range of intrinsic and extrinsic insults, including oxidative and genotoxic stress, DNA damage, telomere attrition, oncogenic activation, mitochondrial dysfunction, or chemotherapeutic agents. Senescent cells enter a state of irreversible growth arrest accompanied by the release of SASP factors, including proinflammatory cytokines, chemokines, and proteinases drive the inflammation cycle and activation of inflammasomes. As our body ages, senescent cells accumulate and increase the release of SASP factors leading to chronic, low-grade inflammation that drives age-related diseases and conditions.

Chemotherapy Induced Senescence in Cancer

Cancer chemotherapy efficacy is based on the assumption that treatment-induced apoptosis or necrosis of tumor cells results in prolonged patient survival. However, in addition to cytotoxic activity, chemotherapy also can cause tumor cells to enter a therapy-induced senescence ("TIS") state with SASP characteristics. The persistence of viable and metabolically active senescent tumor cells after chemotherapy has been attributed to worse overall survival in patients. Systemic chemotherapy has also been found to elevate normal tissue senescence. Therefore, we believe therapeutic approaches that alleviate chemotherapy-induced SASP in normal tissue may lead to a better quality of life for cancer patients.

Approaches for Treating Chronic and Induced Inflammation: Senolytics and Senomorphics

Current clinical efforts to counteract TIS and age-related senescent cell activity have focused on senolytic chemical drugs that selectively induce senescent cell death and senomorphic chemical drugs that reduce the secretion of SASP factors. Despite the promise of senolytics and senomorphics, their efficacy in early phase clinical studies reported to date has been limited. Further, the specificity, toxicity, and optimal treatment schedule of these pharmaceutical agents in the cancer setting have yet to be determined. We have developed an alternative strategy to eliminate senescent cells using well-characterized protein immunotherapeutics including those that stimulate effector immune cells and reduce TGF-ß activity. This strategy is supported by our findings that TIS tumor cells upregulate NKG2D and other ligands on their surface for efficient recognition and killing by effector NK cells and $CD8^+$ T cells and suppression of TGF-ß activity enhances these anti-tumor/anti-senescent cell responses.

To date, therapeutic approaches to reduce aberrant inflammasome activity have focused on inhibitors of various inflammasome components and downstream mediators of inflammation. We believe there is considerable interest in therapeutics that specifically block inflammasome activity upstream. However, these product candidates are still in early phase clinical testing and their bioavailability, off- and on-target toxicity, and utility profiles are still being investigated. Our approach is to deactivate inflammasome pathways in monocytes and macrophages through the immunosuppressive activities of Tregs with our immunomodulator molecules. This approach does not rely on inhibiting specific inflammasome components but utilizes natural processes of the immune system to attenuate and rebalance chronic self-perpetuating proinflammatory responses.

Our Strategy

Our goal is to develop transformative immunotherapies to lengthen health span by disrupting the link between cellular senescence, chronic inflammation, and aging-related diseases. Our strategy for efficiently validating our approach includes the following key components:

- Focus resources on internally-developed molecules, TOBI platform, and manufacturing processes, without relying on third-party licensing for key intellectual property.
- Focus our resources on the development of two primary internally-developed molecules, HCW9218 and HCW9302, for which we can establish strong IP protection, demonstrate best activity in animal models, develop therapeutics that are well tolerated, and can be administered by subcutaneous injection.
- Focus on cancer indications in initial clinical development of our lead product candidate, HCW9218, in indications with high unmet medical need or where side effects of standard-of-care therapy diminishes healthspan.
- Continue to engage with NCI-Designated Comprehensive Cancer Centers and the identified Primary Investigators who have high interest in participating in our clinical trials as clinical sites.
- Expand clinical evaluation of senolytic/senomorphic product candidates to other age-related indications following establishment of a safe treatment regimen in cancer patients for HCW9218.
- Out-license limited rights for certain HCW molecules outside of primary focus, especially cell therapy treatments.
- Explore co-development deals with big pharma for lead molecules.

Risks Related to Our Business and Investment in our Common Stock

Investing in our common stock involves a high degree of risk. You should carefully consider the risks highlighted in the section titled “Risk Factors” immediately following this prospectus summary before making an investment decision. We may be unable for many reasons, including those that are beyond our control, to implement our business strategy successfully. Some of these risks are that:

- We have incurred significant losses since our inception and we expect to incur losses for the foreseeable future, and we may never achieve profitability.
- All of our product candidates are in preclinical or early-stage clinical development and clinical drug development is a lengthy and expensive process with uncertain timelines and outcomes.
- Results of preclinical studies of our product candidates may not be predictive of the results of future preclinical studies or clinical trials.
- Our product candidates may have serious adverse, undesirable, or unacceptable side effects or other properties that may delay or prevent marketing approval.

- Public health crises such as pandemics or similar outbreaks could materially and adversely affect our preclinical studies and clinical trials, business, financial condition, and results of operations.
- The development and commercialization of biopharmaceutical products is subject to extensive regulation.
- 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.
- We expect to rely on patents and other intellectual property rights to protect our technology, including product candidates and our immunotherapy platform, the prosecution, enforcement, defense, and maintenance of which may be challenging and costly.
- Even if this offering is successful, we will require substantial additional funding, which may not be available to us on acceptable terms, or at all.

If we are unable to adequately address these and other risks we face, our business, financial condition, operating results, and prospects may be adversely affected.

Corporate Information

We were incorporated in Delaware on April 2, 2018. Our principal executive offices are located at 2929 N Commerce Parkway, Miramar, FL 33025. Our telephone number at that location is (954) 842-2024. References in the prospectus to "we," "our," "us," "HCW Biologics," and the "Company" refer to HCW Biologics Inc. Our corporate website address is www.hcwbiologics.com. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

HCW BIOLOGICS INC. and TOBI are trademarks of HCW Biologics Inc. All other brand names or trademarks appearing in this prospectus are the property of their respective holders. Solely for convenience, the trademarks and trade names in this prospectus 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.

Implications of Being an Emerging Growth Company and Smaller Reporting Company

As a company with less than $1.07 billion in revenue during our last completed fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements that are otherwise applicable generally to public companies. These reduced reporting requirements include:

- an exemption from compliance with the auditor attestation requirement on the effectiveness of our internal control over financial reporting;
- an exemption from compliance with any requirement that the Public Company Accounting Oversight Board (the "PCAOB"), has adopted regarding a supplement to the auditor's report providing additional information about the audit;
- reduced disclosure about our executive compensation arrangements;
- an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or a stockholder approval of any golden parachute arrangements; and
- extended transition periods for complying with new or revised accounting standards.

We will remain an emerging growth company until the earliest to occur of: (i) the end of the first fiscal year in which our annual gross revenue is $1.07 billion or more; (ii) the end of the first fiscal year in which we are deemed to be a “large accelerated filer,” as defined in the Securities Exchange Act of 1934, as amended (the “Exchange Act”); (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities; and (iv) the end of the fiscal year during which the fifth anniversary of this offering occurs. We may choose to take advantage of some, but not all, of the available benefits under the JOBS Act. We are electing to use extended transition periods available under the JOBS Act for complying with new or revised accounting standards, but we currently intend to take advantage of the other exemptions discussed above. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

The Offering	
Common stock offered by us	7,000,000 shares.
Common stock to be outstanding after the offering	35,650,520 shares (or 36,700,520 shares if the underwriters exercise the option to purchase additional shares in full).
Option to purchase additional shares of common stock	The underwriters have an option to purchase a maximum of 1,050,000 additional shares of common stock from us. The underwriters can exercise this option at any time within 45 days from the date of this prospectus.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $47.5 million (or approximately $55.3 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of $8.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to advance the development of HCW9218 and HCW9302, to continue development of other discovery programs for cancer and other age-related diseases, including preclinical studies, IND-enabling activities, and clinical trials, build our own cGMP manufacturing plant and optimize our manufacturing capabilities, and provide additional working capital and general corporate purposes. See the section entitled “Use of Proceeds” for additional information.
Nasdaq Global Market symbol	“HCWB”
Material U.S. federal income tax considerations for non-U.S. holders	For a discussion of the material U.S. federal income tax considerations that may be relevant to prospective investors who are non-U.S. holders, please see “Material U.S. Federal Income Tax Considerations for Non-U.S. Holders.”
Insider participation	Certain of our directors and existing stockholders or their affiliates, including our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer and Vice President of Clinical Operations, have agreed to purchase an aggregate of approximately 1,480,625 shares of our common

	stock in this offering at the initial public offering price. The underwriter will receive the same underwriting discount on any shares purchased by these parties as they will on any other shares sold to the public in this offering.
Risk factors	Investing in our common stock involves a high degree of risk. You should carefully read and consider the information set forth under "Risk Factors" and all other information in this prospectus before investing in our common stock.

We refer to our Series A redeemable preferred stock, Series B redeemable preferred stock, and Series C redeemable preferred stock as our "redeemable preferred stock" in this prospectus, as well as for financial reporting-term purposes and in the financial tables included in this prospectus, as more fully explained in Note 8 to our annual audited financial statements.

Except as otherwise indicated, all information in this prospectus is based upon 28,650,520 shares of our common stock outstanding as of March 31, 2021, and excludes:

- 653,355 shares of our common stock issuable upon exercise of stock options outstanding as of March 31, 2021, having a weighted-average exercise price of $0.16 per share; and
- 2,400,000 shares of common stock reserved for future grant or issuance under our 2021 Equity Incentive Plan (the "2021 Plan") (which includes 464,486 shares of our common stock as of March 31, 2021 reserved for future grant under our 2019 Equity Incentive Plan (the "2019 Plan"), that will be added to the shares reserved for future issuance under our 2021 Plan upon effectiveness of that plan if the shares are not issued or subject to outstanding grants under the 2019 Plan at that time), which will become effective in connection with this offering and contains provisions that automatically increase its share reserve each year, as more fully described in "Executive Compensation – Equity Incentive Plans."

Except as otherwise indicated, all information in this prospectus reflects and assumes:

- a three (3)-for-seven (7) reverse split of our outstanding capital stock to be effected prior to the completion of this offering;
- the automatic conversion of the following securities into Class A common stock immediately prior to the filing and effectiveness of our amended and restated certificate of incorporation (the "Conversion"):
  - all of our outstanding shares of Class B common stock into an aggregate of 4,285,714 shares of Class A common stock;
  - all of our outstanding shares of redeemable preferred stock into an aggregate of 23,768,420 shares of Class A common stock;
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the closing of this offering; and
- no exercise by the underwriters of their option to purchase additional shares of common stock from us in this offering.

Summary Financial Information

We derived the summary statements of operations data for the years ended December 31, 2019 and 2020 (except the pro forma share and net loss per share information) and balance sheet data as of December 31, 2020 from our audited financial statements included elsewhere in this prospectus. We derived the summary statements of operations data for the three months ended March 31, 2020 and 2021 (except pro forma share and net loss per share information) and balance sheet data as of March 31, 2021 (except pro forma and pro forma as adjusted financial information) from our unaudited condensed financial statements included elsewhere in this prospectus. We have included all adjustments consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those unaudited condensed financial statements. The summary financial data in this section are not intended to replace the financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in any future period.

	Year Ended December 31,		Three Months Ended March 31,	
(in thousands, except share and per share data)	2019	2020	2020	2021
			(unaudited)	
Statements of Operations Data:				
Revenues	$ —	$ 4,100	$ —	$ —
Operating expenses:				
Research and development	5,391	7,255	1,678	2,330
General and administrative	1,974	2,669	719	1,082
Total operating expenses	7,365	9,924	2,397	3,412
Loss from operations	(7,365)	(5,824)	(2,397)	(3,412)
Interest and other income, net	72	22	21	568
Net loss	$ (7,293)	(5,802)	$ (2,376)	$ (2,844)
Less: cumulative preferred dividends earned in the period	(490)	(1,272)	(280)	(477)
Net loss available for distribution to common stockholders	$ (7,783)	$ (7,074)	$ (2,656)	$ (3,321)
Net loss per share, basic and diluted	$ (1.82)	$ (1.49)	$ (0.56)	$ (0.69)
Weighted average shares outstanding, basic and diluted	4,286,528	4,739,285	4,717,542	4,839,871
Unaudited pro forma net loss per share		$ (0.24)		$ (0.10)
Unaudited pro forma weighted average shares outstanding, basic and diluted[1]		24,428,371		28,608,291

	As of March 31, 2021 (unaudited)		
(in thousands)	Actual	Pro Forma[2]	Pro Forma As Adjusted[3]
Balance Sheets Data:			
Cash, cash equivalents and accounts receivable	$ 8,156	$ 8,156	$ 55,677
Working capital[4]	8,452	8,452	55,973
Total assets	12,928	12,928	60,449
Redeemable preferred stock	31,607	—	—
Accumulated deficit	(20,027)	(17,889)	(17,889)
Total stockholders' (deficit) equity	(20,026)	11,581	59,101

(1) The unaudited pro forma weighted average shares outstanding, basic and diluted, reflect the weighted average of shares of common stock and redeemable preferred stock, based on the conversion of the redeemable preferred stock, according to the date of issuance. Outstanding stock options were considered anti-dilutive and were excluded from the calculation.

(2) The pro forma column reflects the automatic conversion of 23,768,420 shares of our redeemable preferred stock into an equivalent number of shares of common stock immediately prior to the completion of this offering. The redeemable preferred stock earns a 6% cumulative dividend as long as it remains outstanding. Upon Conversion, the accrued and unpaid dividend is forfeited. See Note 8 of the Notes to the audited financial statements for further explanation of the redeemable preferred stock.

(3) The pro forma as adjusted column reflects (i) the items described in footnote (1) above and (ii) the sale and issuance of shares of our common stock by us in this offering, at the initial public offering price of $8.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

(4) We define working capital as current assets less current liabilities.

RISK FACTORS

This offering involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information in this prospectus before deciding whether to invest in shares of our common stock. We believe the risks described below are the risks that are material to us as of the date of this prospectus. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected. This could cause the trading price of our common stock to decline, and you may lose part or all of your investment.

This prospectus also contains certain forward-looking statements that involve risks and uncertainties. These forward-looking statements refer to our future plans, objectives, expectations and intentions. These forward-looking statements may be identified by the use of words such as "expects," "anticipates," "intends," "plans," and similar expressions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could contribute to these differences include those discussed below and elsewhere in this prospectus.

Risks Related to our Financial Position and Need for Additional Capital

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

Since our inception, we have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials, and have incurred significant operating losses. For the years ended December 31, 2019 and 2020, and the three months ended March 31, 2021, we reported a net loss of $7.3 million, $5.8 million and $2.8 million, respectively. As of March 31, 2021 the Company had cash and cash equivalents of $6.9 million. Since inception to March 31, 2021, the Company incurred cumulative net losses of $17.9 million. To date, we have financed our operations primarily through the sale of our redeemable preferred stock, and to a lesser extent, upfront payments received under our exclusive worldwide license with Wugen Inc. ("Wugen License") for certain rights to two of our internally-developed molecules and proceeds from an SBA Paycheck Protection Loan ("PPP loan") obtained through the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") which was forgiven.

Our losses have resulted principally from expenses incurred in the research and development of our product candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our product candidates. The only revenue we have generated to date relates to our Wugen License. We have not generated any revenues from product sales. We anticipate that our expenses will increase substantially as we:

- undertake our initial Phase 1b/2 clinical trial for HCW9218 in pancreatic cancer;
- continue to advance the preclinical and clinical development in pursuit of immunotherapeutic treatments for other indications such as fibrotic diseases and autoimmune diseases using our lead product candidates, HCW9218 and HCW9302;
- initiate preclinical studies and clinical trials for additional product candidates that we may identify in the future;
- scale up our manufacturing process and capabilities to support our clinical trials of our product candidates;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our clinical development, manufacturing, and commercialization efforts;

- continue to develop, perfect, and defend our intellectual property portfolio; and
- incur additional legal, accounting, or other expenses in operating our business, including the additional costs associated with operating as a public company.

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

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

Because of the numerous risks and uncertainties associated with pharmaceutical products and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA, or other regulatory authorities to perform studies in addition to those we currently anticipate, if there are any delays in completing our clinical trials or the development of any of our product candidates or if there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim, our expenses could increase and commercial revenue could be further delayed and more uncertain.

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

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

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

To date, we have funded our operations primarily through the sale of redeemable preferred stock and to a lesser extent, the proceeds of upfront payments from the Wugen License and the proceeds of a PPP loan. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of HCW9218 and HCW9302, initiate additional clinical trials, and continue to research, develop, and conduct preclinical studies of our other product candidates.

In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development programs or any future commercialization efforts.

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

- the scope, timing, progress, costs, and results of discovery, preclinical development, laboratory testing, and clinical trials for our product candidates;
- the costs, timing, and outcome of regulatory review of any of our product candidates;
- the cost of manufacturing clinical supplies of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the extent to which we earn additional revenues under our licensing agreement with Wugen to develop certain cellular therapy products or enter into, maintain, and derive revenues from other licensing agreements, including agreements to out-license HCW9302 and HCW9213 and other product candidates, research and other collaborations, joint ventures and other business arrangements;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the cost of building a sales force in anticipation of product commercialization;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in business, products, and technologies.

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

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our operations with our existing cash and cash equivalents and accounts receivable, the net proceeds from this offering, equity or debt financings, and upfront and milestone and royalties payments, if any, received from future licenses or collaborations. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, or acquiring, selling, or licensing intellectual property rights, which could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technology, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results, and prospects.

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

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, we have implemented recommended public health guidance measures, limited the number of on-site staff and operated on a staggered schedule, which has altered our operations and processes. Similar changes from normal business activities have occurred at our key vendors and partners. We have experienced delays in the development of our lead product candidates as a result of the ongoing pandemic, including delays with certain third-party vendors conducting preclinical IND-enabling studies. Additionally, the worldwide demand and rapid development of COVID-19 diagnostics, vaccines and therapeutics has limited and may continue to limit the availability of services and materials necessary for our product candidates' manufacture and testing. While we are using our best efforts to mitigate these disruptions, we expect that our clinical development program timelines, including the timing of the IND submissions, may continue to be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition, and results of operations.

As a result of the COVID-19 pandemic, or similar pandemics, and related public health guidance measures and orders, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition, and results of operations.

Potential disruptions include but are not limited to:

- COVID-19-related delays or interruptions at the contract testing or manufacturing operations, our laboratories, or in the supply chain;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- patients withdrawing from our future clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;

- delays in clinical sites receiving the supplies and materials needed to conduct our planned clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state, or local governments, employers, and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures, or mass transit disruptions;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

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

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

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

The successful development of our product candidates will depend on several factors, including the following:

- timely completion of successful clinical trials and preclinical studies for which the FDA, or any comparable foreign regulatory authority agree with the design, endpoints, or implementation;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting our planned clinical trials or future clinical trials;
- initiation and successful patient enrollment in, and completion of, additional clinical trials on a timely basis;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe and effective as a treatment for our targeted indications or, in the case of an applicable product candidate which is regulated as a biological product, that the applicable product is safe, pure, and potent for our targeted indications;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities; and
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved.

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

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

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

Our immunotherapy platform technology is based on novel technology that is unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.

We are developing a pipeline of product candidates using our internally-developed immunotherapy platform technology. We have not received regulatory approval for any of our product candidates. The scientific research that forms the basis of our efforts to develop product candidates with our immunotherapy platform technology is still ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our immunotherapy platform technology is both preliminary and limited. Given the novelty of our technology, we intend to work closely with the FDA and other regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted by the FDA and other regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies. Moreover, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of our immunotherapy platform technology, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. Additionally, even if our lead product candidates, such as HCW9218 and HCW9302, are approved, we will need to educate medical personnel regarding the potential efficacy and safety benefits of incorporating product candidates, such as HCW9218 and HCW9302 into existing treatment regimens, including in combination with other treatments for certain types of cancer. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our share price.

The potential longer term growth of our business depends on our efforts to leverage our immunotherapy platform technology to expand our portfolio of molecules and product candidates, which may require substantial financial resources and may ultimately be unsuccessful.

The potential longer term growth of our business depends upon our ability to utilize our internally-developed immunotherapy technology platform to build a pipeline of molecules and product candidates and either progress those product candidates through clinical development for the treatment of a variety of different types of diseases or out-license those molecules to third parties. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various cancers and aging-associated diseases, as well as other immunotherapy molecules, we may not be able to develop product candidates that are safe and effective. Research programs to identify new molecules, indications, and product candidates require substantial technical, financial, and human resources whether or not we ultimately identify any product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates; or
- potential product candidates may on further study be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective drugs.

Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. There are a number of FDA requirements that we must satisfy before we can commence a clinical trial. If we are able to identify additional potential product candidates, satisfaction of these regulatory requirements will entail substantial time, effort, and financial resources. We may never satisfy these requirements. Any time, effort, and financial resources we expend on development of other product candidates may impair our ability to continue development and commercialization of HCW9218 for oncological and other indications, and we may never commence clinical trials of such development programs despite

expending significant resources in pursuit of their development. If we do commence clinical trials of other product candidates, these product candidates may never demonstrate sufficient safety and efficacy to be approved by the FDA or other regulatory authorities. If any of these events occur, we may be forced to abandon our development efforts for such program or programs, which would harm our business.

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

As of March 31, 2021, we had 40 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 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 future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

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

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

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

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

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

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

In the near term, we are dependent on the success of HCW9218. If we are unable to complete the clinical development of, obtain marketing approval for or successfully commercialize HCW9218, or if we experience significant delays in doing so, our business would be substantially harmed.

We do not currently have products approved for sale and are investing a significant portion of our efforts and financial resources in the development of HCW9218. Although we have other programs in preclinical development and we intend to develop additional product candidates in the coming years, it will take additional investment and time for such product candidates to reach the same stage of development as HCW9218, and there can be no assurance that they will ever do so. Our prospects are substantially dependent on our ability to develop and obtain marketing approval for, and successfully commercialize, HCW9218 in one or more disease indications.

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

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.

From time to time, we may also disclose interim data from our preclinical studies and 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. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

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. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

Results of preclinical studies of our product candidates may not be predictive of the results of future preclinical studies or clinical trials.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we or any collaborator for such candidates must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure, and potent in humans. Before an investigational new drug (“IND”) application can be submitted to the FDA and become effective, which is a prerequisite for conducting clinical trials on human subjects in the United States, a product candidate must successfully progress through extensive preclinical studies, which include preclinical laboratory testing, animal studies, and formulation studies in accordance with Good Laboratory Practices.

Success in preclinical studies does not ensure that later preclinical studies or clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, including our non-human primate studies, may not be predictive of the results of outcomes in subsequent clinical trials on human subjects. Product candidates in clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies.

If we fail to receive positive results in preclinical studies or clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

All of our product candidates are in preclinical or early-stage clinical development. 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. Clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to obtain regulatory authorization to commence a trial;
- delays in or failure to obtain institutional review board (“IRB”), approval at each site;
- delays in or failure to reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites — we are currently engaged in preliminary negotiations with a potential sponsor for an IND for HCW9218, but these negotiations, and any other discussions with potential clinical sites may not reach an agreement;
- difficulty in recruiting clinical trial investigators of appropriate competencies and experience;
- delays in establishing the appropriate dosage levels in clinical trials;
- delays in or failure to recruit and enroll suitable patients to participate in a trial, particularly considering study inclusion and exclusion criteria and patients’ prior lines of therapy and treatment;
- the difficulty in certain countries in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results;

- lower than anticipated retention rates of patients in clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delays adding new investigators or clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or governmental authorities, as applicable, to suspend or terminate a trial if it is found that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unfavorable characteristics of the product candidate, or if such undesirable effects or risks are found to be caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- changes in regulatory requirements, policies, and guidelines;
- manufacturing sufficient quantities of a product candidate for use in clinical trials;
- the quality or stability of a product candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications that may make our product candidates no longer relevant;
- third-party actions claiming infringement by our product candidates in clinical trials outside the United States and obtaining injunctions interfering with our progress; and
- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or disease, including the COVID-19 pandemic.

In addition, even if the regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or similar application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Ethics Committees or IRBs at the medical institutions where the clinical trials are conducted. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted, by the Data Review Committee or Data Safety Monitoring Board for such trial or by the FDA, or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations.

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

Our lead product candidate, HCW9218, is still in preclinical development and will require completion of IND-enabling activities before we are prepared to submit an IND for regulatory approval. We cannot predict with any certainty if or when we might complete these activities and submit an IND for regulatory approval of HCW9218 or whether any such IND will be approved by the FDA. We cannot provide any assurance that the FDA will authorize us to initiate any of our planned clinical trials on a timely basis, or at all, or that the FDA will agree with the design of our protocol. We may also seek feedback from the FDA or other regulatory authorities on our clinical development program, and the FDA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of HCW9218 could be harmed, and our ability to generate revenues from HCW9218 may be delayed. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or IRBs or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators may decide the design of our clinical trials is flawed, for example if our trial protocol does not evaluate treatment effects in trial subjects for a sufficient length of time;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- preclinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional preclinical studies before we proceed with certain clinical trials, limit the scope of our clinical trials, halt ongoing clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators, IRBs or ethics committees may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, IRBs or ethics committees to suspend or terminate the trials; and
- regulators may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a risk evaluation and mitigation strategy ("REMS").

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are conducted or their ethics committees, by the data review committee or data safety monitoring board for such trial or by the FDA, European Medicines Agency ("EMA") or other foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class of products to which our product candidates belong.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling or a REMS that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our development costs will also increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, including to add additional patients or arms, which could result in increased costs and expenses and/or delays. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or a comparable foreign regulatory may not permit us to proceed.

We may not be able to file INDs for any of our product candidates on the timelines we expect, if at all. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that require us to suspend or terminate clinical trials. Commencing each of these clinical trials will be subject to finalizing the trial design and selection of relevant endpoints based on discussions with the FDA and other regulatory authorities. Any guidance we receive from the FDA or other regulatory authorities is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect. Successful completion of our clinical trials is a prerequisite to submitting a new drug application, or NDA, to the FDA for each drug candidate and, consequently, the ultimate approval and commercial marketing of each drug candidate. There is also no assurance that, even if completed, our ongoing or any future clinical trials of drug candidates will be successful or will generate positive clinical data.

Our product candidates may have serious adverse, undesirable, or unacceptable side effects or other properties that may delay or prevent marketing approval. If such side effects are identified following approval, if any, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

In the event that any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit approvals of such products and require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies, or issue other communications containing warnings or other safety information about the product;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a REMS plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the dose or the way the product is administered, conduct additional clinical trials, or change the labeling of the product;

- we may be subject to limitations on how we may promote or manufacture the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators, or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of any products.

The manufacture of our product candidates is complex. Our third-party manufacturers may encounter difficulties in production, which could delay or entirely halt their ability to supply our product candidates for clinical trials or, if approved, for commercial sale.

Our product candidates are considered to be biologics and the process of manufacturing biologics is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We do not own or operate any cGMP manufacturing facilities. We rely, and expect to continue to rely, on third-party contract development and manufacturing organizations for the manufacture of our product candidates for preclinical and clinical testing. To date, we and our contract manufacturers have limited experience in the manufacturing of cGMP batches of our product candidates. Our contract manufacturers must comply with cGMP, regulations, and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. To date, we and our contract manufacturers have only produced smaller cGMP batches of our product candidates and have not scaled up the manufacturing process for later-stage clinical trials and commercialization. Some of our product candidates may require the development of new processes to scale up, which could cause delays in the scale-up of manufacturing, as well as greater costs that could negatively impact the financial viability of our product candidates.

The process of manufacturing our biologic product candidates is extremely susceptible to product loss due to contamination, oxidation, equipment failure, or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, this could lead to withdrawal of our products from the market, and such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Moreover, if the FDA determines that our third-party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMP, the FDA may not approve our Biologics License Application (“BLA”), until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.

Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications as a result of defects or storage over an extended period of time, undertake costly remediation efforts, or seek more costly manufacturing alternatives. As part of our process development efforts, we also may make changes to our manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials.

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

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. These trials and other trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal, or adverse events. For example, there have been delays in commencing clinical trials of HCW9201 as a result of the ongoing pandemic. These types of developments could cause us to delay the trial or halt further development.

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

Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

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

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

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

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

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

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

Risks Related to Our Regulatory Environment

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

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

We have not previously submitted a BLA to the FDA or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product

candidates will receive regulatory approval. Obtaining approval of a BLA can be a lengthy, expensive, and uncertain process, and as a company we have no experience with the preparation of a BLA submission or any other application for marketing approval. In addition, the FDA has the authority to require a REMS, plan 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 the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, or regulatory authorities may not accept a submission due to, among other reasons, the content or formatting of the submission;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

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

engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning or untitled letters;
- issue, or require us to issue, safety-related communications, such as safety alerts, field alerts, “Dear Doctor” letters to healthcare professionals, or import alerts;
- impose civil or criminal penalties;
- suspend, limit, or withdraw regulatory approval;
- suspend any of our preclinical studies and clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers’ facilities; or
- seize or detain products, refuse to permit the import or export of products, or require us to conduct a product recall.

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

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration, if left in place, may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA’s ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict the extent to which these orders, if left in place by the Biden Administration, will impact the FDA’s ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA’s ability to

hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to licensed biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, including product pre-approval inspections reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed, or become more expensive.

Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, vendors, customers, and third-party payors in the United States and elsewhere are subject to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, and other healthcare laws and regulations, which could expose us to substantial penalties, contractual damages, reputation harm, administrative burdens, and diminished profits.

Healthcare providers, healthcare facilities and institutions, physicians, and third-party payors in the United States and elsewhere 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 professionals, healthcare facilities and institutions, principal investigators, consultants, customers, and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws that affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any

kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, including stock options. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other the other hand. Any arrangements with prescribers must be for *bona fide* services and compensated at fair market value. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, which prohibit, among other things, including through civil whistleblower or qui tam actions, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by, among other things, engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires, among other things, certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services ("CMS"), information related to certain payments and other transfers of value to physicians, as defined by statute, and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to

healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and

- similar healthcare laws and regulations in foreign jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct 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. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our product candidates, if approved. Compensation under some of these arrangements includes the provision of stock or stock options in addition to cash consideration. Because of the complex and far-reaching nature of these laws, it is possible that governmental authorities could conclude that our payments to physicians may not be fair market value for *bona fide* services or that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of noncompliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. 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 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, and 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.

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.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively the "ACA"), was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA of importance to the pharmaceutical and biotechnology industries, which includes biologics, are the following:

- manufacturers and importers of certain branded prescription drugs, including certain biologics, with annual sales of more than $5 million made to or covered by specified federal healthcare programs are required to pay an annual, nondeductible fee according to their market share of all such sales;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% of the average manufacturer price for most branded drugs, biologics, and biosimilars and to 13.0% for generic drug, and cap of the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price ("AMP");
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted, or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health program, commonly referred to as the "340B Program;"
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, also known as the "Physicians Payment Sunshine Act;"
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- a licensure framework for follow-on biologic products.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the Tax Cuts and Jobs Act of 2017, repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the "individual mandate." In December 2019, a U.S. District Court upheld a ruling that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In March 2020, the Supreme Court of the United States agreed to hear the appeal of this decision, and oral argument was held in November 2020. It is unclear how this and other efforts to challenge, repeal, or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted which, among other things, have reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers. These new laws or any other similar laws introduced in the future, as well as regulatory actions that may be taken by CMS, may result in additional reductions in Medicare and other healthcare funding, which could negatively affect our customers and accordingly, our financial operations. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. Additionally, individual states in the United States have passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing and costs. Similar developments have occurred outside of the United States, including in the European Union where healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. To obtain reimbursement or pricing approval in some European Union member states, we may be required to conduct studies that compare the cost-effectiveness of our product candidates to other therapies that are considered the local standard of care.

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Even if we are able to commercialize any product candidate, coverage and adequate reimbursement may not be available or such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing, and reimbursement for drug products vary widely from country to country. Some countries require approval of the sale price of a drug product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription drug product pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, such as government authorities, private health insurers, and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed

for drug products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely.

There may be significant delays in obtaining reimbursement for newly-approved drug products, and coverage may be more limited than the purposes for which the drug product is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drugs product will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution.

Interim reimbursement levels for new drug products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drug products that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drug products may be reduced by mandatory discounts or rebates required by third-party payors and by any future relaxation of laws that presently restrict imports of drug products from countries where they may be sold at lower prices than in the United States. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because some of our product candidates will be physician-administered subcutaneous injectables, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used.

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 follow 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. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement, or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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

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

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

In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information. These state laws include the recently enacted California Consumer Privacy Act, which establishes additional data privacy rights for residents of the State of California. Similar laws have been proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging.

Our clinical trial programs and research collaborations outside the United States may implicate international data protection laws, including, in Europe, the General Data Protection Regulation ("GDPR"), which became effective in 2018. The GDPR imposes stringent operational requirements for processors and controllers of personal data. Among other things, the GDPR requires detailed notices for clinical trial subjects and investigators, as well as requirements regarding the security of personal data and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. If our privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions requiring us to change the way we use personal data and/or fines. In addition to statutory enforcement, a personal data breach can lead to negative publicity and a potential loss of business. Further, following the United Kingdom's withdrawal from the E.U. effective as of December 31, 2020, we will have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, which may have differing requirements. If we fail to comply with United Kingdom data protection laws we may be subject to litigation, regulatory investigations, enforcement notices, and/or enforcement actions, as well as negative publicity and a potential loss of business.

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

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

We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, and could result in adverse publicity that could harm our business. Moreover, even if we take all necessary action to comply with regulatory requirements, we could be subject to a hack or data breach, which could subject us to fines and penalties, as well as reputational damage.

If we or any collaborators fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our clinical candidates. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

If we fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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. Our competitors may, among other things:

- have significantly greater financial, manufacturing, marketing, drug development, technical, and human resources than we do;
- develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- establish superior proprietary positions covering our products and technology;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Should any of these factors occur, our business, financial condition, and results of operations could be materially adversely affected.

In addition, any collaborators may decide to market and sell products that compete with the product candidates that we have agreed to license to them, and any competition by our collaborators could also have a material adverse effect on our future business, financial condition, and results of operations.

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If the market opportunity for any product candidate that we or our strategic partners develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.

We intend to initially focus our product candidate development on treatments for various oncology indications. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor

treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or the third-party to whom we relinquish such rights may not take full advantage or be properly qualified to take full advantage of such valuable rights. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business.

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:

- the timing of market introduction;
- the terms of any approvals and the countries in which approvals are obtained;
- the number and clinical profile of competing products;

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support;
- adverse publicity about our product candidates;
- availability of coverage, adequate reimbursement, and sufficient payment from health maintenance organizations and other insurers, both public and private, for our product candidates, or the procedures utilizing our product candidates, if approved;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities; and
- other potential advantages over alternative treatment methods.

If our product candidates fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

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

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

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

Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or

interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the European Union has had an established regulatory pathway for biosimilars since 2004. However, biosimilars can only be authorized once the period of data exclusivity on the reference biological medicine has expired.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues, and we may not generate adequate or sufficient revenues from them or be able to reach or sustain profitability.

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.

Pharmaceutical manufacturers are required to register their facilities and list their products manufactured after beginning drug manufacturing and then annually thereafter with the FDA and certain state and foreign agencies. 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 or laboratory facility used by us or our strategic partners, may result in restrictions on the product or on the manufacturing or laboratory 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 could also lead to plant

shutdown or the delay or withholding of product approval by the FDA in additional indications, or by foreign regulators in any indication. Certain countries may impose additional requirements on the manufacturing of drug products or drug substances, and on manufacturers, as part of the regulatory approval process for products in such countries. The failure by our third-party manufacturers to satisfy such requirements could impact our ability to obtain or maintain approval of our products in such countries.

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

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

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

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

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any

related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

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

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

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all. If our strategic collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. In instances where we do enter into collaborations, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects, and financial condition:

- 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;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- we may be required to relinquish important rights such as marketing, distribution, and intellectual property rights;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors;
- we and our collaboration partner may disagree regarding the development plan for product candidates on which we are collaborating (for example, we may disagree with a collaboration partner regarding target indications, inclusion or exclusion criteria for a clinical trial, or the decision to seek front line therapy approval versus second, third, or fourth line therapy approval);
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- business combinations or significant changes in a collaborator’s business strategy may adversely affect our willingness to complete our obligations under any arrangement; or

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

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. Our reliance on a single third-party manufacturer exposes us to certain risks, including the following:

- we may be unable to identify replacement manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve the use of any manufacturers of our product candidates. This approval would require new testing and cGMP compliance inspections by the FDA. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products;
- initial replacement manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately or timely;
- under our exclusive license agreement with Wugen, we are contractually obligated to oversee the manufacturing and supply of our internally-developed fusion molecules HCW9201 and HCW9206 in the manufacture of Wugen's cellular therapeutics, and if our single third-party manufacturer is unable to timely manufacture our product or produce the quantity and quality required to meet our and Wugen's clinical needs, then Wugen has priority over us which could result in our financial results and the commercial prospects for our product candidates being harmed, our costs could increase and our ability to generate revenue could be delayed; and
- our ability to develop our product candidates could be materially and adversely impacted if the single third-party manufacturer upon which we rely were to experience a significant business challenge,

disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory, or reputational issues.

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.

If we are unable to obtain sufficient raw and intermediate materials on a timely basis or if we experience other manufacturing or supply difficulties, our business may be adversely affected.

The manufacture of certain of our product candidates requires the timely delivery of sufficient amounts of raw and intermediate materials. We work closely with our suppliers to ensure the continuity of supply, but cannot guarantee these efforts will always be successful. Further, while efforts are made to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier. While we believe that alternative sources of supply exist where we rely on sole supplier relationships, there can be no assurance that we will be able to quickly establish additional or replacement sources for some materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our product candidates in a timely or cost-effective manner.

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

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

Risks Related to Intellectual Property and Information Technology

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

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

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

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

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned patent

applications may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our owned patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

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

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

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

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

If we were to initiate legal proceedings against a third party to enforce a patent related to one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States or in certain jurisdictions in Europe, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, novelty, non-obviousness, written description or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar invalidity and/or unenforceability claims before administrative bodies in the United States or abroad, even outside the context of litigation through opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation actions or proceedings. The outcome following legal assertions of invalidity and unenforceability during patent litigation or administrative proceedings is unpredictable. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our technologies, product candidates, methods or certain aspects of our immunotherapy platform technology. Such a loss of patent protection could have a material adverse impact on our business.

There is also a risk that, even if the validity of our patents is upheld, the court will construe our patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover our own products or the other party's products. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, 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 litigation. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

We may fail to identify relevant third-party patents or may incorrectly interpret the relevance, scope, or expiration of a third-party patent which might adversely affect our ability to develop our immunotherapy platform technology and product candidates.

We cannot guarantee that our operations and activities do not, or will not in the future, infringe existing or future patents. We also cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to our immunotherapy platform technology or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit, or otherwise interfere with our ability to make, use, and sell our product candidates or any products, if approved. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents are issued. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, and unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technology, our product candidates, or the use thereof. As such, there may be applications of third parties now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit, or otherwise interfere with our ability to make, use, or sell our product candidates or any products, if approved.

The scope of a patent claim is determined by an interpretation of law and, among other considerations, the written disclosure in a patent and the patent's prosecution history. The claim scope sought in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance, including through interferences, post-grant proceedings, opposition proceedings, or other intellectual property proceedings to address issues or errors that may render claims of the issued patent either wholly or partially invalid or unenforceable. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our immunotherapy platform technology, product candidates and their respective methods of use, manufacture, and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

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.

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.

Any current and potential intellectual property litigation also could force us to do one or more of the following:

- stop marketing, selling, incorporating, manufacturing, or using our product candidates or any products, if approved, in the United States and/or other jurisdictions that use the subject intellectual property;
- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, including the obligation to pay royalties, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;
- redesign those products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be impossible or technically infeasible; or
- pay damages, including the possibility of treble damages and attorneys' fees in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

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, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

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.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential collaborators, partners, or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world.

During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in both the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or PCT filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar medications. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our product candidates and any products, if approved, our business and results of operations will be adversely affected. 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 patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Depending upon the timing, duration, and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended.

However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

We expect there may be only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect. While we will endeavor to try to protect our technology, products, and product candidates with intellectual property rights such as patents throughout the world, as appropriate, the process of obtaining patents is time-consuming, expensive, and sometimes unpredictable in other countries. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all markets. As such, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

International applications under the Patent Cooperation Treaty ("PCT"), are usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe our product candidates may be marketed. We have not, and will not, file for patent protection in all national and regional jurisdictions where such protection may be available. Filing, prosecuting, and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and, therefore, the scope and strength of our intellectual property rights will vary from jurisdiction to jurisdiction. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. It is common that depending on the country, the scope of patent protection may vary for the same product candidate and/or technology. As such, we do not know the degree of future protection that we will have on our technology and product candidates in different jurisdictions.

Competitors may use our or our collaboration partners' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or our collaboration partners have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our or our collaboration partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions, particularly certain developing countries, do not protect intellectual property rights, particularly those relating to pharmaceuticals or biologics, to the same extent as laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being

invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain significant commercial advantage from the intellectual property that we develop or license.

Some countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

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

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

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

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to make product candidates similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- the patents of third parties may have an adverse effect on our business;

- we or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technology without infringing, misappropriating, or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we cannot predict the degree and range of protection any issued patents will afford us against competitors, whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications, or whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license; and
- we may not develop additional technologies that are patentable.

Should any of these events occur, they could significantly harm our business, results of operations, and prospects.

Composition of matter patents for biological and pharmaceutical products such as our product candidates are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications covering composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological complexity and legal complexity. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain.

In September 2011, the America Invents Act (the “AIA”), was enacted in the United States, resulting in significant changes to the U.S. patent system. An important change introduced by the AIA was a transition to a

"first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention, which went into effect on March 16, 2013. Therefore, a third party that now files a patent application in the USPTO before we do could be awarded a patent covering an invention of ours even if we created the invention before it was created by the third party. While we are cognizant of the time from invention to filing of a patent application, circumstances could prevent us from promptly filing patent applications for our inventions.

Among some of the other changes introduced by the AIA were changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its continued implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, and the patent applications of our collaborators, and the enforcement or defense of our issued patents.

Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, there is complexity and uncertainty related to European patent laws. For example, European patent laws are stringent in the type of amendments that are allowed during prosecution, and the complexity and uncertainty of European patent laws have also increased in recent years. These limitations and requirements could adversely affect our ability to obtain new patents in the future that may be important for our business.

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.

Trade secrets and/or confidential know-how can be difficult to protect or maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, we generally require our employees, consultants, contractors, collaborators, advisors, and other third parties to enter into confidentiality agreements with us. Despite these efforts, any of these parties may unintentionally or willfully breach the agreements and disclose our confidential information, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. 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 obtained illegally and is using trade secrets and/or confidential know-how is also expensive, time-consuming, and unpredictable.

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

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

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

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

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

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

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign governmental patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents within prescribed time limits. If we fail to maintain the patents and patent applications covering our product candidates or if we otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

We collect and maintain information in digital form that is necessary to conduct our business, and we are dependent on our information technology systems and those of third parties to operate our business. In the ordinary course of our business, we collect, store, and transmit large amounts of confidential information, including intellectual property, proprietary business information, and personal information, and data to comply with cGMP and data integrity requirements. It is critical that we do so in a secure manner to maintain data security and data integrity of such information. 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. Cybersecurity attacks are constantly increasing in sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. Our systems may be subject to attacks and could be targeted by foreign actors for purposes of economic espionage. Due to the nature of some of such attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches.

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

Risks Related to Ownership of Our Common Stock

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

The market price of our common stock may be highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors listed below and other factors describe in this “Risk Factors” section:

- the commencement, enrollment, or results of preclinical studies and clinical trials and trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority’s review of such filings, including, without limitation, the issuance by the FDA of a “refusal to file” letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a preclinical study or clinical trial, not to initiate a preclinical study or clinical trial or to terminate an existing preclinical study or clinical trial;
- adverse actions taken by regulatory agencies with respect to our preclinical studies or clinical trials, manufacturing supply chain or sales and marketing activities, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations, including, but not limited to, preclinical study or clinical trial requirements for approvals;
- any adverse changes to our relationship with manufacturers or suppliers;
- manufacturing, supply or distribution shortages;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technology;
- variations in our results of operations;
- our cash position;

- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immuno-oncology in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures, or capital commitments;
- our inability to establish collaborations, if needed;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- changes in the market valuations of similar companies;
- press reports, whether or not true, about our business;
- sales or perceived potential sales of our common stock by us or our stockholders in the future;
- overall fluctuations in the equity markets;
- ineffectiveness of our internal controls;
- changes in accounting practices or principles;
- changes or developments in the global regulatory environment;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the Nasdaq Stock Market, or Nasdaq, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on, and may lose some or all of, your investment.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

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.

Prior to this offering, as of June 30, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates owned approximately 90.7% of our outstanding voting stock (excluding any stock options exercisable within 60 days of such date held by such persons) and, upon the closing

of this offering, that same group will own approximately 75.9% of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares and excluding an aggregate of approximately 1,480,625 shares that our directors or existing stockholders have agreed to purchase in this offering). Therefore, even after this offering these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

Our common stock price could decline as a result of sales of a large number of shares of common stock after this offering or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

Upon the completion of this offering, 35,650,520 shares of our common stock will be outstanding (or 36,700,520 shares if the underwriters exercise their option to purchase additional shares from us in full), based on the number of shares outstanding as of March 31, 2021.

All shares of common stock sold in this offering will be freely tradable without restriction or further registration under the Securities Act (including an aggregate of approximately 1,480,625 shares that our directors and existing stockholders have agreed to purchase in this offering) unless held by our "affiliates" as defined in Rule 144 under the Securities Act. The resale of the remaining 28,650,520 shares, or 80.4% of our outstanding shares of common stock following this offering, is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with this offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning 181 days after the date of this prospectus. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements, and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act. For more information, see "Shares Eligible for Future Sale."

We intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares that may be issued under our equity incentive plans, these shares will be able to be sold in the public market upon issuance, subject to the lock-up agreements described under "Underwriting."

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

There has been no prior public market for our common stock, and an active trading market may not develop or be sustained.

There has been no public market for our common stock prior to this offering. The initial public offering price for our common stock was determined through negotiations among the underwriters and us and may vary from the market price of our common stock following this offering. An active or liquid market in our common stock may not develop upon closing of this offering or, if it does develop, it may not be sustainable. The lack of

an active market may impair the value of your shares, your ability to sell your shares at the time you wish to sell them and the prices that you may obtain for your shares. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to acquire other companies, products, or technologies by using our common stock as consideration.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- our inability to achieve desired efficiencies, synergies or other anticipated benefits from such acquisitions or strategic partnerships;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Our management team has broad discretion to use the net proceeds from this offering and its investment of these proceeds may not yield a favorable return. They may invest the net proceeds from this offering in ways with which investors disagree.

Our management will have broad discretion over the use of net proceeds from this offering, and could spend the net proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. If we do not invest or apply the net proceeds from this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline.

The trading market for our common stock will be influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. If one or more

of these analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline.

If you purchase shares of our common stock in our initial public offering, you will experience substantial and immediate dilution.

The initial public offering price of $8.00 per share, is substantially higher than the net tangible book value per share of our outstanding common stock immediately following the completion of this offering. If you purchase shares of common stock in this offering, you will experience substantial and immediate dilution in the pro forma net tangible book value per share of $(4.10) per share as of March 31, 2021. That is because the price that you pay will be substantially greater than the pro forma net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock. You will experience additional dilution when those holding stock options exercise their right to purchase common stock under our equity incentive plans or when we otherwise issue additional shares of common stock. See “Dilution.”

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

We are an “emerging growth company” as defined in the 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 report 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 could be an emerging growth company for up to five years following the completion of our initial public offering. Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than $1.07 billion in annual revenue;
- the date we qualify as a “large accelerated filer,” with at least $700 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering.

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

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

The requirements of being a public company may strain our resources, result in more litigation, and divert management's attention.

As a public company, we will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), the listing requirements of Nasdaq, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this prospectus and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our resources and seriously harm our business.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. When we lose our status as an "emerging growth company" and a "smaller reporting company," and become an "accelerated filer" or a "large accelerated filer," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we will need to implement additional financial and management controls, reporting systems and procedures and 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.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

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, each to be in effect immediately prior to the completion of this offering, will contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

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

As a Delaware corporation, we will be 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 will provide 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, to be in effect immediately prior to the completion of this offering, will provide 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 will provide that the federal district courts of the United States will be 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.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

As of December 31, 2019, and 2020, we had available federal net operating loss ("NOL") carryforwards of $9.1 million and $14.8 million, respectively. We also had available state NOLs carryforwards of approximately $9.1 million and $15.2 million, as of December 31, 2019 and 2020, respectively. As of December 31, 2020, we also had federal tax credits of $0.13 million, which may be used to offset future tax liabilities. The federal and state NOLs will carryforward indefinitely and be available to offset up to 100% of taxable income for taxable years before 2021 and 80% of taxable years staring after 2020.

Use of our NOL carryforwards and tax credit carryforwards depends on many factors, including having current or future taxable income, which cannot be assured. Our U.S. NOL and tax credit carryforwards could expire unused and be unavailable to offset future taxable income or income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. In addition, for taxable years beginning after December 31, 2020, the deductibility of federal NOLs generated in taxable years beginning after December 31, 2017 is limited to 80% of our taxable income in such year (after taking into account utilization of NOLs generated in taxable years beginning before January 1, 2018), where taxable income is determined without regard to such NOL deduction itself. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and certain corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOL and tax credit carryforwards to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders (or groups of stockholders), each of whom owns at least 5% of a corporation's stock, increases by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We believe we may have experienced ownership changes in the past, and we believe it is likely that we will experience an additional ownership change in the future as a result of this offering or subsequent shifts in our stock ownership, some of which are outside our control. If finalized, Treasury Regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOL and tax credit carryforwards if we undergo an additional ownership change as a result of this offering.

If we earn taxable income in the future, we expect that our ability to use existing NOL and tax credit carryforwards to offset such taxable income will be materially limited as a result of these ownership changes.

The application of such limitations may cause U.S. federal income taxes (and possibly state income taxes) to be paid by us earlier than they otherwise would be paid if such limitations were not in effect and could cause such NOLs and tax credit carryforwards to expire unused, in each case reducing or eliminating the benefit of such NOLs and tax credit carryforwards.

To the extent we are not able to offset our future taxable income with our NOLs or offset future taxes with our tax credit carryforwards, this would adversely affect our operating results and cash flows. These same risks can arise in the context of state income and franchise tax given many states conform to federal law and rely on federal authority for determining state NOLs.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Recent changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act ("TCJA"), which significantly reformed the Code. The TCJA, among other things, contains significant changes to corporate taxation, including reducing the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limiting the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), limiting the deduction for net operating losses, or NOLs, arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks for losses arising in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely), imposing a one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, eliminating U.S. tax on foreign earnings (subject to certain important exceptions), allowing immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits.

As part of Congress' response to the COVID-19 pandemic, the Families First Coronavirus Response Act ("FFCR Act"), was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the TCJA. It also provides that NOLs arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30% to 50% of adjusted taxable income.

Regulatory guidance under the TCJA, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. It is also likely that Congress will enact additional legislation in connection with the COVID-19 pandemic, some of which could have an impact on us. In addition, it is uncertain if and to what extent various states will conform to the TCJA, the FFCR Act or the CARES Act. We urge prospective investors in our common stock to consult with their legal and tax advisors with respect to any recently enacted tax legislation, or proposed changes in law, and the potential tax consequences of investing in or holding our common stock.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements within the meaning of the federal securities laws. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- the implementation of our business model, strategic plans for our business and our product candidates;
- our ability to retain the continued service of our key executives and to identify, hire and retain additional qualified professionals;
- the initiation, timing, progress and results of clinical trials for HCW9218;
- the initiation, timing, progress and results of preclinical activities, IND-enabling activities and clinical trials for HCW9302;
- progress on HCW molecules currently in the TOBI discovery program for cancer, inflammatory diseases, and age-related diseases;
- our research and development programs;
- our plans to develop our current and future product candidates;
- the utility of our TOBI platform in identifying and discovering product candidates;
- our ability to rely on partners to successfully development and commercialize licensed molecules that are outside of our strategic focus;
- our ability to enter into strategic arrangements and/or collaborations for the co-development of our lead product candidates, and to realize the potential benefits of such arrangements;
- the timing of and our ability to submit applications for and obtain and maintain regulatory approvals for our current and future product candidates;
- our estimates regarding the market opportunity for our product candidates, if approved;
- our expenditures regarding our ability to fund our operating expenses and capital expenditure requirements with our cash and cash equivalents and the proceeds of this offering;
- the potential advantages of our current and future product candidates;
- the rate and degree of market acceptance and clinical utility of our products, if approved;
- our estimates regarding the potential market opportunity of our current and future product candidates;
- our commercialization, marketing and manufacturing capabilities strategy;
- our intellectual property position;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our expectations with regarding to the use of proceeds of this offering;

- our estimates regarding expenses, future revenue, timing of any future revenue, capital requirements, and needs for additional financing;
- impact of governmental laws and regulations:
- our competitive position;
- developments relating to our competitors and our industry;
- our ability to maintain and establish collaborations or obtain additional funding;
- the potential direct or indirect impact of the COVID-19 pandemic on our business, operations, and the markets and communities in which we and our partners, collaborators, vendors, and customers operate;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act; and
- other risk factors included under “Risk Factors” in this prospectus.

In addition, in this prospectus, the words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “predict,” “potential,” and similar expressions, as they relate to our company, our business, and our management, are intended to identify forward-looking statements. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

Forward-looking statements speak only as of the date of this prospectus. You should not put undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information, except to the extent required by applicable laws. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

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

MARKET AND INDUSTRY DATA AND FORECASTS

We obtained the industry, market, and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies, and publicly available information in addition to research, surveys, and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section entitled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately $47.5 million, based on the initial public offering price of $8.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise in full their option to purchase additional shares, we estimate that the net proceeds from this offering will be approximately $55.3 million.

The principal purposes of our selling shares in this offering are to obtain additional capital, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use the net proceeds of this offering as follows:

- approximately $6.4 million to advance the development of HCW9218, including IND-enabling activities and Phase 1b/2 clinical trials in patients with pancreatic and other solid tumor cancers;
- approximately $3.6 million to advance the development of HCW9302, including research and development, pre-clinical studies to identify the disease indications for which HCW9302 is most promising, and Phase 1 clinical trials in patients with alopecia areata;
- approximately $0.8 million on discovery programs, to conduct experiments to demonstrate which molecules have the highest potential, highest tolerability, greatest commercial potential, and strongest intellectual property protection;
- approximately $12.5 million to build our own cGMP manufacturing plant and optimize our manufacturing capabilities; and
- the balance on salaries and benefits for all employees; general and administrative activities, including legal, accounting and financial reporting; and general corporate purposes.

The expected use of the net proceeds from this offering, together with our existing cash and cash equivalents, represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including results from our research and development efforts for our programs, the timing and success of our preclinical studies, the status of and results from clinical trials and the timing and outcome of regulatory submissions, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. Due to the numerous risks and uncertainties associated with product development, at this time, we cannot reasonably estimate the amount of additional funding that will be necessary to complete the development of any of our product candidates or our discovery programs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering, together with our existing cash and cash equivalents, we estimate that such funds will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 24 months. We have based our estimates as to how long we expect we will be able to fund our operations on assumptions that may prove to be wrong. We could use our available capital resources sooner than we currently expect, in which case we would need to obtain additional funding, which may not be available to use on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any determination to pay dividends to holders of our common stock will be at the discretion of our board of directors and will depend on many factors, including our financial condition, results of operations, liquidity, earnings, projected capital and other cash requirements, legal requirements, restrictions in the agreements governing any indebtedness we may enter into, our business prospects, and other factors that our board of directors deems relevant.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2021 on:

- An actual basis;
- A pro forma basis, giving effect to the Conversion: (i) the conversion of the outstanding shares of our Class B common stock as of March 31, 2021 into 4,285,714 shares of our Class A common stock, (ii) the conversion of the outstanding shares of our redeemable preferred stock as of March 31, 2021 into 23,768,420 shares of our Class A common stock and forfeiture of accrued and unpaid accumulated dividends; and (iii) the effectiveness of our amended and restated certificate of incorporation, as if such conversions, reclassification and effectiveness had occurred on March 31, 2021; and
- A pro forma as adjusted basis, giving effect to (i) the pro forma adjustments set forth above and (ii) the sale and issuance of shares of our common stock by us in this offering, based upon the initial public offering price of $8.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the section of this prospectus entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and related notes included elsewhere in this prospectus.

	As of March 31, 2021 (unaudited)		
	Actual	Pro Forma	Pro Forma As Adjusted
	(In thousands, except share and per share data)		
Cash, cash equivalents and accounts receivable	$ 8,156	$ 8,156	$ 55,677
Redeemable preferred stock, par value $0.0001 – 60,950,215 shares authorized; 23,768,420 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	$ 31,607	$ —	$ —
Stockholders’ (deficit) equity:			
Preferred stock, $0.0001 par value – no shares authorized, issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma; and 10,000,000 shares authorized, no shares issued and outstanding, pro forma as adjusted	—	—	—
Common stock, par value $0.0001 – 84,950,215 shares authorized; 4,882,100 shares issued and outstanding, actual; 84,950,215 shares authorized, 28,650,520 shares issued and outstanding, pro forma; and 250,000,000 shares authorized, 35,650,520 shares issued and outstanding, pro forma as adjusted	1	3	3
Additional paid-in capital	—	29,467	76,987
Accumulated deficit	(20,027)	(17,889)	(17,889)
Total stockholders’ (deficit) equity	(20,026)	11,581	59,101
Total capitalization	$ 11,581	$ 11,581	$ 59,101

The number of shares of our common stock to be outstanding after the completion of this offering excludes:

- 653,355 shares of our common stock issuable upon exercise of stock options outstanding as of March 31, 2021, having a weighted-average exercise price of $0.16 per share; and
- 2,400,000 shares of common stock reserved for future grant or issuance under our 2021 Plan (which includes 464,486 shares of our common stock as of March 31, 2021, reserved for future grant under our 2019 Plan that will be added to the shares reserved for future issuance under our 2021 Plan upon effectiveness of that plan if the shares are not issued or subject to outstanding grants under the 2019 Plan at that time), which will become effective in connection with this offering and contains provisions that automatically increase its share reserve each year, as more fully described in “Executive Compensation – Equity Incentive Plans.”

DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering. Our historical net tangible book value as of March 31, 2021 was $(20.0) million, or $(4.10) per share of common stock. Our historical net tangible book deficit is the amount of our total tangible assets less our total liabilities, redeemable preferred stock, and accrued and unpaid accumulated dividends. Historical net tangible book deficit per share represents our historical net tangible book deficit divided by the number of shares of our common stock outstanding as of March 31, 2021. Our pro forma net tangible book value as of March 31, 2021, before giving effect to this offering, was $11.6 million, or $0.40 per share of our common stock. Our pro forma net tangible book value before the issuance of shares in this offering gives effect to the automatic conversion of our outstanding redeemable preferred stock into our common stock and forfeiture of accrued and unpaid accumulated dividends immediately prior to the completion of this offering.

After giving effect to our sale of 7,000,000 shares of our common stock in this offering at the initial public offering price of $8.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been $59.1 million, or $1.66 per share. This represents an immediate increase in net tangible book value of $1.25 per share to our existing stockholders and an immediate dilution of $6.34 per share to new investors purchasing shares of common stock in this offering. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$8.00
Historical net tangible book value per share as of March 31, 2021	$(4.10)	
Pro forma increase in net tangible book value per share	$ 4.51	
Pro forma net tangible book value per share as of March 31, 2021	$ 0.40	
Increase in net tangible book value per share attributable to new public investors	$ 1.25	
Pro forma as adjusted net tangible book value per share after giving effect to this offering		$1.66
Dilution in pro forma net tangible book value per share to new investors in this offering		$6.34

The following table summarizes the pro forma on an as adjusted basis as described above, as of March 31, 2021, the differences between the existing stockholders and new public investors with respect to the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid or to be paid to us at the initial public offering price of $8.00 per share, and before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	28,650,520	80.4%	$ 29,469,742	34.5%	$ 1.03
New public investors	7,000,000	19.6%	56,000,000	65.5%	$ 8.00
Total	35,650,520	100.0%	$85,469,742	100.0%	

Certain of our directors and existing stockholders or their affiliates, including our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer and Vice President of Clinical Operations, have agreed to purchase an aggregate of approximately 1,480,625 shares of our common stock in this offering at the initial public offering price. See the footnotes to the table in the section titled “Principal Stockholders” for additional information regarding the amount of shares of our common stock that our director and existing stockholders have agreed to purchase in this offering.

The total number of shares of our common stock reflected in the discussion and table above is based upon 28,650,520 shares of our common stock outstanding on a pro forma basis as of March 31, 2021 and excludes:

- 653,355 shares of our common stock issuable upon exercise of stock options outstanding as of March 31, 2021, having a weighted-average exercise price of $0.16 per share; and
- 2,400,000 shares of common stock reserved for future grant or issuance under our 2021 Plan (which includes 464,486 shares of our common stock as of March 31, 2021 reserved for future grant under our 2019 Plan that will be added to the shares reserved for future issuance under our 2021 Plan upon effectiveness of that plan if the shares are not issued or subject to outstanding grants under the 2019 Plan at that time), which will become effective in connection with this offering and contains provisions that automatically increase its share reserve each year, as more fully described in "Executive Compensation – Equity Incentive Plans."

To the extent that any outstanding options are exercised, new options are issued under our share-based compensation plans or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering.

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 the section entitled "Summary Financial Information" and our financial statements and related notes appearing elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. 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 identified below and those discussed in the section entitled "Risk Factors." This discussion and analysis is based upon our historical financial statements included in this prospectus. All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31.

Overview

We are an innovative preclinical stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation, and age-related diseases. We believe age-related low-grade chronic inflammation, or "inflammaging," is a significant contributing factor to several chronic diseases and conditions, such as cancer, cardiovascular disease, diabetes, neurodegenerative disease, and autoimmune disease. We believe our approach has the potential to provide an innovative treatment of these age-related diseases.

Our gateway indication is oncology. Advances in immuno-stimulatory and anti-immunosuppressive therapeutics have revolutionized cancer treatment. Our lead molecule, HCW9218, is designed with both of these functionalities – it rejuvenates the immune system to reduce senescence, and it captures TGF-ß to neutralize its immunosuppressive activity. We are preparing to submit an IND for a Phase 1b/2 clinical trial in pancreatic cancer to evaluate HCW9218, which includes completing drug product testing and nonclinical animal toxicity/pharmacokinetic studies, as well as finalizing clinical protocol. Pending the submission and FDA acceptance of the IND to proceed, we expect to initiate this clinical trial by the end of 2021 after obtaining IRB approval of our clinical research, completing clinical site initiation, and finalizing clinical trial agreements. However, we have not submitted the IND for the planned trial, and we cannot provide any assurance that the FDA will authorize us to initiate our planned clinical trials on a timely basis, or at all. In the event that the FDA does not accept our IND, we may also be required to seek feedback, and the feedback may be unfavorable. In the event we do not receive feedback on a timely basis, or we are required to change the design of our clinical protocol or address other feedback, clinical development of our products would be delayed and our costs may increase. Moreover, if the FDA does not accept the IND we file, we may be required to conduct additional preclinical testing or other IND-enabling activities, which would result in further delay and additional costs.

We are initially developing HCW9218 as an injectable immunotherapeutic for patients with solid tumors. Our initial goal is to evaluate HCW9218 in patients with cancer as we attempt to minimize the side effects of chemotherapy through stimulating anti-tumor effector immune cell responses, blocking TGF-ß immunosuppressive activity, eliminating chemotherapy-induced senescent cells in tumors and normal tissues (i.e., senolytic effect), and reducing SASP factor activity (i.e., senomorphic effect). We are leveraging extensive clinical expertise to structure clinical trials with clear, objective, and measurable endpoints. We expect to manage our clinical trials internally, relying on our in-house expertise in managing clinical trials conducted in collaboration with National Cancer Institute (NCI)-Designated Comprehensive Cancer Centers. Currently, we are engaged in preliminary discussions with seven leading institutions who have shown interest in participating in our clinical trials as clinical sites. We are presently working with the identified Principal Investigators from these institutions to establish clinical development strategies for our product candidates and to refine study protocols for pancreatic, ovarian, breast, prostate, and colorectal cancer trials. Because the discussions with these clinical sites and Principal Investigators are considered preliminary, we are not certain we will be successful in reaching an agreement with any or all of these institutions. The course of these discussions and whether we might need to

identify alternative clinical sites could impact the start date for our clinical trials. Any delays in our clinical trials could increase our costs and slow down the development and approval process, which could harm our commercial prospects.

We plan to initiate Phase 1b/2 clinical trials for oncology indications in the second half of 2021, working with leading institutions affiliated with the National Cancer Institute, first in patients with pancreatic cancer, then expanding to patients with breast, ovarian, prostate, and colorectal cancers. The aim of these studies is to evaluate HCW9218 as an adjunct therapy to chemotherapy. In the pancreatic cancer trial, the Phase 1b portion will be a dose escalation study of HCW9218 as monotherapy in refractory patients with advanced pancreatic cancer. The Phase 2 portion of this clinical trial will include a cohort of patients receiving HCW9218 as monotherapy and a cohort of patients receiving HCW9218 as an adjunct to chemotherapy. Pending submission and FDA acceptance of the IND to proceed with a company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in patients with pancreatic cancer, we plan to have an additional clinical trial to evaluate HCW9218 in solid tumors with an investigator-sponsored IND. Our ability to proceed with this trial depends on the submission and acceptance of both INDs for our company-sponsored pancreatic cancer clinical trial and the investigator-initiated solid tumor clinical trial as well as finalizing our agreement with the sponsor. We are currently engaged in preliminary discussions with an institution that has expressed interest to be a sponsor for an IND using HCW9218 as an adjunct to chemotherapy in patients with solid tumors (breast, ovarian, prostate, and colorectal cancers). However, these discussions are preliminary, and we may not succeed in reaching an agreement with this institution. Depending on the course of these discussions and whether we need to seek an alternative sponsor for an IND, there could be a delay in initiating a Phase 1b/2 clinical trial to evaluate HCW9218 in patients with solid tumors. Any delays in our clinical trials could increase our costs and slow down the development and approval process, which could harm our commercial prospects.

We have combined our deep understanding of disease-related immunology with our expertise in advanced protein engineering to internally develop our TOBI (Tissue factOr-Based fusIon) discovery platform for the design of immunotherapeutic drugs. This modular and tunable technology has allowed us to generate a novel pipeline of internally-developed product candidates capable of activating and targeting desired immune responses and blocking unwanted immunosuppressive activities. Using our TOBI platform, we have successfully developed molecules that can be administered by subcutaneous injection as well as adoptive cell therapy approaches. We have selected two molecules as our lead product candidates: HCW9218 and HCW9302. We have chosen these product candidates because we believe they have the potential to become transformative immunotherapeutics, which can be administered by subcutaneous injection.

To date, we have funded our operations primarily with proceeds from the sale and issuance of redeemable preferred stock and to a lesser extent, the proceeds of upfront payments from an out-license agreement. From inception to March 31, 2021, we have raised net cash proceeds of $29.4 million from the issuance of redeemable preferred stock. We have incurred significant operating losses to date. Our cumulative net losses were $9.3 million, $15.1 million, and $17.9 million as of December 31, 2019 and 2020 and March 31, 2021, respectively. Our net losses were $7.3 million, $5.8 million, and $2.8 million for the years ended December 31, 2019 and 2020 and the three months ended March 31, 2021, respectively. As of March 31, 2021, we had an accumulated deficit of $20.0 million and cash and cash equivalents of $6.9 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future, as we continue our clinical development activities, particularly if and as we:

- Advance the development of our lead product candidate, HCW9218, and clinical trials for oncology, and if approved by the FDA, commercialization;
- Advance preclinical development of other indications for HCW9218, including fibrotic indications;
- Advance the preclinical development of our second lead product candidate, HCW9302, for auto-immune diseases, such as alopecia areata, and metabolic diseases, such as Type 2 Diabetes;

- Establish our own domestic manufacturing capability;
- Maintain, expand, and protect our intellectual property portfolio;
- Scale up our clinical and regulatory capabilities; and
- Expand operational and management information systems as well as investor relations, legal, accounting, and audit services required to operate as a public company.

As a result of these anticipated expenditures, we will need substantial additional financing to support our continuing operations and pursuit of our clinical development strategy. Until such time as we can generate significant revenues from product sales, if ever, we expect to finance our operations through a combination of equity offerings, collaborations, strategic alliances, co-development deals, and out-licensing arrangements. We may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition, and we may need to significantly delay, reduce, or eliminate the development and commercialization of one or more of our product candidates.

We believe that the anticipated net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. If we have based this estimate on assumptions that may prove to be wrong, we could exhaust our available capital resources sooner than we expect. See “Liquidity and Capital Resources.” Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations and fund capital expenditure requirements. Because of the numerous risks and uncertainties associated with our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the preclinical and clinical development of our product candidates.

Recent Developments

We established our first out-license arrangement in December 2020, when we entered into an exclusive worldwide license agreement with Wugen, Inc., or the Wugen License, for limited rights to develop cell therapy treatments using two HCW fusion protein molecules. We partnered with Wugen because of their expertise in developing cell-based therapies for cancer. We believe these molecules are capable of generating highly activated memory-like NK (“ML-NK”) cells in a short time frame, and large-scale NK-cell expansion without relying on feeder cells. Two Phase 2 clinical trials were initiated in January 2021 by Washington University with support from Wugen. One trial is using *ex vivo* induced ML-NK cells against relapsed/refractory acute myeloid leukemia (“r/r AML”) with donor leukocyte infusion (“DLI”) after haploidentical stem cell transplantation. The second Phase 2 clinical trial is using *ex vivo* induced ML-NK cells against r/r AML. Patient enrollment has commenced, and preliminary data from these clinical trials are expected to begin to become available in the second half of 2021.

Under the Wugen License, the upfront payment was $4.1 million, consisting of shares of Wugen common stock with a fair value of $1.6 million on the effective date of the Wugen License and $2.5 million. The stock portion of the upfront payment consisted of shares of common stock representing a 10% equity ownership position in Wugen as of the effective date of the Wugen License. The $2.5 million cash portion of the upfront payment resulted from the sale of non-financial assets to Wugen including cGMP-grade clinical materials needed to begin Phase 2 clinical trials. We may receive additional payments in the future, based upon the occurrence of certain development milestones with a value of over $200 million. We are eligible to receive additional payments for commercialization milestones as well as single-digit royalties for commercial sales once product sales commence. The achievement of milestones or product sales was not probable; hence no amounts have been recognized as revenue as of March 31, 2021.

We retained all other rights and use of the licensed molecules not granted under the Wugen License, including regulatory T cell-based cellular therapy, injectable rights, and manufacturing rights. We intend to enter

into two supply agreements with Wugen to provide cGMP and non-cGMP grade licensed molecules based on industry-standard terms, one agreement for development supply and one agreement for commercial supply. According to the terms of the license, Wugen will fund all future clinical development and commercialization activities for cell therapy treatments for any indications it develops utilizing the licensed molecules covered by the Wugen License. Deferred revenue represents amounts received in advance of the related performance obligation being satisfied. As of March 31, 2021, we recognized deferred revenue of $239,000. There were no revenues reported for the three months ended March 31, 2021.

Trends and Uncertainties - COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a pandemic, which continues to spread throughout the United States and the world. The spread of COVID-19 has caused significant volatility in the U.S. and international markets. There is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the U.S. and international economies and, as such, we are unable to determine if it will have a material impact on our operations.

The ultimate extent of the impact of the COVID-19 pandemic will depend on future developments which are highly uncertain, including new information that may emerge concerning the severity and expected duration of the COVID-19 pandemic, and public health actions taken to contain or prevent its spread, among others. Accordingly, we cannot fully predict the full extent to which our business and results of operations will be affected. In particular, we have seen many clinical trial sites delay patient enrollment in clinical trials as a result of the COVID-19 pandemic. Other required IND-enabling activities, such as toxicology studies, have also been slowed due to the volume of COVID-19 related trials that have been initiated during the pandemic. We expect these factors to impact the speed of enrollment and processing for our trials. However, to a large extent, during the COVID-19 pandemic we have managed to avoid significant delays in the advancement of basic science and research and development conducted on site at our laboratory facilities during government-mandated shelter in place orders.

Components of Our Results of Operation

Revenues

To date, we have not generated any revenue from product sales and do not expect to generate revenue from product sales in the foreseeable future. In the near term, our revenues will be derived from out-licenses, collaborative agreements and co-development deals. For the year ended December 31, 2020, we recognized revenues of $4.1 million resulting from the Wugen License which consisted of a license fee paid in-kind with shares of Wugen common stock with a fair value of $1.6 million on the effective date of the Wugen License, and the sale of non-financial assets for $2.5 million.

We have retained the manufacturing rights under the terms of the Wugen License. We intend to enter into supply agreements with Wugen to provide cGMP and non-cGMP grade licensed molecules based on industry-standard terms, one agreement for development supply and one agreement for commercial supply. During the three months ended March 31, 2021, Wugen ordered research and clinical grade materials and made an advance payment on this order. As of March 31, 2021, we recognized $239,000 of deferred revenue which represents the receipt of unconditional payments in advance of the satisfaction of the underlying performance obligation.

In future periods, under the terms of the Wugen License, we may be eligible to receive additional cash payments that will be recognized as revenue, including development and commercialization milestones and single-digit royalties based on annual net sales of licensed products.

Operating Expenses

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

Research and Development

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

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

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

For the years ended December 31, 2019 and 2020, we were eligible for tax credits based on research and development activities within the United States and Florida. These tax incentives are recognized as a contra expense to the related areas, including FICA and other payroll taxes as well as sales tax. We recognized approximately $239,000 and $250,000 of tax credits for the years ended December 31, 2019 and 2020, respectively. For further information on tax credits, see Note 13 to our audited financial statements which appears elsewhere in this prospectus.

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. We expect our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our lead product candidates, advance into later stages of development, begin to conduct larger clinical trials, expand our product pipeline, continue to maintain, expand, protect, and enforce our intellectual property portfolio, and establish our own manufacturing capabilities. In particular, we expect our research and development expenses will increase substantially as we progress to Phase 2 and Phase 2/3 clinical trials for our lead product candidates, primarily due to the increased size and duration of later-stage clinical trials.

The duration, costs, and timing of the clinical development of our product candidates are highly uncertain and will depend on a variety of factors, including, but not limited to:

- Number and scope of preclinical and IND-enabling studies;
- Successful and timely patient enrollment in, and completion of, clinical trials;

- Per subject trial costs;
- Number of trials required for regulatory approval;
- Number of sites included in the trials;
- Number of subjects needed for each trial;
- Cost and timing of manufacturing of cGMP materials for clinical trials;
- Receipt of regulatory approvals from applicable regulatory authorities;
- Establishing commercial manufacturing capabilities; and
- Costs to maintain, defend, and enforce our intellectual property rights.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

General and Administrative Expenses

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

We expect that our general and administrative expenses will be higher in the foreseeable future. We anticipate increased expenses relating to our operations as a public company, including increased costs for the hiring of additional personnel, and for payment to outside consultants, including lawyers and accountants, to comply with additional regulations, corporate governance, internal control and similar requirements applicable to public companies, as well as increased costs for insurance.

Other Income (Expense), Net

Other income (expense), net consists of interest earned on our cash, cash equivalents, other income related to non-operating activities, and other non-operating expenses.

Results of Operations

The following table summarizes our results of operations for the periods indicated:

	Year Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Revenues	—	$ 4,099,750	$ —	$ —
Operating Expenses:				
Research and development	5,390,757	7,255,227	1,678,424	2,329,812
General and administrative	1,974,517	2,669,048	718,568	1,082,360
Total operating expenses	7,365,274	9,924,275	2,396,992	3,412,172
Loss from operations	(7,365,274)	(5,824,525)	(2,396,992)	(3,412,172)
Interest and other income, net	72,353	22,324	21,478	568,176
Net loss	**$ (7,292,921)**	**$ (5,802,201)**	**$ (2,375,514)**	**$ (2,843,996)**

Revenue

Comparison of the Years ended December 31, 2019 and December 31, 2020

On December 24, 2020, we entered into the Wugen License. We assessed the Wugen License and determined this was a transaction with a customer and should be accounted for under Topic 606. The three performance obligations that had been satisfied as of the effective date of the Wugen License were: (1) exclusive worldwide license, (2) vials of HCW9201, and (3) R&D know-how.

The estimated transaction price for performance obligations that have been satisfied as of December 31, 2020 is $4.1 million. This is the first time we have entered into an out-license arrangement and the first time the Company has established prices for its goods and services. Accordingly, the standalone selling price of the various performance obligations is uncertain, and we determined that an observable standalone selling price is not available for the identified performance obligations under the Wugen License. Where a standalone selling price is not directly observable, then we will estimate the standalone selling price considering marketing conditions, entity-specific factors, and information about the customer that is reasonably available. The process for determining a standalone selling price involves significant judgment and includes consideration of multiple factors, including assumptions related to the market opportunity and the time needed to commercialize a product candidate pursuant to the relevant license, estimated direct expenses and other costs.

We first determined the standalone selling price at $2.5 million for the vials of HCW9201 and the R&D know-how. The prices were determined based on developing the know-how and the costs incurred in producing the vials. The standalone selling price for the license was determined using the residual approach and was priced at $1.6 million.

As of December 31, 2020, we recorded $2.5 million in Accounts receivable, as the cash payment for the sale of the non-financial assets were due after the reporting period. The Company records amounts as accounts receivable when the right to consideration is deemed unconditional.

Comparison of Three Months ended March 31, 2020 and March 31, 2021

We intend to enter into supply agreements with Wugen to provide cGMP and non-cGMP grade licensed molecules based on industry-standard terms, one agreement for development supply and one agreement for commercial supply. These two agreements represent additional performance obligations under the Wugen License. The standalone selling price for these materials has been determined using industry-standard “cost plus” terms for supply agreements. As of March 31, 2021, the development supply agreement was not finalized. As of March 31, 2021, we recognized $239,000 of deferred revenue, included within accrued liabilities and other liabilities on the unaudited condensed balance sheet as of March 31, 2021 that appears elsewhere in this registration statement of which this prospectus forms a part. Deferred revenue represents the payments received in advance of the performance obligation to deliver research and clinical grade materials being satisfied.

Research and Development Expenses

Comparison of Years Ended December 31, 2019 and December 31, 2020

The following table summarizes our research and development expenses for the years ended December 31, 2019 and 2020:

	Year Ended December 31,			
	2019	2020	$ Change	% Change
Salaries, benefits and related expenses	$1,905,494	$2,726,046	$ 820,552	43%
Manufacturing and materials	1,692,658	2,560,351	867,693	51%
Preclinical expenses	1,260,947	1,188,018	(72,929)	-6%
Clinical trials	71,726	234,498	162,772	227%
Other expenses	459,932	546,314	86,382	19%
Total research and development expenses	**$5,390,757**	**$7,255,227**	**$1,864,470**	**35%**

Research and development expenses increased $1.9 million, or 35%, from $5.4 million for the year ended December 31, 2019 to $7.3 million for the year ended December 31, 2020. The increase was primarily attributable to salaries, benefits, and related expenses due to increased headcount and additional manufacturing and materials costs incurred through our CMO as we ramped up manufacturing.

Salaries, benefits, and related expenses increased $820,552, or 43%, from $1.9 million for the year ended December 31, 2019 to $2.7 million for the year ended December 31, 2020, reflecting the full year impact of headcount added in Q2 2019, including our Chief Scientific Officer and Vice President of Clinical Operations and the Vice President of Development.

Manufacturing and materials expense increased $867,693, or 51%, from $1.7 million for the year ended December 31, 2019 to $2.6 million for the year ended December 31, 2020. The increase reflects the ramping up of manufacturing activities. In the year ended December 31, 2019, we initiated manufacturing projects for two HCW molecules. By the end of 2019, we successfully launched cGMP production with manufacturing runs adequate to support clinical trials. During the year ended December 31, 2020, various testing and quality control procedures were conducted on the materials manufactured in 2019 and 2020 to ensure materials met all expected quality requirements. Beginning in May 2020, we launched manufacturing for three additional molecules as well as larger cGMP production runs of the internally-developed affinity ligand used in our manufacturing process.

Expenses associated with preclinical activities, including research and development, preclinical studies, and IND-enabling activities, declined by 6% from 2019 to 2020. Virtually all of these expenses consist of experimental material expense, which include costs of production and purification of research-grade HCW molecules and costs for obligatory animal testing required in the process of obtaining regulatory approval for INDs for new immunotherapeutic molecules. These costs include the cost of toxicology studies that were launched in early 2021 for HCW9218 that will be used in the clinical trials for oncology which are expected to initiate by the end of 2021.

Historically, we incurred preclinical expenses to narrow the field from over 30 potential immunotherapeutic molecules we develop internally, to the product candidates with the greatest therapeutic potential for the treatment of age-related diseases. Our strategy was to conduct experiments to demonstrate which molecules had the highest utility, highest tolerability, greatest commercial potential, and strongest intellectual property protection. As a result of this work, we identified HCW9218, which is the lead molecule that will be the basis of the oncology clinical trials that we intend to initiate in 2021. In preparation for clinical trials, during the year ended December 31, 2020, our activities shifted to IND-enabling activities for the upcoming clinical trials in pancreatic cancer as well as the basket trial with breast, colorectal, ovarian, and prostate cancer patients.

Expenses associated with clinical trials including professional fees related to regulatory filings, increased by $162,772, or 227%, from $71,726 for the year ended December 31, 2019 to $234,498 for the year ended December 31, 2020. As we advance our product candidates through clinical development, we expect our clinical trial expenses to increase significantly, as we conduct larger, later-stage clinical trials and expand the number of indications we advance in clinical development.

Other expenses consist primarily of direct depreciation costs for scientific equipment and allocation for rent expense. The increase from the year ended December 31, 2019 to the year ended December 31, 2020 is attributable to an increase in depreciation resulting from the purchase of laboratory equipment which was capitalized.

Comparison of the Three Months ended March 31, 2020 and March 31, 2021

The following table summarizes our research and development expenses for the three months ended March 31, 2020 and 2021:

	Three Months Ended March 31,			
	2020	2021	$ Change	% Change
Salaries, benefits and related expenses	$ 730,273	$ 696,971	$ (33,302)	-5%
Manufacturing and materials	552,272	762,052	209,780	38%
Preclinical expenses	225,961	676,342	450,381	199%
Clinical trials	41,236	49,965	8,729	21%
Other expenses	128,682	144,482	15,800	12%
Total research and development expenses	**$1,678,424**	**$2,329,812**	**$651,388**	**39%**

Research and development expenses increased $651,388, or 39%, from $1.7 million for the three months ended March 31, 2020 to $2.3 million for the three months ended March 31, 2021. The increase was primarily attributable to an increase in expenses for manufacturing materials and preclinical activities, offset by a decline in salaries, benefits and related expenses.

Salaries, benefits, and related expenses declined $33,302, or 5%, from $730,273 for the three months ended March 31, 2020 to $696,971 for the three months ended March 31, 2021. The decrease was primarily caused by the impact of the reimbursement of certain expenses under the terms of the Wugen License, offset by an increase in costs for the Company-sponsored employee health insurance program.

Manufacturing and materials expenses increased $209,780, or 38%, from $552,272 for the three months ended March 31, 2020 to $762,052 for the three months ended March 31, 2021. In the period ended March 31, 2020, we began to initiate manufacturing activities. By March 31, 2021, we had ramped up to full cGMP manufacturing capabilities, producing five internally-developed molecules. In the three months ended March 31, 2021 costs were primarily from a 200-liter cGMP run for HCW9218, establishment of the HCW9206 Master Cell Bank, the initiation of the technology transfer and development runs for HCW9206, and the initiation of manufacturing of HCW9302.

Expenses associated with preclinical activities increased $450,381, or 199%, from $225,961 for the three months ended March 31, 2020 to $676,342 for the three months ended March 31, 2021. The majority of this increase was attributable to the cost of toxicology studies. The cost of experimental materials also contributed to this increase.

General and Administrative Expenses

Comparison of Years Ended December 31, 2019 and December 31, 2020

The following table summarizes our general and administrative expenses for the years ended December 31, 2019 and 2020:

	Year Ended December 31,			
	2019	2020	$ Change	% Change
Salaries, benefits, and related expenses	$ 877,779	$1,492,382	$614,603	70%
Professional services	493,087	447,093	(45,994)	-9%
Facilities and office expenses	233,827	243,241	9,414	4%
Depreciation	171,418	233,039	61,621	36%
Rent expense	77,115	100,972	23,857	31%
Other expenses	121,291	152,321	31,030	26%
Total general and administrative expenses	**$1,974,517**	**$2,669,048**	**$694,531**	**35%**

General and administrative expenses increased $694,531, or 35%, for the year ended December 31, 2020 compared to the prior year. The increase is attributed primarily to the full-year impact of headcount increases on our expenses for salaries, benefits, and related expenses. We increased headcount in administrative functions primarily throughout the second half of 2019, including hiring our Chief Financial Officer, Senior Vice President for Business Development, and the Director for Legal Affairs.

Professional services reflect costs for fees incurred in connection with patent filings, business development, and fees for audit and valuation services. These costs decreased by $45,994 in the year ended December 31, 2020 compared to the prior year due to a decline in legal fees paid for patient filings.

Comparison of the Three Months ended March 31, 2020 and March 31, 2021

The following table summarizes our general and administrative expenses for the three months ended March 31, 2020 and March 31, 2021:

	Three Months Ended March 31,			
	2020	2021	$ Change	% Change
Salaries, benefits and related expenses	$394,075	$ 499,222	$105,147	27%
Professional services	144,954	393,624	248,670	172%
Facilities and office expenses	64,253	59,725	(4,528)	-7%
Depreciation	59,384	66,642	7,258	12%
Rent expense	25,233	24,996	(237)	-1%
Other expenses	30,669	38,151	7,482	24%
Total general and administrative expenses	**$718,568**	**$1,082,360**	**$363,792**	**51%**

General and administrative expenses increased $363,792, or 51%, for the three months ended March 31, 2021 compared to the three months ended March 31, 2020. The increase was primarily attributable to an increase in salaries, benefits, and related expenses and professional fees. The increase in salaries, benefits, and related expenses is primarily attributable to a performance-related bonus that was earned in connection with entering into the Wugen License. Professional services increased primarily due to legal services required for patent filings.

We expect to incur increasing general and administrative expenses as a result of operating as a public company, including expenses for SEC reporting, investor relations, additional insurance requirements, and other administrative expenses. We expect to increase our administrative function to support the growth in our business and public company reporting requirements.

Other Income (Expense), Net

For the years ended December 31, 2019 and 2020, other income (expense), net declined from $72,353 to $22,324, respectively, due to lower interest rates earned on money market accounts. For the three months ended March 31, 2020 and 2021, other income (expense), net increased from $21,478 to $568,176 due to the forgiveness of the PPP loan and accrued interest.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have funded our operations primarily from the issuance of redeemable preferred stock and, since 2021, from cash generated from out-license arrangements. From our inception in 2018 through March 31, 2021, we raised net proceeds of approximately $34.6 million primarily through sales of our redeemable preferred stock. As of March 31, 2021, we had cash and cash equivalents of $6.9 million. After giving effect to the settlement of the $1.25 million of Accounts receivable we are owed in connection with the Wugen License, we estimate that we will have adequate capital to meet our operating expenses, capital expenditure requirements, and contractual obligations for a period of at least one year following the date that our most recent financial statements were issued. Further, we believe our current cash balance plus the net proceeds of the offering will be sufficient capital to fund our operating expenses, capital expenditure requirements, and contractual obligations for at least the next 24 months.

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

- Timing, progress, costs, and results of our ongoing preclinical studies and clinical trials of our immunotherapeutic products;
- Impact of COVID-19 on the timing and progress of our clinical trials and our ability to identify and enroll patients;
- Costs, timing, and outcome of regulatory review of our product candidates;
- Number of trials required for regulatory approval;
- Whether we enter into any collaboration or co-development agreements and the terms of such agreements;
- Effect of competing technology and market developments;
- Cost of maintaining, expanding, and enforcing our intellectual property rights; and
- Costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive regulatory approval.

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

Comparison of the Years Ended December 31, 2019 and December 31, 2020

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,	
	2019	2020
Cash used in operating activities	$ (6,765,168)	$ (10,431,326)
Cash used in investing activities	(1,460,091)	(186,682)
Cash provided by financing activities	13,446,680	11,718,008
Net increase in cash and cash equivalents	**$ 5,221,421**	**$ 1,100,000**

Operating Activities

Net cash used in operating activities was $6.8 million for the year ended December 31, 2019 and $10.4 million for the year ended December 31, 2020.

Cash used in operating activities for the year ended December 31, 2019 consisted primarily of net loss for the period of $7.3 million and an increase of $662,221 in prepaid expenses and other assets, partially offset by $421,817 of depreciation and amortization and an increase in accounts payable and other liabilities of $766,394.

Cash used in operating activities for the year ended December 31, 2020 consisted primarily of net loss for the period of $5.8 million and an increase in Accounts receivable of $2.5 million pursuant to the Wugen License, partially offset by $595,911 of depreciation and amortization.

Investing Activities

During the years ended December 31, 2019 and 2020, the cash used in investing activities reflects the purchase of scientific lab equipment and general office equipment.

Financing Activities

During the years ended December 31, 2019 and 2020, cash provided by financing activities was $13.4 million and $11.7 million, respectively.

Cash provided by financing activities for the year ended December 31, 2019 consisted primarily of an increase of $13.4 million from proceeds from the issuance of Series B redeemable preferred stock.

Cash provided by financing activities for the year ended December 31, 2020 consisted of an increase of $11.1 million from proceeds from the issuance of Series C redeemable preferred stock and an increase of $563,590 from proceeds from an SBA Paycheck Protection Loan (“PPP loan”).

Comparison of the Three Months Ended March 31, 2020 and March 31, 2021

The following table summarizes our cash flows for the periods indicated:

	Three Months Ended March 31,	
	2020	2021
Cash used in operating activities	$ (1,981,448)	$ (1,489,802)
Cash used in investing activities	(100,857)	(23,279)
Cash used in financing activities	—	(86,615)
Net decrease in cash and cash equivalents	**$ (2,082,305)**	**$ (1,599,696)**

Operating Activities

Net cash used in operating activities was $2.0 million for the three months ended March 31, 2020 and $1.5 million for the three months ended March 31, 2021.

Cash used in operating activities for the three months ended March 31, 2020 consisted primarily of net loss for the period of $2.4 million, offset by an increase of $188,247 in prepaid expenses and other assets, an increase of $57,916 in accounts payable and other liabilities as well as a non-cash adjustment of $147,903 for depreciation and amortization.

Cash used in operating activities for the three months ended March 31, 2021 consisted primarily of net loss for the period of $2.8 million, a decrease of $150,356 due to an increase in prepaid expenses and other assets, and an adjustment for a non-cash charge of $567,311 resulting from the forgiveness of the PPP loan and accrued interest. These were offset by cash provided by operating activities resulting from a decrease in accounts receivable, an increase in accounts payable and other liabilities, and an adjust for a non-cash charge for depreciation and amortization. Accounts receivable decreased by $1.2 million, primarily due to the collection of a payment of $1.2 million from Wugen Inc. Accounts payable and other liabilities increased by $713,055 primarily due to increases of $239,000 in deferred revenue, $194,000 in accrued legal expenses, and $221,000 in accounts payable. An adjustment for non-cash charges for depreciation and amortization provided cash from operations of $158,806.

Investing Activities

Cash used in investing activities for the three months ended March 31, 2020 and 2021 consisted of purchases of equipment.

Financing Activities

During the three-month period ended March 31, 2021, cash used by financing activities decreased due to the offering costs, offset by an increase due to the issuance of common stock upon the exercise of vested employee stock options.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2020:

	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
PPP Loan	$ 567,311	$ —	$—	$ —	$ 567,311
Operating Lease	208,000	36,000	—	—	244,000
Purchase Obligation	3,882,444	—	—	—	3,882,444
Total obligations	**$4,657,755**	**$36,000**	**$—**	**$ —**	**$4,693,755**

In May 2020, we received a PPP loan in the principal amount of $563,590. We qualified for a loan based on the criteria in Section 1102 of the CARES Act: that is, allowable monthly expenses such as payroll, rent, and utilities. As of December 31, 2020, we reported $567,311 within Accrued liabilities and other liabilities on the balance sheet which appears elsewhere in this prospectus. This balance consists of principal and accrued and unpaid interest. We received full loan and interest forgiveness in January 2021.

We lease operating facilities in Miramar, Florida under non-cancelable operating lease agreements and a short-term sublease agreement. We are currently seeking a new location for our operations and expect to enter into a new lease by the beginning of 2022.

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, non-clinical studies and testing, and other services and products. These contracts generally provide for termination following a certain period after notice and therefore we believe that our cancelable obligations under these agreements are not material and they are not included in the table above.

Quantitative and Qualitative Disclosures about Market Risk

Our primary objectives in our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks include, but are not limited to, interest rate sensitivity. We had cash and cash equivalents of $8.5 million as of December 31, 2020, which consisted of bank deposits and highly liquid money market funds.

Emerging Growth Company Status

The JOBS Act permits us, as an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies and thereby allows us to delay the adoption of those standards until those standards would apply to private companies.

We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our common stock less attractive to investors.

Critical Accounting Policies, Significant Judgements and Use of Estimates

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

Revenue Recognition

For the year ended December 31, 2020, we adopted provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers ("Topic 606"). Under Topic 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. 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.

- Identification of the Contracts with the Customers

We evaluate every contract to determine whether it in its entirety or in part represents a contract with a customer, or a collaboration agreement and, based on this determination, apply appropriate accounting guidance.

We account for a contract with a customer that is within the scope of Topic 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods or services to be transferred can be identified, (iv) the arrangement has commercial substance, and (v) collection of substantially all of the consideration to which we will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

- Identification of the Performance Obligations

The promised goods or services in our collaboration and option arrangements consist of research and development services. The arrangements also have options for additional items (i.e., license rights). Options are considered to be marketing offers and are to be accounted for as separate contracts when the customer elects such options, unless we determine the option provides a material right which would not be provided without entering into the contract. The determination as to whether such options are material rights requires significant management judgment, and management considers factors such as other similar arrangements, market data, and the terms of the contractual arrangement to make such conclusion.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when: (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of our customer to develop the intellectual property on their own, and whether the required expertise is readily available.

- Determination of the Transaction Price

We estimate the transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of the potential payments and the likelihood that the payments will be received. We utilize either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

All contingent future payments, which include research, development, regulatory, and sales-based royalty payments, have not been considered in the initial analysis, as they are contingent upon option(s) being exercised or are subject to significant risk of achievement.

- Allocation of Transaction Price

We allocate the transaction price based on the estimated standalone selling price. We must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction, and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration related to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for satisfying each performance obligation.

- Recognition of Revenue

We assessed the Wugen License and determined this was a transaction with a customer and should be accounted for under Topic 606. There are five performance obligations contained in the Wugen License. Two are related to supply agreements that have not been finalized, and we will assess revenue recognition when these agreements are completed. The three performance obligations remaining are: (1) exclusive worldwide license, (2) vials of HCW9201, and (3) transfer of R&D know-how.

The estimated transaction price for performance obligations that have been satisfied as of December 31, 2020 is $4.1 million. This is the first time we have entered into an out-license arrangement and the first time the Company has established prices for its goods and services. Accordingly, the standalone selling price of the various performance obligations is uncertain, and we determined that an observable standalone selling price is not available for the identified performance obligations under the Wugen License. Where a standalone selling price is not directly observable, then we will estimate the standalone selling price considering market conditions, entity-specific factors, and information about the customer that is reasonably available. The process for determining a standalone selling price involves significant judgment and includes consideration of multiple factors, including assumptions related to the market opportunity and the time needed to commercialize a product candidate pursuant to the relevant license, estimated direct expenses, and other costs.

We first determined the standalone selling price at $2.5 million for the vials of HCW9201 and the R&D know-how. The prices were determined based on developing the know-how and the costs incurred in producing the vials. The standalone selling price for the license was determined using the residual approach and was priced at $1.6 million.

As of December 31, 2020, we recorded $2.5 million in accounts receivable, as the cash payment for the sale of the non-financial assets were due after the reporting period. The Company records amounts as accounts receivable when the right to consideration is deemed unconditional.

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, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require a reporting entity to develop its own assumptions.

Fair Value

Under the Wugen License, we received shares of common stock of Wugen on the effective date of the Wugen License. We estimated that the fair value of the stock was $1.6 million. As the common stock of Wugen is not currently publicly traded, the fair value was determined based on inputs other than a public market price. We relied primarily on the most recent third-party financing completed by Wugen. In addition, we considered the results of a third-party valuation assessment. Since our ownership interest in Wugen is less than 20% and we do not have significant influence over the operations of Wugen, we account for these securities as a cost method investment. We will carry this investment at cost less impairment, adjusted for observable price changes in

orderly transactions for an identical or similar investment of the same investee. In the event that a public market becomes available for the common stock of Wugen in the future and the shares are freely tradeable, we will recognize changes in fair value according to the market price in other income in the statements of operations.

Research and Development Costs

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. We may perform research and development for our own internally-developed drug candidates and technology development or for certain third parties under collaborative arrangements. For our internally-developed drug candidates and our internal technology development programs, we invest own funds without reimbursement from a third party. Where we perform research and development activities under a clinical joint development collaboration, we record the partner's share of collaboration expenses as a reduction to research and development expense when reimbursement amounts are due under the agreement.

We record an accrued expense for the estimated costs of our contract manufacturing activities performed by third parties. 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, we assess 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 we consider the process to be the delivery of a good, we recognize the expense when the drug product is delivered, or otherwise bears risk of loss. If we consider 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. We recognize and amortize upfront payments and accrue 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. We base our estimates on the best information available at the time. However, additional information may become available to us which may allow us to make a more accurate estimate in future periods. In this event, we 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.

Stock-based Compensation

As described in Note 1 and Note 10 to our audited financial statements which appear elsewhere in this prospectus, 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 and performance-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 the vesting period based on the evaluation of the probability of achievement of each respective milestone and the related estimated date of achievement.

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:

- *Expected term*—The expected term of stock options with service-based vesting 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 its common stock.

Determination of the Fair Value of Our Common Stock

As there has been no public market for our common stock historically prior to this offering, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering a third-party valuation of common stock and our board of directors' assessment of additional objective and subjective third-party financing events and other factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Prior to this offering, for third-party valuations performed in connection with the valuation of our common stock, we used the Black-Scholes option-pricing model. Third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting Practice Aid entitled, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, which may be as a date later than the most recent third-party valuation date, including:

- the prices at which we sold shares of redeemable preferred stock and the superior rights and preferences of the redeemable preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical and planned clinical trials for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;

- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our redeemable preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering ("IPO"), or a sale of our company considering prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

For financial reporting purposes, it is our policy to perform a contemporaneous valuation when a material number of stock awards or options are granted. As a private company, we relied primarily on the evidence of third-party financings to support valuation of common stock. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change, and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

After the completion of this offering, our board of directors will determine the fair value of each share of underlying common stock based on its closing price as reported on the date of grant according to the quoted market price on the primary stock exchange on which our common stock is traded.

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, 2019 and 2020, we had available federal net operating loss ("NOL") carryforwards of $9.1 million and $14.8 million, respectively. We also had available state NOLs carryforwards of approximately $9.1 million and $15.2 million, as of December 31, 2019 and 2020, respectively. The Federal and State NOLs will carryforward indefinitely and be available to offset up to 100% of taxable income for taxable years before 2021 and 80% of taxable years staring after 2020.

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 NOL carryforwards and 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 annual financial statements appearing elsewhere in this prospectus for more information about recent accounting pronouncements.

BUSINESS

Overview

We are an innovative preclinical stage biopharmaceutical company focused on discovering and developing novel immunotherapies to lengthen health span by disrupting the link between chronic, low-grade inflammation and age-related diseases. We believe age-related low grade chronic inflammation, or "inflammaging," is a significant contributing factor to several chronic diseases and conditions, such as cancer, cardiovascular disease, diabetes, neurodegenerative diseases, and autoimmune diseases. We believe our approach has the potential to provide an innovative treatment of these age-related diseases.

Our gateway indication is oncology. Advances in immuno-stimulatory and anti-immunosuppressive therapeutics have revolutionized cancer treatment. Our lead molecule, HCW9218, is designed with both of these functionalities – it rejuvenates the immune system to reduce senescence, and it captures TGF-ß to neutralize its immunosuppressive activity. We are preparing to submit an IND for a Phase 1b/2 clinical trial in pancreatic cancer to evaluate HCW9218, which includes completing drug product testing and nonclinical animal toxicity/pharmacokinetic studies, as well as finalizing clinical protocol. Pending the submission and FDA acceptance of the IND to proceed, we expect to initiate this clinical trial by the end of 2021 after obtaining IRB approval of our clinical research, completing clinical site initiation, and finalizing clinical trial agreements. However, we have not submitted the IND for the planned trial, and we cannot provide any assurance that the FDA will authorize us to initiate our planned clinical trials on a timely basis, or at all. In the event that the FDA does not accept our IND, we may also be required to seek feedback, and the feedback may be unfavorable. In the event we do not receive feedback on a timely basis, or we are required to change the design of our clinical protocol or address other feedback, clinical development of our products would be delayed and our costs may increase. Moreover, if the FDA does not accept the IND we file, we may be required to conduct additional preclinical testing or other IND-enabling activities, which would result in further delay and additional costs.

We are initially developing HCW9218 as an injectable immunotherapeutic for patients with solid tumors. We are endeavoring to develop a novel cancer immunotherapeutic designed with multiple mechanisms of action, with the ability to eliminate senescent cells and the proinflammatory factors they secrete and inhibit the activity of a highly immunosuppressive cytokine, TGF-ß.

We have combined our deep understanding of disease-related immunology with our expertise in advanced protein engineering to internally develop our TOBI (Tissue factOr-Based fusIon) discovery platform for the design of immunotherapeutic drugs. This modular and tunable technology has allowed us to generate a novel pipeline of internally-developed product candidates capable of activating and targeting desired immune responses and blocking unwanted immunosuppressive activities. Using our TOBI platform, we have successfully developed molecules that can be administered by subcutaneous injection as well as adoptive cell therapy approaches. We have selected two molecules as our lead product candidates: HCW9218 and HCW9302. We have chosen these product candidates because we believe they have the potential to become transformative immunotherapeutics, which can be administered to patients by subcutaneous injection.

HCW9218 was designed to simultaneously stimulate effector T cell and natural killer ("NK") cell responses and inhibit the activity of TGF-ß and its immunosuppressive effect. We are initially developing HCW9218 for treatment of patients with solid tumors. We plan to submit an IND and initiate Phase 1b/2 clinical trials by the end of 2021, working with leading institutions affiliated with the National Cancer Institute, first in patients with pancreatic cancer, then expanding to patients with breast, ovarian, prostate, and colorectal cancers. The aim of these studies is to evaluate HCW9218 as an adjunct therapy to chemotherapy. In the pancreatic cancer trial, the Phase 1b portion will be a dose escalation study of HCW9218 as monotherapy in refractory patients with advanced pancreatic cancer. The Phase 2 portion of this clinical trial will include a cohort of patients receiving HCW9218 as monotherapy and a cohort of patients receiving HCW9218 as an adjunct to chemotherapy. Pending submission and FDA acceptance of the IND to proceed with a company-sponsored Phase

1b/2 clinical trial to evaluate HCW9218 in patients with pancreatic cancer, we plan to have an additional clinical trial to evaluate HCW9218 in solid tumors with an investigator-sponsored IND. Our ability to proceed with this trial depends on the submission and acceptance of both INDs for our company-sponsored pancreatic cancer clinical trial and the investigator-initiated solid tumor clinical trial as well as finalizing our agreement with the sponsor. We are currently engaged in preliminary discussions with an institution that has expressed interest to be a sponsor for an IND using HCW9218 as an adjunct to chemotherapy in patients with solid tumors (breast, ovarian, prostate, and colorectal cancers). However, these discussions are preliminary, and we may not succeed in reaching an agreement with this institution. Depending on the course of these discussions and whether we need to seek an alternative sponsor for an IND, there could be a delay in initiating a Phase 1b/2 clinical trial to evaluate HCW9218 in patients with solid tumors. Any delays in our clinical trials could increase our costs and slow down the development and approval process, which could harm our commercial prospects. Our initial goal is to evaluate HCW9218 in patients with cancer as we attempt to minimize the side effects of chemotherapy through stimulating anti-tumor effector immune cell responses, blocking TGF-ß immunosuppressive activity, eliminating chemotherapy-induced senescent cells in tumors and normal tissues (i.e., senolytic effect) and reducing SASP factor activity (i.e., senomorphic effect). We are leveraging extensive clinical expertise to structure clinical trials with clear, objective, and measurable endpoints. We expect to manage our clinical trials internally, relying on our in-house expertise in managing clinical trials conducted in collaboration with National Cancer Institute (NCI)-Designated Comprehensive Cancer Centers. Currently, we are engaged in preliminary discussions with seven leading institutions who have shown interest in participating in our clinical trials as clinical sites. We are presently working with the identified Principal Investigators from these institutions to establish clinical development strategies for our product candidates and to refine study protocols for pancreatic, ovarian, breast, prostate, and colorectal cancer trials. Because the discussions with these clinical sites and Principal Investigators are considered preliminary, we are not certain we will be successful in reaching an agreement with any or all of these institutions. The course of these discussions and whether we might need to identify alternative clinical sites could impact the start date for our clinical trials. Any delays in our clinical trials could increase our costs and slow down the development and approval process, which could harm our commercial prospects.

Chemotherapy is the current standard-of-care for treating most forms of cancer. However, these treatments inevitably result in toxicity and unwanted side effects. Multiple studies have revealed that increased normal tissue cellular senescence can promote tumor progression, creating a link between aging and cancer. The persistence of viable and metabolically active senescent tumor cells after chemotherapy has been attributed to worse overall survival in patients. Tumor cells can undergo senescence and secrete proinflammatory factors, termed the SASP, in response to chemotherapy. SASP factors promote TIS cancer cells to re-enter the growth cycle with stemness characteristics which can result in disease relapse and metastasis. One of the key SASP factors is TGF-ß, well known for its immunosuppressive role in cancer progression. In healthy tissue, TGF-ß is transiently activated in response to tissue injury, resulting in collagen production and, ultimately, healing of the tissue. However, when TFG-ß becomes continuously active, studies have shown that it induces pathological effects associated with inflammation.

HCW9302 is our internally-developed IL-2-based fusion molecule that expands Treg cells that we created with our TOBI platform. This fusion molecule expands Treg cells *in vivo* and *ex vivo* as an injectable or cell-based strategy to reduce inflammation. We completed *in vivo* animal studies which demonstrated the ability of HCW9302 to reduce inflammation allowing for the potential to treat a wide variety of autoimmune and aging-related diseases. We expect to initiate a Phase 1 clinical trial for HCW9302, for the alopecia areata indication, to establish safety in the first half of 2022. Upon completion of these trials, we plan to build on the safety data established with alopecia areata and expand indications in Phase 2 clinical trials for HCW9302 in Type 2 Diabetes or atherosclerosis.

Studies have demonstrated that low-grade chronic inflammation is a major contributing factor for a number of age-related diseases. The induction and retention of low-grade inflammation in an aging human body is mainly the result of the accumulation of non-proliferative senescent cells and persistent activation of protein complexes, known as inflammasomes. There are two underlying processes to inflammaging: “Priming” by senescent cells and the SASP factors they secrete, which promotes the activation of inflammasomes, and “Activation” which occurs with the activation of inflammasomes, creating a chronic state of non-resolving inflammation. In response to physiological or environmental stress, normal tissue cells enter a senescent state of irreversible growth arrest accompanied by the SASP. Release of SASP factors including proinflammatory cytokines, chemokines, and proteinases drive the inflammation cycle and activation of inflammasomes. As our body ages, senescent cells accumulate and increase the release of SASP factors leading to chronic, low-grade inflammation, and organ/tissue damage. In addition, in cancer patients, chemotherapy treatment can drive tumor cells to senescence, resulting in increased drug-resistance, immune evasion and disease relapse, and tumor metastasis. Studies have shown that strategies to reduce or eliminate senescent cells can delay, prevent, and improve age-related dysfunctions.

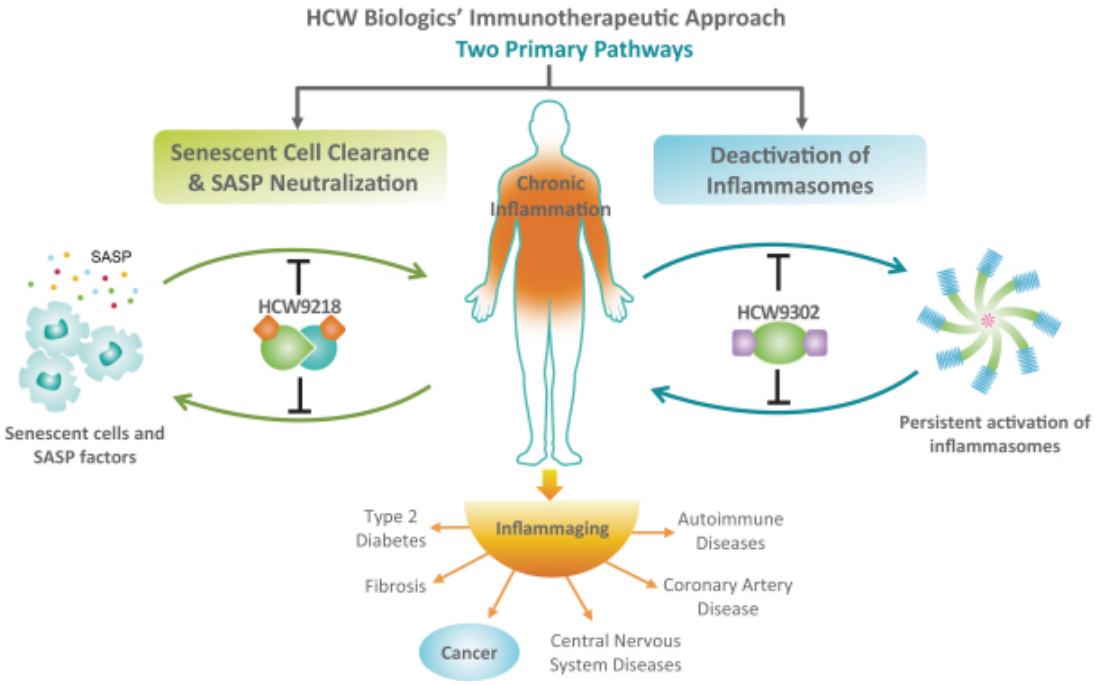
In addition, as the first line of defense to infections or tissue injuries, our innate immune system activates inflammasomes to initiate protective immune responses. Similar to senescent cells, activated inflammasomes promote the release of proinflammatory factors. Unresolved activation of inflammasomes due to chronic infection or persistent tissue injury leads to chronic low-grade inflammation which perpetuates this cycle. To date, there has been limited clinical success in targeting senescent cell accumulation or aberrant inflammasome activity using small molecule-based approaches. Studies have found the immune cell activity in young individuals is capable of limiting these processes, which we believe indicates that immunotherapeutic approaches that combine relevant stimulatory and inhibitory components may provide a means of treating aging-related diseases by addressing chronic inflammation.

We have internally-developed over 30 molecules using our TOBI platform. Our core focus will be the development of our lead product candidates, HCW9218 and HCW9302, as transformative immunotherapeutics, administered subcutaneously. We are actively seeking to out-license certain rights for molecules with great potential but outside of our focus area. We signed our first out-license agreement at the end of 2020 when we entered into an exclusive worldwide license with Wugen, Inc. (“Wugen”), a company that specializes in cell-based therapies for cancer. Wugen licensed limited rights to develop, manufacture, and commercialize cell therapy treatments for cancer based on two of our internally-developed multi-cytokine fusion protein molecules. Our clinical-stage molecule is currently being evaluated for generation of ML-NK cell products in two Phase 2 studies with patients with r/r AML. The studies were initiated by Washington University and are supported by Wugen. Patient enrollment and treatment have commenced, and human data from these clinical trials are expected to begin to become available in the second half of 2021.

We are advancing a pipeline of fusion immunotherapy product candidates for the treatment of inflammaging and the associated age-related diseases. They exhibit potent senolytic and senomorphic and inflammasome deactivation activities and utilize natural processes of the immune system to attenuate and rebalance chronic self-perpetuating proinflammatory responses. We believe our approach has the potential to provide an innovative treatment of these age-related diseases.

Our Approach

Our unique approach is to utilize our internally-developed TOBI platform to create novel multi-functional immunotherapeutics to rejuvenate our immune system to reduce the accumulation of senescent cells and to expand Treg cells to suppress the activity of inflammasomes, as shown in the figure below:

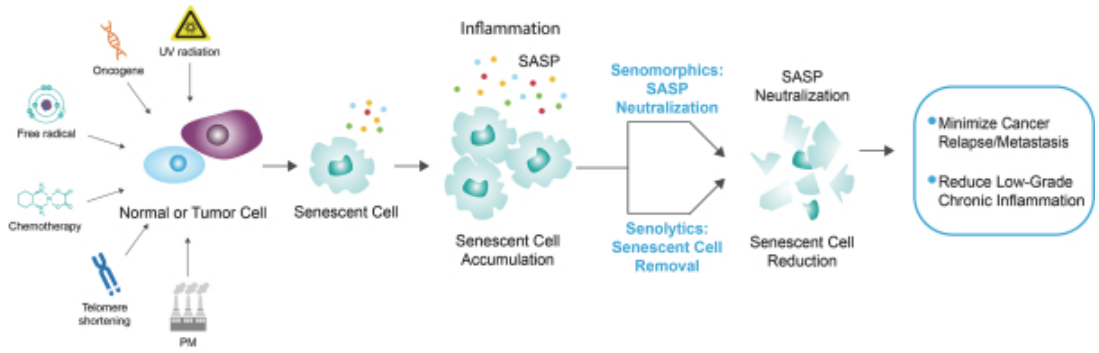


We believe this approach would eliminate the main drivers of inflammation and address the underlying development and sustainment of these factors as an innovative strategy to treat age-related diseases. We are also using our platform technology to generate product candidates to direct the immune system against solid and hematological cancers to be used as an adjunct to chemotherapies.

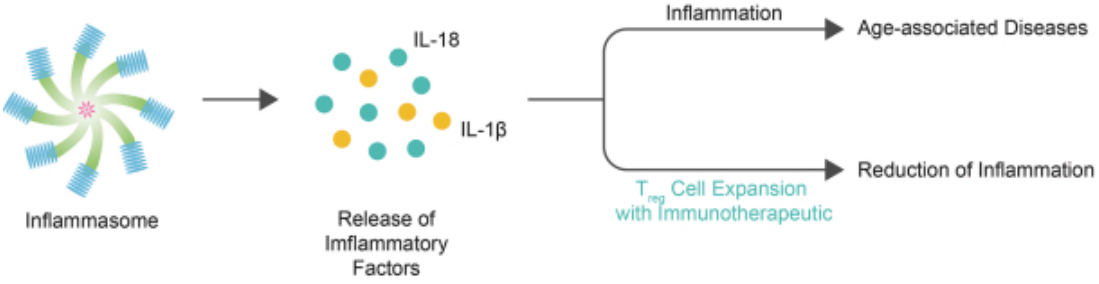
The Science of Chronic Inflammation

Senescence is a form of irreversible cell growth arrest accompanied by phenotypic changes, resistance to apoptosis, and activation of damage-sensing signaling pathways. Senescence is considered a stress response that can be induced by a wide range of intrinsic and extrinsic insults, including oxidative and genotoxic stress, DNA damage, telomere attrition, oncogenic activation, mitochondrial dysfunction, or chemotherapeutic agents.

Senescent cells remain metabolically active and can influence tissue hemostasis, disease, and aging through their SASP. Senescence is considered to be a physiologic process and is important in promoting wound healing, tissue homeostasis, regeneration, and regulation of fibrosis. Senescence also plays a role in tumor suppression. The accumulation of senescent cells, due to the aging of our immune cells, also drives aging and aging-related diseases and conditions. The SASP can trigger chronic inflammatory responses and consequently augment chronic inflammatory conditions to promote tumor growth. The connection between senescence and aging was initially based on the observation that senescent cells accumulate in aged tissue. The use of transgenic models has enabled the detection of senescent cells systematically in many aging-related disorders. Studies have demonstrated that senescent cells play an adverse role in aging-related disorders.



Inflammasomes are large, multimeric protein complexes that are another contributing factor to chronic inflammation. Their assembly in innate immune cells and other cells is triggered by a variety of stimuli and culminates in the activation of caspase-1 which then cleaves pro-interleukin ("IL")-1ß to IL-1ß. To date, diverse inflammasomes have been discovered. Among the various inflammasomes identified, the nucleotide-binding oligomerization domain, leucine-rich repeat-containing receptor ("NLR") family pyrin domain-containing 3 (NLRP3) inflammasome is best characterized. The NLRs are recognized as the key sensors of pathogens and danger signals known as PAMPs and DAMPs. The NLRP3 inflammasome has a two-step activation mechanism: "priming", which entails induction of Pro-IL-1ß and NLRP3, and "activation", wherein a functional inflammasome complex is assembled following uptake of PAMPs or DAMPs. The pathology of various diseases, including Alzheimer's disease, Parkinson's disease, and atherosclerosis has been linked to hyperactivation of the NLRP3 inflammasome.



Chemotherapy Induced Senescence in Cancer

Cancer chemotherapy efficacy is based on the assumption that treatment-induced apoptosis or necrosis of tumor cells results in prolonged patient survival. However, in addition to cytotoxic activity, chemotherapy also can cause tumor cells to enter a TIS state with SASP characteristics. The persistence of viable and metabolically active senescent tumor cells after chemotherapy has been attributed to worse overall survival in patients. This may be due to the observation that TIS cancer cells can gain stemness characteristics that result in recurrence of more aggressive therapy-resistant tumors. TGF-ß, besides its well-known immunosuppressive role in cancer progression, is considered one of the key SASP factors. It induces or accelerates, and maintains a senescent phenotype in various cell types including fibroblasts, bronchial epithelial cells, and cancers in an autocrine/paracrine manner. Therefore, TGF-ß neutralization should be considered as a part of the strategy for senescent cell removal and reduction of SASP factors.

Systemic chemotherapy has also been found to elevate normal tissue senescence. Multiple studies have revealed that increased normal tissue cell senescence can promote tumor progression, creating a link between aging and cancer. Breast cancer survivors who received chemotherapy as a part of treatment have been found to have accelerated aging and increased incidence of cancer recurrence. Survivors from childhood cancers post-chemotherapy treatment also have been found to have high rates of developing secondary cancer, spinal

disorders, and pulmonary diseases in adulthood. Furthermore, it is well established that clinical use of chemotherapies is associated with long-term damage to normal tissues and organs resulting from accumulation of TIS cells and proinflammatory SASP factors. Therefore, we believe that therapeutic approaches that alleviate chemotherapy-induced SASP in normal tissue may lead to a better quality of life for cancer patients.

Approaches for Treating Chronic and Induced Inflammation: Senolytics and Senomorphics

Current clinical efforts to counteract TIS and age-related senescent cell activity have focused on senolytic chemical drugs that selectively induce senescent cell death and senomorphic chemical drugs that reduce the secretion of SASP factors. Despite the promise of senolytics and senomorphics, their efficacy in early phase clinical studies reported to date has been limited. Further, the specificity, toxicity, and optimal treatment schedule of these pharmaceutical agents in the cancer setting have yet to be determined. We have developed an alternative strategy to eliminate senescent cells using well-characterized protein immunotherapeutics including those that stimulate effector immune cells and reduce TGF-ß activity. This strategy is supported by our findings that TIS tumor cells upregulate NKG2D and other ligands on their surface for efficient recognition and killing by effector NK cells and $CD8^+$ T cells and suppression of TGF-ß activity enhances these anti-tumor/anti-senescent cell responses.

To date, therapeutic approaches to reduce aberrant inflammasome activity have focused on inhibitors of various inflammasome components (i.e., NLRP3 and other NLRs, ASC, Caspase-1) and downstream mediators of inflammation (i.e., IL-1ß, IL-18, gasdermin D, etc.). This approach is validated based on the regulatory approval of three biologics that inhibit IL-1 activity (anakinra, a recombinant form of the naturally occurring IL-1Ra; rilonacept, a soluble chimeric Fc fusion protein of IL-1R1 and IL-1R3; and canakinumab, a humanized monoclonal antibody specific for neutralizing IL-1ß). Together, these molecules are approved for treatment of cryopyrin-associated periodic syndrome, a multisystemic IL-1ß–mediated disease due to a gain of function in NLRP3; rheumatoid arthritis; systemic juvenile idiopathic arthritis and other auto-inflammatory diseases. We believe there is considerable interest in therapeutics that specifically block inflammasome activity upstream. However, these product candidates are still in early phase clinical testing and their bioavailability, off- and on-target toxicity, and utility profiles are still being evaluated. Our approach is to deactivate inflammasome pathways in monocytes and macrophages through the immunosuppressive activities of Tregs with our immunomodulator molecules. This approach does not rely on inhibiting specific inflammasome components but rather utilizes natural processes of the immune system to attenuate and rebalance chronic self-perpetuating proinflammatory responses.

Our Strategy

Our goal is to develop transformative immunotherapies to lengthen healthspan by disrupting the link between cellular senescence, chronic inflammation, and aging-related diseases. Our strategy for efficiently validating our approach includes the following key components:

Focus resources on internally-developed intellectual property, including molecules, TOBI platform, and manufacturing processes, without relying on third-party licensing for key intellectual property.

- Our TOBI platform is a new approach to construct multi-functional fusion proteins and fusion protein complexes, using a novel TF-based scaffold platform. Multiple protein targets (e.g. cytokine, scFvs, ligands, etc.) can be packaged as a single molecule to engage immunostimulatory functions and address many signaling pathways simultaneously. Fusion protein complexes have *ex vivo* and *in vivo* applications for stimulating NK and T cells.
- Over 30 molecules have been created and characterized internally for *ex vivo* (i.e., to support cell therapies) and *in vivo* (i.e., as injectables) activation and expansion of NK, $CD8^+$ T, Tscm, and Treg cells.

- Fusion protein complexes are readily purified using internally-developed affinity chromatography. Purified fusion protein complexes are highly stable immunotherapeutics. Large-scale cGMP manufacturing runs have been demonstrated.

Focus our resources on the development of two primary internally-developed molecules for which we can establish strong IP protection, best activity in animal models, are well tolerated and can be administered by subcutaneous injection.

- The activity of HCW9218 has been established in multiple *in vivo* animal studies, including reduction of cellular senescence and SASP factors in naturally-aged mice and elimination of cancer senescent cells caused by therapy-induced senescence to enhance chemotherapies and remove the off-target effects caused by chemotherapy.
- We have completed *in vivo* animal studies demonstrating the activity of HCW9218 in reversing Type 2 Diabetes and as an anti-fibrotic agent.
- We have demonstrated the activity of HCW9302 to treat a wide variety of autoimmune and aging-related diseases in relevant animal models.

Focus on cancer indications in initial clinical development of our lead product candidate, HCW9218, in indications with high unmet medical need or where side effects of standard-of-care therapy diminishes healthspan.

- Cancer is our gateway indication. We are currently developing our lead product candidate, HCW9218, an adjunct therapy to treat refractory pancreatic, breast, ovarian, colorectal and prostate cancers. We anticipate submitting the INDs for these trials late in the second half of 2021 but we cannot provide any assurance that the FDA will authorize us to proceed and initiate our planned clinical trials on a timely basis, or at all.
- Clinical trials will allow us to evaluate the development of our novel immunotherapeutics as we attempt to augment chemotherapy while minimizing the side effects of chemotherapy against cancer. Our clinical trial design will be designed to have clear, objective endpoints against which we can measure the success of our cancer treatment.
- Because of our highly efficient design for neutralizing TGF-ß, we have targeted cancer indications with TGF-ß mediated immunosuppression and fibrotic tumor microenvironment (i.e., pancreatic, breast cancer).
- We plan to advance well-characterized immunotherapeutics with multiple mechanisms of action: effector immune cell activation, suppression of TGF-ß, reduction of senescent cells (i.e., senolytics), and reduction of SASP (i.e., senomorphics).

Leverage established clinical trial network.

- Our management team has extensive experience managing clinical trials, enabling us to reduce dependency on a contract research organization for our trials. Our founder and clinical development team have a track record of success in developing immuno-oncology therapeutics from bench to bedside.
- We are engaged in preliminary discussions with seven leading NCI-Designated Comprehensive Centers who have shown interest in participating in our clinical trials as clinical sites. After submission of the IND and while we await acceptance by the FDA for our IND, we will work with the identified Principal Investigators from these institutions to establish clinical development strategies for our product candidates and to refine study protocols. Because the discussions with these clinical sites and Principal Investigators are considered preliminary, we are not certain we will be successful in reaching an agreement with any or all of these institutions. The course of these discussions and whether we might need to identify alternative clinical sites could impact the start date for our clinical trials. Any delays in our clinical trials could increase our costs and slow down the development and approval process, which could harm our commercial prospects.

Expand clinical evaluation of senolytic/senomorphic product candidates to other age-related indications following establishment of a safe treatment regimen in cancer patients for HCW9218.

- We plan to submit an IND and initiate clinical development in fibrotic diseases leveraging our ability to reduce the proinflammatory activity of TGF-ß.
- We also plan to submit an IND and initiate clinical development in metabolic disease indications, specifically Type 2 Diabetes, leveraging our ability to reduce senescent cells and reduce SASP factors.

Out-license limited rights for certain HCW molecules outside of primary focus.

- We selected our two primary product candidates from a portfolio of 30 internally-developed molecules. We believe out-licensing certain rights to molecules that are outside of our primary focus will allow us to potentially commercialize more of these molecules through licensing partners. We intend to continue to seek partners for out-licenses for HCW internally-developed molecules with strong clinical potential, but outside of our primary focus areas (i.e., adoptive cell therapies).

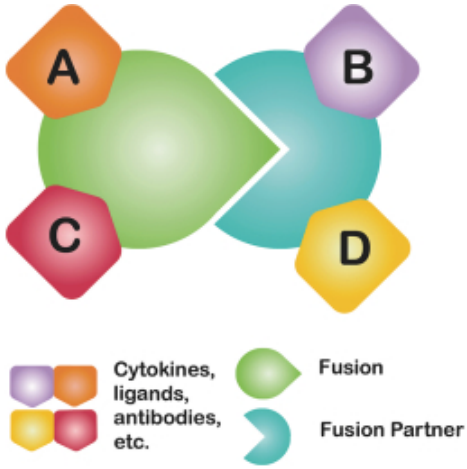
Explore co-development deals with big pharma for lead molecules.

- We are actively seeking co-development deals for the further advancement of our lead molecules, clinical development, and commercialization.
- With the proceeds of this offering, we believe we will be well-positioned to advance the development of lead molecules internally.

Our Internally-Developed TOBI Platform

TOBI (Tissue factOr-Based fusIon) platform is a new approach to construct multi-functional fusion proteins and fusion protein complexes using a novel TF scaffold platform. The extracellular domain of human TF was selected as it has a rigid elongated structure comprised mainly of ß-sheets with its N- and C-termini located at distal ends of the polypeptide, permitting genetic fusions of other protein domains without anticipated steric interference. This TF domain does not interact with the cell membrane phospholipid bilayer and, as a result, does not exhibit procoagulant activity. This TF domain is expressed at high levels by most cell types and is not expected to be immunogenic in humans. Consistent with these properties, we found that genetic fusion to the TF domain promoted increased production of difficult-to-express proteins, such as IL-15. Additionally, the TF fusion proteins could be readily purified by affinity chromatography using an anti-TF antibody and low pH elution conditions, like those used in Protein A-based affinity purification of therapeutic antibodies.

To generate multichain protein complexes, we also incorporated genetic fusions to the human IL-15 and IL-15Rα domains as shown in the figure below. When co-expressed in CHO cells, the fusion proteins form a soluble stable heterodimeric complex through high-affinity interactions between IL-15 and IL-15Rα domains. This approach offers an alternative to immunoglobulin (Fc) and other engineered protein scaffolds, which typically require introduction of multiple mutations or other non-human sequences or complicated *in vitro* assembly/purification methods to generate bi- or multi-specific complexes.



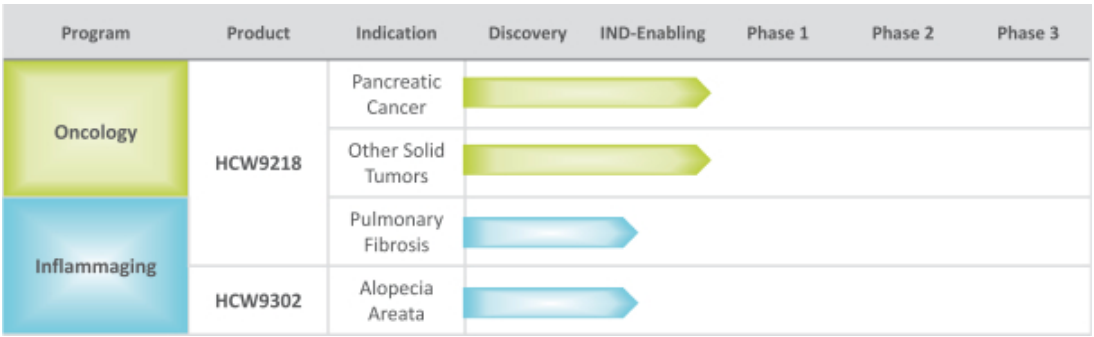
Using the TOBI platform, we have constructed more than 30 fusion complexes comprising various cytokines, ligands, receptors, and single-chain antibodies, including disease-targeting antibodies and immune checkpoint inhibitors. The modular fusion components are carefully selected to stimulate, inhibit, and/or target specific immune responses using a knowledge-based disease-relevant strategy and in many cases, are designed to provide synergistic and balanced activities for optimal therapeutic benefit. The resulting fusion proteins are rigorously tested in state-of-the-art cell culture systems and disease-specific animal models to verify their utility for the intended clinical use and targeted indications.

TOBI also provides a scalable approach for generating large-scale cGMP-grade heteromeric fusion protein complexes to support clinical applications.

Our Programs

Overview of TOBI Product Candidates

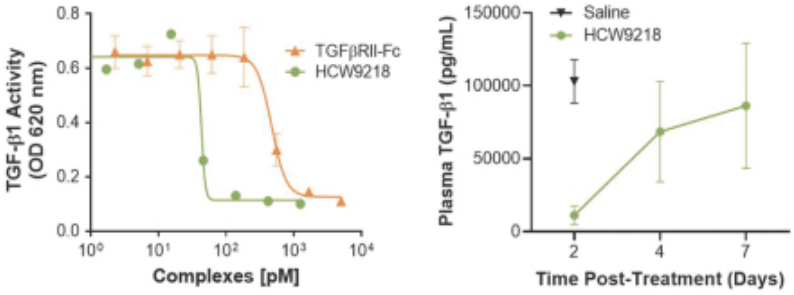
We are leveraging our modular TOBI platform to discover and design product candidates for the treatment of a wide range of cancers and aging-related diseases. Our lead immunotherapeutic program is summarized in the table below:



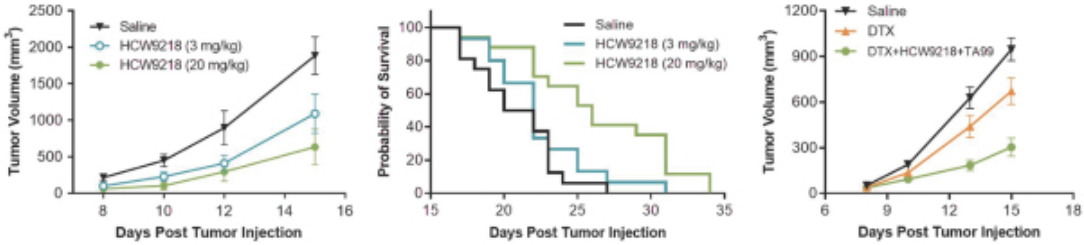
HCW9218

Advances in immunostimulatory and anti-immunosuppressive therapeutics have revolutionized cancer treatment. However, novel immunotherapeutics with these dual functions are not frequently constructed. We

have used our TOBI platform to construct a heterodimeric bifunctional fusion molecule HCW9218. This complex comprises extracellular domains of the human TGF-ß receptor II and a human IL-15/IL-15 receptor α complex. HCW9218 potently activates NK cells and CD8+ T cells *in vitro* and *in vivo* to promote their proliferative and metabolic activities and enhances their cytotoxicity against tumor targets. This fusion complex also exhibited TGF-ß neutralizing activity *in vitro* (left) and sequestered plasma TGF-ß in mice (right).



In animal models, HCW9218 displayed strong anti-tumor activity mediated by NK cells and CD8+ T cells, and increased infiltration of NK cells and CD8+ T cells into tumors. HCW9218 was well tolerated in preclinical studies, with a half-life sufficient to provide long lasting biological activity. HCW9218 may serve as a novel therapeutic to simultaneously provide immunostimulation and lessen immunosuppression associated with tumors and other aging-related diseases. In addition, we showed that HCW9218 has the potential to augment chemotherapy while reducing its therapy-induced adverse effects on normal tissues in animal models. The figures below show that HCW9218 monotherapy reduced tumor growth (left) and prolonged survival (middle), and also enhanced the activity of docetaxel ("DTX") chemotherapy (right) in mice bearing melanoma tumors. We have also found that HCW9218 treatment increases the anti-tumor activity of therapeutic antibodies and immune checkpoint inhibitors in mouse tumor models.



Cancer

The cGMP-grade HCW9218 drug product will be available in the second quarter of 2021 to support clinical development. We are preparing to submit an IND for a Phase 1b/2 clinical trial in pancreatic cancer to evaluate HCW9218, which includes completing drug product testing and nonclinical animal toxicity/pharmacokinetic studies, as well as finalizing clinical protocol. Pending submission and FDA acceptance of the IND to proceed, we expect to initiate this clinical trial by the end of 2021 after obtaining IRB approval of our clinical research, completing clinical site initiation, and finalizing clinical trial agreements. However, we have not submitted the IND for the planned trial, and we cannot provide any assurance that the FDA will authorize us to initiate our planned clinical trials on a timely basis, or at all. In the event that the FDA does not accept our IND, we may also be required to seek feedback, and the feedback may be unfavorable. In the event we do not receive feedback on a timely basis, or we are required to change the design of our clinical protocol or address other feedback, clinical development of our products would be delayed and our costs may increase. Moreover, if the FDA does not accept the IND we file, we may be required to conduct additional preclinical testing or other IND-enabling activities, which would result in further delay and additional costs.

The Phase 1b portion of this clinical trial is a dose escalation study of HCW9218 as monotherapy in refractory patients with advanced pancreatic cancer. The dose escalation portion aims to enroll up to 24 patients with the primary objectives to determine safety, maximum tolerated dose, and the recommended Phase 2 dose ("RP2D"). After determining the RP2D, we expect the Phase 2 portion of this clinical trial to include a cohort of patients receiving HCW9218 as monotherapy and a cohort of patients receiving HCW9218 as an adjunct to chemotherapy. The Phase 2 dose expansion portion aims to enroll up to 42 patients at the RP2D with primary objectives to determine the 6-month progression free survival rate and safety. The secondary objectives of this study are objective response rate, overall survival, time to progression, and duration of response.

Pending submission and FDA acceptance of the IND to proceed with a company-sponsored Phase 1b/2 clinical trial to evaluate HCW9218 in patients with pancreatic cancer, we plan to have an additional clinical trial to evaluate HCW9218 in solid tumors with an investigator-sponsored IND. Our ability to proceed with this trial depends on the submission and acceptance of both INDs for our company-sponsored pancreatic cancer clinical trial and the investigator-initiated solid tumor clinical trial as well as finalizing our agreement with the sponsor. We are currently engaged in preliminary discussions with an institution that has expressed interest to be a sponsor for an IND using HCW9218 as an adjunct to chemotherapy in patients with solid tumors (breast, ovarian, prostate, and colorectal cancers). However, these discussions are preliminary, and we may not succeed in reaching an agreement with this institution. Depending on the course of these discussions and whether we need to seek an alternative sponsor for an IND, there could be a delay in initiating a Phase 1b/2 clinical trial to evaluate HCW9218 in patients with solid tumors. Any delays in our clinical trials could increase our costs and slow down the development and approval process, which could harm our commercial prospects.

We believe HCW9218 has the potential to be an effective immunotherapy against pancreatic cancer, a very aggressive malignancy which is refractory to other immunotherapies including immune checkpoint blockade based on the results of our animal studies. TGF-ß has been shown to play a major role in promoting immunosuppression responses and fibrosis in the tumor microenvironment ("TME") as well as inducing epithelial–mesenchymal transition ("EMT") of pancreatic tumor cells, which facilitates their migratory and invasive capabilities. As a result, elevated serum TGF-ß levels have been shown to correlate with a poor prognosis in patients with pancreatic cancer. Early phase clinical studies have provided evidence that strategies to decrease TGF-ß levels or signaling can provide clinical benefit, including objective responses and prolonged survival, in certain patients with advanced/metastatic pancreatic cancer. Studies in pancreatic tumor mouse models, including research performed in our laboratories, support evaluation of combination therapies including chemotherapy to enhance antigen presentation by tumors, TGF-ß antagonist to reduce TME immunosuppression and immunostimulatory agents to augment anti-tumor T cell and NK cell responses.

The indications we have targeted in our clinical programs have large, unmet medical needs:

- Pancreatic Cancer is the 11th most commonly diagnosed cancer in the U.S., but it is the 3rd leading cause of cancer-related deaths. The 5-year survival rate has a trend of improvement, but the rate still ranges between 5 – 10%. In new cases, approximately two-thirds of the patients are at least 65 years of age. The average age at the time of diagnosis is 70 years old. In the U.S. this year, there will be 60,430 new cases and 48,220 deaths from pancreatic cancer.
- Breast Cancer is one of the leading causes of cancer deaths in U.S. women. Currently there are more than 3.5 million women with a history of breast cancer in the U.S. Approximately one in eight US women (about 12%) will develop invasive breast cancer over the course of her lifetime. About 80% of women diagnosed with breast cancer are age 45 years or older, and about 43% are age 65 years or more. In 2020, there were 276,480 new cases of invasive breast cancer and 48,530 new cases of non-invasive (in situ) breast cancer in the U.S.
- Ovarian Cancer ranks fifth in cancer deaths among U.S. women. Approximately half of all ovarian cancers are found in women aged 63 years or older. In 2020, there were approximately 21,750 new cases and 14,000 deaths in the US.

- Colorectal Cancer is the third most commonly diagnosed cancer and second leading cause of cancer death. In 2020, there were an estimated 104,610 new cases of colon cancer and 43,340 cases of rectal cancer diagnosed in the US. The majority of colorectal cancer cases are in adults ages 50 and older.
- Prostate Cancer is the second leading cause of cancer deaths in men in the U.S. Approximately 60% of cases are diagnosed in men over 65 year of age. In 2020, 191,930 men in the US were diagnosed with prostate cancer.

Other aging-related diseases

We have conducted extensive research on HCW9218 for senescent cell removal (senolytic) and SASP reduction (senomorphic) in various relevant animal models, including those for type 2 diabetes, idiopathic pulmonary fibrosis, and chronological aging. Our data suggest that HCW9218 functions as a potent senolytic and senomorphic agent. We plan to determine the dose level and regimen from our cancer trials and then apply the dose level and treatment regimens to evaluate HCW9218 for aging-related diseases such as diabetes and fibrosis. Type 2 Diabetes affects approximately 30.8 million Americans, and another 88 million American adults have pre-diabetes. Fibrotic diseases we are researching include nonalcoholic steatohepatitis (“NASH”), idiopathic pulmonary fibrosis, and COPD. NASH impacts those suffering with obesity and Type 2 Diabetes, and thus a sharp increase in the prevalence of NASH is expected to follow the trends in these related indications. NASH is expected to become the leading cause of liver transplantation in the U.S. between 2020 – 2025. Another fibrotic disease with a large, unmet medical need is COPD. There are approximately 15 million adults who have been diagnosed with COPD in the U.S., and another approximately 12 million who remain undiagnosed. The 5-year mortality rate for people who suffer with COPD typically ranges from 40% - 70%. Our ultimate goal is to use HCW9218 and HCW9302 to address neurodegenerative diseases, such as Alzheimer’s Disease, Parkinson’s Disease, and Age-related Macular Degeneration.

HCW9302

Treg cells are essential mediators of peripheral tolerance and the global immunoregulatory potential in hosts to self and non-self-antigens. Treg cells achieve this immunoregulatory control through multiple suppressive mechanisms. Alternations in Treg cell development, homeostasis or function can predispose these cells to a variety of disease conditions including allergy, autoimmunity, graft rejection, cancer, and response to immunotherapies. Current research is focused on developing novel therapies to enhance Treg cell functions *in vivo* through use of cytokines and small molecule drugs to support endogenous Treg cell proliferation or activation, *ex vivo* manipulated Treg cells in autologous adoptive cell therapy to promote immunoregulation in settings of autoimmunity, or antigen-specific Treg cells, including chimeric antigen receptor Treg (“CAR-Treg”) cells, to strengthen tolerance in allergies. We have employed our TOBI platform to create HCW9302, an IL-2-based fusion molecule, to expand Treg cells *in vivo* and *ex vivo* as an injectable or cell-based strategy to reduce inflammation and to treat a wide variety of autoimmune and aging-related diseases. In relevant animal models, we have shown encouraging results of HCW9302 treatment in atherosclerosis, diabetes, and alopecia, and this product candidate is currently undergoing IND-enabling studies. cGMP-grade HCW9302 is being manufactured to support clinical trials for treatments of autoimmune diseases.

We are preparing to submit an IND for a Phase 1 clinical trial in alopecia areata to evaluate HCW9302. The timing for this submission will depend on the completion of nonclinical toxicology studies and availability of research material, as well as finalizing clinical protocol. We expect the nonclinical toxicology studies to begin in the second half of 2021 and to be completed in the first half of 2022. This schedule will allow us to submit an IND to the FDA in the first half of 2022. Pending the submission and FDA acceptance of the IND to proceed, we expect to initiate this clinical trial by the end of 2022. However, we have not submitted the IND for the planned trial, and we cannot provide any assurance that the FDA will authorize us to initiate our planned clinical trials on a timely basis, or at all. In the event we do not receive feedback on a timely basis, or we are required to change the design of our clinical protocol or address other feedback, clinical development of our products would be

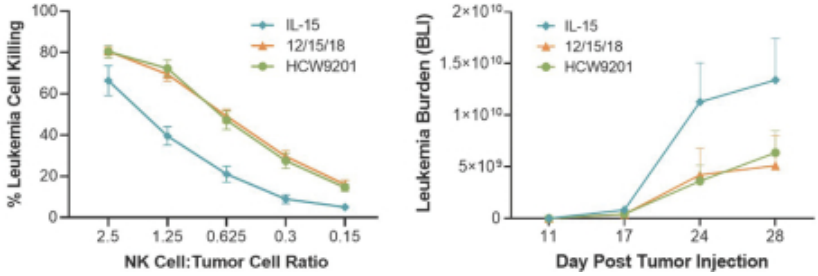
delayed and our costs may increase. Moreover, if the FDA fails to accept the IND we file, we may be required to conduct additional preclinical testing or other IND-enabling activities, which would result in further delay and additional costs.

HCW9201

We believe NK cells are a promising cellular therapy for cancer, with challenges in the field including effector cell persistence, functional activity, and tumor recognition. Recent research has shown that priming blood NK cells with a cytokine cocktail of IL-12, IL-15, and IL-18 ("12/15/18") results in ML-NK cell differentiation and enhanced responses against cancer. However, the lack of available, scalable cGMP-grade reagents has limited the advancement of this approach beyond early phase clinical trials. To address this challenge, we employed our TOBI platform to combine IL-12, IL-15, and IL-18 receptor engagement in a single protein complex ("HCW9201"). Further, we have developed cGMP-compliant production cell lines and scalable production processes to allow the generation of large amounts of HCW9201 that meets product quality characteristics for clinical use.

HCW9201 has been extensively evaluated for its capacity to stimulate activation and proliferation signals in human NK cells. RNAseq and multidimensional mass cytometry studies have revealed strong parallels between the activities of HCW9201 and IL-12/15/18 in generated ML-NK cells. Moreover, HCW9201 stimulation improved NK cell metabolic fitness, and resulted in the DNA methylation remodeling characteristic of memory- like differentiation. NK cells primed with HCW9201 and the 12/15/18 cocktail had similar increases in ML-NK cell cytotoxicity and IFN-g production against leukemia targets. HCW9201- and 12/15/18-primed NK cells also equivalently controlled leukemia *in vivo* in NSG mice. Thus, 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 cGMP-grade ML-NK cell production for cancer therapy.

The figures below show that NK cells primed with HCW9201 and 12/15/18 cocktail killed leukemia cells (left) and controlled leukemia tumors in mice (right) better that NK cells primed with IL-15 alone.



HCW9206

We have used our TOBI platform to combine cytokine IL-7, IL-15, and IL-21 receptor engagement into a single protein complex: HCW9206. Although ML-NK cells have been demonstrated to be beneficial in clinical trials, the initially evaluated NK cell products were derived from fresh prepared apheresis lymphocytes from individual matched donors. Thus, this approach has limitations in the availability of donors and the reproducibility, scalability, and costs of generating clinical-grade ML-NK cells for adoptive cell therapy. To translate this exciting therapy to many patients, we had to develop methods to expand the numbers of NK cells to support a multiple dosing regimen and for multiple patients. We have extensively tested HCW9206 and demonstrated that this complex can expand ML-NK cells without the use of 'feeder cells', the current process for producing NK cells using a cancer cell line that must be removed from the final drug product.

Wugen License: Cellular Therapy Programs

We established our first out-license arrangement in December 2020, when we entered into an exclusive worldwide license agreement with Wugen (the "Wugen License") for limited rights to develop cell therapy-based treatments using two HCW internally-developed fusion protein molecules and improvements thereto, including a clinical-stage and preclinical stage fusion molecule. We believe these molecules are capable of generating highly activated ML-NK cells in a short time frame and large-scale NK-cell expansion without relying on feeder cells. Two Phase 2 clinical trials were initiated in January 2021 by Washington University with support from Wugen, in which certain of these licensed molecules were used. One trial is using *ex vivo* ML-NK cells, induced by the licensed molecule, against r/r AML with donor leukocyte infusion (DLI) after haploidentical stem cell transplantation. The second Phase 2 clinical trial is also using *ex vivo* induced ML-NK cells against r/r AML. Patient enrollment and treatment has commenced, and preliminary data from these clinical trials are expected to begin to become available in the second half of 2021.

We retained manufacturing rights and other rights, including regulatory T cell-based cellular therapy and injectable rights, for licensed molecules under the terms of the Wugen License. We intend to enter into supply agreements with Wugen to provide cGMP and non-cGMP grade licensed molecules based on industry-standard terms, one agreement for development supply and one agreement for commercial supply. According to the terms of the Wugen license, Wugen will fund all future clinical development and commercialization activities for any indications utilizing the licensed molecules for cell therapy as covered by the license. We have the opportunity to receive additional payments for development and commercialization milestones as well as single-digit royalties.

TOBI Discovery Programs

Our discovery efforts for new product candidates are focused on characterizing and expanding our library of fusion molecules with cytokines, chemokines, ligands, receptors, and internally-developed single-chain antibodies, including fusion domains with increased or decreased biological activity, for cancer and other aging-related diseases with an emphasis on neurodegenerative, fibrotic, and autoimmune diseases. Our TOBI discovery programs are summarized in the table below.

Name	Fusion Domains	Activity	Indications
HCW9206	IL-7, IL-15, IL-21	NK cell and $CD8^+$ T cell stimulation	Injectable for cancer
HCW9207	IL-18, IL-15, IL-12, anti-CD16 scFv	NK cell stimulation	Cancer
HCW9212	IL-7, IL-15, IL-21, CD137L	NK cell and $CD8^+$ T cell stimulation	Cancer
HCW9213	Anti-CD3, anti-CD28 scFvs	T cell/Treg stimulation	Cancer, inflammatory diseases
HCW9228	TGRßRII dimer	TGF-ß antagonist	Cancer, fibrotic diseases
Antibodies			
HCW9106	Anti-CD26 scFv	Senescent cell inhibition and targeting	Inflammatory and age-related disease
HCW9107	Undisclosed target	Senescent cell inhibition and targeting	Inflammatory and age-related disease
HCW9108	Undisclosed target	Treg binding, activation, inhibition, and targeting	Inflammatory and age-related disease

Manufacturing

Our product candidates include molecules that are multi-specific fusion protein complexes, such as HCW9201, HCW9206, and HCW9218; bi-specific fusion protein complexes, such as HCW9302; and an

internally-developed affinity ligand used in our manufacturing processes, HCW9101. We have established internally-developed manufacturing processes for producing these fusion molecules from Chinese hamster ovary ("CHO") cells at large scale in a cGMP-compliant setting.

On March 14, 2019, we entered into a manufacturing agreement with EirGenix, Inc. ("EirGenix"), a third-party global contract development and cGMP manufacturer of biologics, for the manufacture of the Company's internally-developed molecules. By the end of 2019, we successfully launched cGMP production with manufacturing runs adequate to support clinical trials. During the year ending December 31, 2020, various testing and quality control procedures were conducted on the materials manufactured in 2019-2020 to ensure materials met all expected quality requirements. We successfully completed production for two molecules, HCW9101 and HCW9201, and initiated three (3) new manufacturing processes for HCW9206, HCW9218 and HCW9302, to produce cGMP-grade materials to support clinical development.

We currently rely on EirGenix and other third-party manufacturers for the cGMP production of larger quantities of our drug product candidates for our clinical trials. Our management team and other internal personnel have extensive cGMP manufacturing experience in order to ensure seamless technology transfer and 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. In some instances, we have reserved resources from third-party manufacturers for the development and manufacture of our product candidates for near-term clinical programs. However, we currently obtain our products from these manufactures 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 replacements 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 the replacements. We mitigate this risk by maintaining an inventory of clinical material for clinical trials we expect to initiate in the next 12-24 months.

We do not own or operate facilities for clinical drug manufacturing, storage, distribution, or quality testing. Currently, all of our clinical manufacturing is outsourced to third-party manufacturers. With proceeds of the offering contemplated in this prospectus, we plan to establish our own manufacturing facilities in the US. We have expertise in building and running cGMP manufacturing facilities for immunotherapeutics. In addition, our manufacturing process is wholly-owned and developed by us, so we will not rely on a third-party for manufacturing expertise or processes.

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. We additionally may rely on regulatory protection afforded through data exclusivity, market exclusivity, and patent term extensions, where available.

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 in the future file, will result in the issuance of patents, or that any issued patents we 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 strive to protect and enhance the internally-developed technology, inventions, and improvements that are commercially important to the development of our business, including seeking, maintaining, and defending patent rights. 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

As of May 15, 2021, we own 50 pending patent applications worldwide, including 10 pending U.S. utility patent applications, 2 pending provisional U.S. patent applications, 6 pending PCT applications, and 32 pending non-U.S. national phase 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 in its early stages and is continually evolving during prosecution of our applications. We own 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 Patent Family

This family includes patent applications with claims directed to compositions of various single-chain chimeric polypeptides created using the TOBI platform. These applications also include methods of use and manufacture thereof and methods of promoting the activation and proliferation of a NK cell or a T cell using our single-chain chimeric polypeptides. As of May 2021, this family, which includes HCW9302, includes 1 pending U.S. utility patent application, and 10 pending patent applications filed in Europe, Australia, Canada, Israel, Japan, New Zealand, Korea, China, Singapore, and Taiwan. The earliest predicted expiration date of any patent issuing from a patent application in this family is 2039.

Multi-Chain Chimeric Polypeptides Patent Family

This family includes patent applications with claims directed to compositions of various multi-chain chimeric polypeptides created using the TOBI platform. These applications also include methods of use and manufacture thereof and methods of promoting the activation and proliferation of a NK cell or a T cell using our multi-chain chimeric polypeptides. As of May 2021, this family, which includes claims encompassing HCW9218, HCW9201, HCW9206, HCW9228, HCW9207, and HCW9212, includes 3 pending U.S. utility patent applications, and 10 pending patent applications filed in Europe, Australia, Canada, Israel, Japan, New Zealand, Korea, China, Singapore, and Taiwan. The earliest predicted expiration date of any patent issuing from a patent application in this family is 2039.

With respect to HCW9218, the composition is claimed in 1 pending U.S. utility patent application and 10 pending patent applications filed in Europe, Australia, Canada, Israel, Japan, New Zealand, Korea, China, Singapore, and Taiwan.

With respect to HCW9201, the composition is claimed in 1 pending U.S. utility patent application and 10 pending patent applications filed in Europe, Australia, Canada, Israel, Japan, New Zealand, Korea, China, Singapore, and Taiwan. Wugen has obtained an exclusive license to these patent applications limited to use of the licensed chimeric polypeptides in manufacturing of certain cellular therapy products.

With respect to HCW 9206, the composition is claimed in 1 pending U.S. utility patent application and 10 pending patent applications filed in Europe, Australia, Canada, Israel, Japan, New Zealand, Korea, China, Singapore, and Taiwan. Wugen has obtained an exclusive license to these patent applications limited to use of the licensed polypeptides in manufacturing of certain cellular therapy products.

Methods of Culturing and Methods of Expansion and Proliferation

These two families include 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 May 2021, these two families, which include methods of using HCW9201 and HCW9206, includes 2 pending U.S. utility patent applications, 1 pending PCT application, and 6 pending national phase patent applications filed in Europe, Australia, Canada, Israel, Japan, 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 of certain cellular therapy products.

Treating Age Related Disorders

These three families include 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 May 2021, these three families, which include methods of using HCW9218, HCW9228 and HCW9302, include 2 pending U.S. utility patent applications, 2 pending provisional U.S. patent applications, 2 pending PCT applications, and 6 pending national phase patent applications filed in Europe, Australia, Canada, Israel, Japan, 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 and third of these two families is 2041.

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 May 2021, this family, which includes methods of using HCW9213 and HCW9302, includes 1 pending U.S. utility patent application and 1 pending PCT application. 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 May 2021, this family, which includes composition claims for HCW9106, includes 1 pending U.S. utility patent application and 1 pending PCT application. 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 broadly 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 i*n 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 and hematological cancers; aging-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 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.

Trademarks

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 License Agreement

In December 2020, we entered into an exclusive worldwide license agreement with Wugen (the “Wugen License”), for rights to use certain HCW fusion protein molecules to develop, manufacture, and commercialize their cellular therapy products. The term of the agreement will expire on a product-by-product and country-by-country basis, upon the later of (i) the expiration of the last-to-expire valid patent claim or (ii) ten (10) years from the first commercial sale of such product.

As consideration for the Wugen License, HCW received shares of Wugen’s common stock equivalent to a 10% ownership interest in Wugen as of the effective date of the Wugen License. The upfront payment for the license fee consisted of common stock of Wugen that had a fair value of $1.6 million on the effective date of the Wugen License. We also agreed to sell Wugen non-financial assets for $2.5 million, including cGMP-grade

clinical materials needed to begin Phase 2 clinical trials in January 2021. We may receive additional payments in the future, based upon the occurrence of certain development milestones with a value of over $200 million. We will be eligible to receive additional payments for commercialization milestones as well as single-digit royalties for commercial sales once product sales commence.

We retained all other rights and use of the licensed molecules outside of Wugen's right to use the molecules to develop, manufacture, and commercialize cellular therapy products. Wugen's rights are limited to use of the licensed molecules in cellular therapy products, which products are a pharmaceutical or biological product, process or therapy that contains or comprises cells (including without limitation, CIML NK cells or T cells) that have been engineered, modified, or otherwise manipulated *ex vivo*, but excludes regulatory T cell-based cellular therapy products. Our retained rights include use of the molecules for injectable therapy product, regulatory T cell-based cellular therapy products, and manufacturing rights to the licensed molecules. We will oversee manufacturing and supply of these licensed molecules to Wugen, utilizing our internally-developed manufacturing process, under supply agreements with Wugen that have industry-standard terms. Wugen will fund all future clinical development and commercialization activities for the cellular therapy treatments developed by Wugen using the licensed molecules.

Contract Research Agreements

We have certain contract research agreements with contractors that were entered into in 2019 and 2020 for the (i) screening and identification of specific human antibodies to three (3) particular proteins that influence the cellular-senescence process and (ii) hybridoma development. We own all rights to the resulting intellectual property, including the antibodies, sequences, and data. To date, we have received several sequences and hybridomas from the contractors. For certain contractors, we are obligated to pay one (1) future milestone payment upon filing and acceptance of an IND for each respective human antibody, however no additional future development or financial obligations are due under these contractor research agreements.

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 which 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 our novel approach is unique from most other existing or investigational therapies across the disease areas where we are focusing our development, we will need to compete 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:

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 AstraZeneca/MedImmune, Bristol Myers Squibb, Merck, Novartis, Pfizer, and Roche/Genentech. 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 immunotoxin, and targeted cancer vaccines.

As we expand to other indications, we will focus on the treatment of fibrotic diseases, including idiopathic pulmonary fibrosis (“IPF”) and NASH. There are currently two (2) approved products for the treatment of IPF; Esbriet, marketed by Roche Holding AG (“Roche”) and Ofev, marketed by Boehringer Ingelheim GmbH. Companies currently developing product candidates in IPF include AbbVie, Galapagos, Indalo, Kadmon Holdings, Inc., Galecto Biotech, Inc., Roche, Liminal BioSciences. Inc., and Pliant Therapeutics. There are currently no FDA approved therapies for the treatment of NASH. There are a number of companies developing product candidates for the treatment of NASH including Intercept, Pfizer Inc., Gilead, Allergan, Novartis, AstraZeneca plc, Eli Lilly & Company, GlaxoSmithKline plc, Amgen, Inc., BMS, Johnson & Johnson, Merck & Co., Inc., Roche, Sanofi S.A., Takeda Pharmaceuticals, Novo Nordisk, Genfit SA, Madrigal Pharmaceuticals, Inc., Viking Therapeutics, Inc., Cirius Therapeutics, Inc., NGM Biopharmaceuticals, Akero Therapeutics, Inc., and Metacrine, Inc. Most of the drugs currently in development for NASH are focused on decreasing liver fat or improving liver inflammation as opposed to direct liver anti-fibrotic approaches.

With respect to our lead internally-developed product candidate, HCW9218, we are not aware of any other competing clinical-stage companies with a first-in-class immunotherapeutic that utilizes multiple mechanisms of action, including the cytokine-based activation of immune cells and neutralization of TGF-ß immunosuppression.

We are aware of several other companies developing programs that utilize IL-2 for the selective expansion of Treg cells, including Amgen Inc., Nektar Therapeutics (in partnership with Eli Lilly & Company), Roche, and Celgene Corporation (“Celgene”). We are also aware of other companies with research or preclinical-stage programs in this area, including Synthorx, Inc., Moderna, Inc., and Xencor, Inc. We are also aware of other companies with PD-1 agonist programs for the treatment of autoimmune diseases, including AnaptysBio, Inc., Celgene, and Eli Lilly & Company.

With respect to our second lead product candidate, HCW9302, we are not aware of other competing clinical-stage companies with a first-in-class immunotherapeutic for deactivation of inflammasomes and reduction of inflammatory cytokines they release through the activation of Treg cells.

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.

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 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 a Biologics License Application ("BLA"). 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. patients 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 patients. Imposition of a clinical hold may be full or partial. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board ("IRB"), for approval. 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.

Clinical trials to support BLAs for marketing approval are typically conducted in three sequential phases. In Phase 1, the initial introduction of the drug or biologic into patients, 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. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the 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 patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the biologic and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the biologic. In rare instances, a single Phase 3 trial may be sufficient when either (1) 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 or (2) the single trial is supported by other confirmatory evidence. 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.

After 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 preclinical, 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 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 or more additional months to consider certain late-submitted information, or information intended to clarify information already provided in the BLA submission.

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 provide substantial evidence that the drug is safe and effective, or the biologic is safe, pure, potent, and effective, in the respective 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 in the BLA submission 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. 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.

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. 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.

Expedited Development and Review Programs

Fast Track Designation and Priority Review

Fast track designation may be granted for a product that is intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the 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 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 greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's BLA 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 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. FDA determines at the time of the filing the BLA whether the proposed product would be a significant improvement and therefore receive a priority review designation. FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

Breakthrough Therapy Designation

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 biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that 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. FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, 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.

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 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. FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, 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 FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

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, 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 FDA approval of a BLA. FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or 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 FDA and certain state agencies. Registration with FDA subjects entities to periodic unannounced inspections by 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"), creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical trials, animal trials, and a clinical trial or trials, unless the Secretary of Health and Human Services waives a required element. A biosimilar product may be deemed interchangeable with a previously approved product if it meets the higher hurdle of demonstrating that it 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 no interchangeable products have been approved under the BPCIA. 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 is still being evaluated by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure, or BLA approval, of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. 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) eighteen 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's application has been 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, or 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 ACA, the Centers for Medicare & Medicaid Services (“CMS”), issued a final rule that requires certain manufacturers of prescription drugs to collect and annually report information on certain

payments or transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning calendar year 2021, manufacturers must collect information regarding payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, and certified nurse-midwives for reporting in 2022. 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. Some states require the reporting of certain drug pricing information, including information pertaining to and justifying price increases. 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. Additionally, we may also be subject to state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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, 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 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 CCPA, which went into effect on January 1, 2020, creates new data privacy obligations for covered companies and provides new privacy rights to California residents. In Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of individuals within the 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 CJEU invalidated the Privacy Shield under which personal data could be transferred from the EEA to United States entities who had self-certified under the Privacy Shield scheme. Moreover, it is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature

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, which exposes us to further compliance risk.

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.

U.S. Healthcare Reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators, and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which 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 the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow-on biologic products, (ii) proscribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted, or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual nondeductible fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, apportioned among these entities according to their market share in certain government healthcare programs (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (now 70%) point of-sale discounts off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research, and (ix) established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, legislative, and judicial efforts to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. For example, the Tax Cuts and Jobs Act, among other things, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In November 2020, the United States Supreme Court held oral arguments on the U.S. Court of Appeals for the Fifth Circuit's decision that held that the individual mandate is unconstitutional. Although the Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is uncertain how the

United States Supreme court ruling, other such litigation, and the healthcare measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. United States federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2030, with the exception of a moratorium from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Legislation is currently pending before Congress that would extend the moratorium through the end of calendar year 2021. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market, and sell any products we may develop.

Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders, and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that sought to implement several of the administration's proposals. As a result, the FDA also released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. The Trump and Biden administrations both issued executive orders intended to favor government procurement from domestic manufacturers. In addition, the Trump administration issued an executive order specifically aimed at the procurement of pharmaceutical products, which instructed the federal government to develop a list of "essential" medicines and then buy those and other medical supplies that are manufactured, including the manufacture of the active pharmaceutical ingredient, in the United States. It is unclear whether this executive order or something similar will be implemented by the Biden Administration.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. CMS also published an interim final rule that establishes a Most Favored Nation ("MFN"), Model for Medicare Part B drug payment. This regulation would substantially change the drug reimbursement landscape as it bases Medicare Part B payment for 50 selected drugs on prices in foreign countries instead of average sales price ("ASP"), and establishes a fixed add-on payment in place of the current 6 percent (4.3 percent after sequestration) of ASP. The MFN drug payment amount is expected to be lower than the current ASP-based limit because U.S. drug prices are generally the highest in the world. On

December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule, and it faces uncertain prospects for implementation.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological 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.

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 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 European Economic Area, or 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 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 EC 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 a NCE. Even if a compound is considered to be a 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 company can complete a full marketing authorization application with their own complete database of pharmaceutical tests, preclinical studies, and clinical trials and obtain MA of 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 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

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.

Employees and Human Capital Resources

As of March 31, 2021, we had 40 full-time employees, 30 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.

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 efforts to recruit and retain a diverse and passionate workforce include providing competitive compensation and benefits packages and ensuring we listen to our employees.

We value innovation, passion, data-driven decision making, persistence and honesty, and are building a diverse environment where our employees can thrive and be inspired to make exceptional contributions to bring novel and more effective therapies to cancer patients.

Research and Development

Research and development expenses for the years ended December 31, 2019 and 2020 were $5.4 million and $7.3 million, respectively, and for the three months ended March 31, 2020 and 2021 were $1.7 million and $2.3 million, respectively.

Property

Our corporate headquarters are located in Miramar, Florida where we occupy approximately 12,250 square feet of space under a lease that expires in February 2022. We use these facilities for research and development laboratories and facilities for manufacturing research-grade materials, as well as offices for all the Company's employees, including clinical development, research, development, quality control, quality assurance, regulatory affairs, and administration.

We are currently investigating purchasing a building in the Miramar area that has approximately 40,000 – 60,000 square feet of space for our employee offices, laboratories, and manufacturing facilities. We expect to begin to relocate our office to the new location after the offering and complete a manufacturing facility by the end of 2022. In the event that we need to extend our existing lease at our current location, we believe we will be able to extend our lease on a month-to-month basis for an indefinite period on commercially reasonable terms.

Legal Proceedings

We are not currently a party to any other material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm, and other factors.

MANAGEMENT

Executive Officers and Directors

The names and ages of our executive officers and directors as of June 30, 2021, are as follows:

Name	Age	Position(s)
Executive Officers:		
Hing C. Wong, Ph.D.(1)	67	Chief Executive Officer and Director
Rebecca Byam	65	Chief Financial Officer
Lee Flowers	75	Senior Vice President of Business Development
Jin-an Jiao, Ph.D.	62	Vice President of Development
Peter Rhode, Ph.D.	63	Chief Scientific Officer and Vice President of Clinical Operations
Non-Employee Directors:		
Scott T. Garrett(1)(2)	71	Director
Rick S. Greene(1)(2)	56	Director

(1) Member of Audit Committee
(2) Member of Compensation Committee

Executive Officers

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

We believe that Dr. Wong is qualified to serve as a member of our board of directors due to the perspective and experience he brings as our founder and Chief Executive Officer, and his extensive experience leading life sciences companies and in the development of immunotherapeutics for cancer and other diseases.

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

Lee Flowers has served as our Senior Vice President of Business Development since September 2019. Prior to joining our company, Mr. Flowers served as Executive Vice President of Dade International, a spin-off of Baxter International Inc., from 1994 to 1996; the Vice President of Venture Development at Baxter Diagnostics, Baxter International Inc.'s largest subsidiary, from 1993 to 1994; and Division President at Baxter Diagnostics from 1991 to 1993. Upon the merger between American Hospital Supply Corporation and Baxter

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

Jin-an Jiao has served as our Vice President of Development since May 2019. Prior to joining our company, Dr. Jiao served as the Vice President of Development at Altor BioScience Corporation from March 2017 to May 2019; the Chief Scientific Officer at SAB Biotherapeutics from July 2014 to March 2017; Head of Product Development at Sanford Applied Biosciences from December 2013 to July 2014; the Executive Vice President of Product Development and Manufacturing at Hematech Inc. from March 2003 to December 2013; the Director of Protein Development at Sunol Molecular Corporation from May 1995 to March 2003; and a group leader of protein biochemistry at Baxter Diagnostics, Baxter International Inc.'s largest subsidiary, from 1992 to 1995. Dr. Jiao received his Ph.D. in Biochemistry from University of Nebraska-Lincoln, and completed his postdoctoral training at the University of California, Berkeley.

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

Non-employee Directors

Scott T. Garrett has served on our board of directors since May 2021. Mr. Garrett is currently a Senior Operating Partner at Water Street Healthcare Partners ("Water Street"). Prior to joining Water Street in 2011, Mr. Garrett served as Chairman, President and Chief Executive Officer of Beckman Coulter, Inc., a leading biomedical company, from 2008 to 2011. Mr. Garrett joined Beckman Coulter, Inc. in 2002 as President, Clinical Diagnostics Division and was promoted to President and Chief Operating Officer in 2003. In January 2005, he became Chief Executive Officer and in 2008, added the position of Chairman. Prior to that, Mr. Garrett served as Vice Chairman and Interim Chief Executive Officer of Kendro Laboratory Products from 1999 to 2001; Chairman, President and Chief Executive Officer of Dade Behring, a leading diagnostics company, from 1994 to 1998; and Operating Partner of Garrett Capital, First Chicago Equity Capital from 1998 to 2002. Mr. Garrett began his career at American Hospital Supply Corporation and continued there after the company was acquired by Baxter International, ultimately serving as Chief Executive of Baxter International's global laboratory business, Baxter Diagnostics from 1992 to 1994. Mr. Garrett serves on the board of Immucor, Inc. and Hologic, Inc. and the boards of companies in which Water Street has an ownership interest, including Orgentec Diagnostics and Pathnostics, Inc. He also serves on the board of the Advanced Medical Technology Association Diagnostics and its Executive Committee. Mr. Garrett received his B.S. degree in mechanical engineering from Valparaiso University and an M.B.A. from the Lake Forest Graduate School of Management. He also completed the Executive Management program at Stanford University Graduate School of Business.

We believe that Mr. Garrett is qualified to serve as a director because of his experience as a Chief Executive Officer and in other senior leadership positions with biomedical and diagnostics companies, which enables him to bring to our board of directors an operational perspective as well as valuable insights and experience.

Rick S. Greene has served on our board of directors since May 2021. Mr. Greene is currently the Chief Financial Officer of Epiphany Dermatology. Prior to joining Epiphany Dermatology in March 2018, Mr. Greene

served as the Chief Financial Officer of Altor Bioscience Corporation from 2015 to 2018, Vice President and Chief Financial Officer of Cumberland Pharmaceuticals from 2011 to 2015, Executive at Crowe Horwath LLP from 2007 to 2011, Director at LBMC from 2005 to 2007, Chief Financial Officer at Surgical Alliance Corporation from 2002 to 2005, Senior Manager at Ernst & Young LLP from 1998 to 2002 and 1987 to 1997, and Director Financial Operations at Phycor Inc from 1997 to 1998. Mr. Greene received his B.S. degree in accounting from Carson-Newman University and is currently registered as a Certified Public Accountant (inactive) in the state of Tennessee.

We believe that Mr. Greene is qualified to serve as a director because of his extensive professional experience in financial management and reporting, operations and business development, and in the healthcare industry.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Composition of Our Board of Directors

The holders of common stock and redeemable preferred stock have designated and our board of directors has appointed Mr. Garrett and Mr. Greene to our board of directors as representatives of the holders of the common stock and redeemable preferred stock. The provisions of the voting agreement by which the directors are currently elected will terminate, and there will be no contractual obligations regarding the election of our directors upon the completion of this offering.

Following this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated bylaws and amended and restated certificate of incorporation that will become effective immediately prior to the completion of this offering.

Our board of directors will initially be composed of three directors and the board will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting of stockholders following election. Our directors will be divided among the three classes as follows:

- the Class I director will be Scott T. Garrett and his term will expire at our first annual meeting of stockholders following this offering;
- the Class II director will be Rick S. Greene and his term will expire at our second annual meeting of stockholders following this offering; and
- the Class III director will be Hing C. Wong, Ph.D. and his term will expire at our third annual meeting of stockholders following this offering.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Board Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his background, employment, and affiliations, our board of directors has determined that Scott T. Garrett and Rick S. Greene do not have relationships that would interfere with

the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the listing standards of Nasdaq. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares held by each non-employee director and the transactions described in the section titled "Certain Relationships and Related Party Transactions."

Board Committees

Our board of directors has established an audit committee and a compensation committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Our audit committee consists of Scott T. Garrett, Rick S. Greene and Hing C. Wong, Ph.D. The chair of our audit committee is Rick S. Greene.

In May 2021, our board of directors determined that Messrs. Garrett and Greene satisfy the independence criteria for audit committee members set forth in Rule 10A-3 under the Exchange Act. Dr. Wong is not an independent director and, because he is our Chief Executive Officer, he is also not independent for purposes of audit committee membership under Rule 10A-3.

Under applicable Nasdaq rules, we are permitted to phase-in our compliance with the independence requirements for our audit committee. The phase-in periods with respect to director independence allow us to have only one independent member on our audit committee upon the listing date of our common stock, a majority of independent members on our audit committee within 90 days of the listing date and a fully independent audit committee within one year of the listing date. We are taking advantage of these phase-in rules with respect to Dr. Wong's service on our audit committee, and we expect that by the first anniversary of our listing on Nasdaq, our audit committee will comply with the applicable independence requirements.

Our board of directors has determined that Rick S. Greene is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, our board of directors has examined each audit committee members scope of experience or the nature of their employment.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control, and financial statement audits, and to oversee our independent registered public accounting firm. Specific responsibilities of our audit committee include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence, and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;

- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually that describes our internal quality control procedures, any material issues with such procedures and any steps taken to deal with such issues when required by applicable law; and
- approving or, as required, pre-approving audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Our audit committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable listing standards of Nasdaq.

Compensation Committee

Our compensation committee consists of Scott T. Garrett and Rick S. Greene. The chair of our compensation committee is Scott T. Garrett. Our board of directors has determined that each member of the compensation committee is independent under the listing standards of Nasdaq, and a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans, and programs, and to review and determine the compensation to be paid to our executive officers, directors, and other senior management, as appropriate.

Specific responsibilities of our compensation committee include:

- reviewing and recommending to our board of directors the compensation of our chief executive officer and other executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending, and terminating incentive compensation and equity plans, severance agreements, bonus plans, change-of-control protections, and any other compensatory arrangements for our executive officers and other senior management; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation philosophy.

Our compensation committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable listing standards of Nasdaq.

Director Nominations

We do not have a standing nominating committee though we intend to form a corporate governance and nominating committee as and when required to do so by law or Nasdaq rules. In accordance with Rule 5605(e)(2) of the Nasdaq rules, a majority of the independent directors may recommend a director nominee for selection by our board of directors. Our board of directors believes that the independent directors can satisfactorily carry out the responsibility of properly selecting or approving director nominees without the formation of a standing nominating committee. The directors who will participate in the consideration and recommendation of director nominees are Messrs. Garrett and Greene. In accordance with Rule 5605(e)(1)(A) of the Nasdaq rules, all such directors are independent. As there is no standing nominating committee, we do not have a nominating committee charter in place.

Our board of directors will also consider director candidates recommended for nomination by our stockholders during such times as they are seeking proposed nominees to stand for election at the next annual meeting of stockholders (or, if applicable, a special meeting of stockholders). Our stockholders that wish to nominate a director for election to our board of directors should follow the procedures set forth in our bylaws.

We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, our board of directors considers educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that will apply to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. In connection with the completion of this offering, our code of business conduct, and ethics will be made available under the Corporate Governance section of our website at https://hcwbiologics.com. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently or has been at any time one of our officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Director Compensation

Prior to this offering, we did not have a formal policy with respect to compensation payable to our non-employee directors for service as directors. We have reimbursed our directors for expenses associated with attending meetings of our board of directors and in October of 2019 we granted stock purchase rights to the former chair of our board of directors. We did not provide our non-employee directors with any cash, equity or other compensation in 2020 and as of December 31, 2020, none of our directors held any stock awards. The compensation of Dr. Wong as Chief Executive Officer is set forth below under "*Executive Compensation — Employment Agreement with Dr. Hing Wong*".

Non-Employee Director Compensation Policy

Our new non-employee director compensation policy, which becomes effective as of the closing of this offering, is designed to obtain and retain the services of qualified persons to serve as members of our board of directors.

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

Annual Cash Retainer

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

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

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

Equity Grants

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

Each non-employee director who is elected or appointed for the first time to our board of directors during the two months prior to and after the closing of this offering will be granted a stock option to purchase shares of our common stock with a grant date fair value (disregarding estimated forfeitures related to service-based vesting) of $100,000. The initial option grant will fully vest on the one-year anniversary of the date such director was elected or appointed to our board of directors, subject to the director's continued service through the vesting date.

In addition, on the date of each annual meeting of our stockholders beginning with the 2022 annual meeting, we will grant each continuing non-employee director who has served on our board of directors for at least 6 months prior to the such annual meeting a stock option to purchase shares of our common stock with a grant date fair value (disregarding estimated forfeitures related to service-based vesting) of $100,000. The annual option grant will fully vest on the earlier of the one-year anniversary of the date of grant and the date of the next annual meeting of our stockholders, subject to the director's continued service through the vesting date.

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

Expense Reimbursement

Our non-employee director compensation policy also provides that we will reimburse our non-employee directors for reasonable expenses incurred in connection with the performance of their duties, in accordance with our travel and expense policy as in effect from time to time.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table provides information concerning all plan and non-plan compensation awarded to, earned by or paid to our Chief Executive Officer and each of our two other most highly compensated officers, whom we collectively refer to as "named executive officers," during the year ended December 31, 2020.

Name and Principal Position	Fiscal Year	Salary($)	Bonus($)	Option Awards($) (1)	Non-Equity Incentive Plan Compensation($)	All Other Compensation($) (2)	Total($)
Hing C. Wong, Ph.D. *Chief Executive Officer*	2020	$360,000	$ —	$ —	$ —	$ 14,400	$374,400
Rebecca Byam *Chief Financial Officer*	2020	275,000	—	— (3)	—	11,000	286,000
Peter Rhode, Ph.D. *Chief Scientific Officer and Vice President of Clinical Operations*	2020	219,714	—	1,800	—	8,788	230,302

(1) The amounts reported in this column represent the aggregate grant date fair value of the stock options granted under our 2019 Plan to our named executive officers in 2020 as computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the dollar amount recognized for financial statement reporting purposes of the equity awards reported in this column are set forth in Note 9 to our audited financial statements included in this prospectus. Note that the amounts reported in this column reflect the accounting value for these equity awards and do not correspond to the actual economic value that may be received by our named executive officers from the equity awards.

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

(3) Ms. Byam's 2019 equity award contains performance conditions covering the 2020 fiscal year and she was not granted additional equity in 2020.

2020 Outstanding Equity Awards at Year-End Table

The following table provides information regarding the outstanding stock option awards held by our named executive officers as of December 31, 2020.

		Option Awards(1)			
		Number of Securities Underlying Unexercised Options			
Name	Grant Date	Exercisable	Unexercisable	Exercise Price(2)	Expiration Date
Hing C. Wong, Ph.D.	N/A	—	—	—	—
Rebecca Byam(3)	12/19/2019	—	107,999	0.14	12/19/2029
Peter Rhode, Ph.D(4)	12/19/2019	—	68,571	0.14	12/19/2029
Peter Rhode, Ph.D(5)	12/22/2020	—	8,571	0.21	12/22/2030

(1) All of the outstanding equity awards were granted under our 2019 Plan and are subject to acceleration of vesting as described in "—Employment, Severance, and Change of Control Agreements" below.

(2) This column represents the fair market value of a share of our common stock on the date of grant.

(3) These option shares were part of a stock option grant covering 135,000 shares of our common stock. 20% of the total shares subject to the stock option grant vested on October 10, 2020; 20% of the total shares subject to the stock option grant will vest on October 10, 2021; 25% of the total shares subject to the stock option grant will vest on October 10, 2022; and 35% of the total shares subject to the stock option grant will vest on October 10, 2023, subject to Ms. Byam's continuous service through the applicable vesting date. The option is subject to additional vesting acceleration as described in "Employment Agreement with Ms. Rebecca Byam" below.

(4) These option shares were part of a stock option grant covering 85,713 shares of our common stock. 20% of the total shares subject to the stock option grant vested on May 30, 2020; 20% of the total shares subject to the stock option grant will vest on May 30, 2021; 25% of the total shares subject to the stock option grant will vest on May 30, 2022; and 35% of the total shares subject to the stock option grant will vest on May 30, 2023, subject to Dr. Rhode's continuous service through the applicable vesting date.

(5) These option shares were part of a stock option grant covering 8,571 shares of our common stock. 20% of the total shares subject to the stock option grant vested on December 22, 2021; 20% of the total shares subject to the stock option grant will vest on December 22, 2022; 25% of the total shares subject to the stock option grant will vest on December 22, 2023; and 35% of the total shares subject to the stock option grant will vest on December 22, 2024, subject to Dr. Rhode's continuous service through the applicable vesting date.

Employment, Severance, and Change of Control Arrangements

Employment Agreement with Dr. Hing Wong

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

Cash Bonus Opportunities

In accordance with the employment agreement, Dr. Wong is eligible for a cash bonus each calendar year up to an initial target amount of 60% of his annual base salary based on Dr. Wong's achievement of certain objective and subject criteria established by our board of directors or the compensation committee of our board of directors. For 2021, the cash bonus opportunity will be split into two distinct components: (i) a cash bonus equal to 30% of his base salary for a successful completion of this offering with a pre-money valuation of the Company equal to or in excess of $200 million and (ii) a cash bonus equal to 30% of his base salary if his performance meets or exceeds his established performance goals.

Equity Incentive Grant

Per Dr. Wong's employment agreement, during the 60 day period after this offering, the Company promises to negotiate in good faith with him regarding the terms of a grant of a stock option, restricted stock units and/or other equity incentives in accordance with the terms of the Company's 2021 Plan. If the equity award is granted as a stock option, it will have an exercise price per share equal to the fair market value per share of our common stock on the date of grant. The equity award will also provide that if, in connection with a change of control of the Company (as defined in the 2021 Plan), the acquiror does not assume or substitute for the equity award, then it will vest in full effective as of immediately prior to the closing of such transaction.

Severance Benefits

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

Employment Agreement with Ms. Rebecca Byam

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

Cash Bonus Opportunities

In accordance with the employment agreement, Ms. Byam is eligible for the following cash bonuses each year: (i) a base bonus equal to 50% of Ms. Byam's annual base salary and based on Ms. Byam's achievement of specific performance metrics mutually agreed upon by Ms. Byam and our Chief Executive Officer prior to the given bonus year, and (ii) additional bonus opportunities for performance by her that exceeds her established objectives, payable at the discretion of our board of directors.

Stock Option Grants

Per her employment agreement, on October 11, 2019, the Company granted Ms. Byam the initial stock option to purchase 135,000 shares of our common stock, which vests over a four-year period. Additionally, Ms. Byam is eligible to be granted the following stock option awards under the terms of her employment agreement: (i) a stock option to purchase 135,000 shares of our common stock, to be granted to Ms. Byam upon our closing of a private placement equity financing of at least $20 million; and (ii) a stock option to purchase 135,000 shares of our common stock, to be granted to Ms. Byam upon an initial public offering by us having a pre-money valuation of at least $200 million (collectively, the "Performance Options"). The Performance Options, if granted, will (i) have an exercise price equal to the fair market value per share of our common stock as of the date of grant, as determined in good faith by our board of directors; and (ii) vest over a three-year period following the triggering event for the grant.

Severance Benefits

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

Employment Agreement with Dr. Peter Rhode

We entered into an employment agreement with Dr. Rhode, the Company's Chief Scientific Officer and Vice President of Clinical Operations, dated July 6, 2021, which became effective on July 15, 2021. The employment agreement provides the general terms of Dr. Rhode's employment, including a $230,000 base salary (which may not be reduced by the Company to less than 90% of his base salary during the prior year without Dr. Rhode's consent), an opportunity to earn cash bonus incentives, an additional equity award after the closing of this offering, and certain severance rights if he is terminated by the Company without cause. The employment agreement provides for a three-year term of employment, unless earlier terminated in accordance with the terms of the employment agreement. Dr. Rhode is employed by us at will.

Cash Bonus Opportunities

In accordance with the employment agreement, Dr. Rhode is eligible for a cash bonus each calendar year up to an initial target amount of 30% of his annual base salary based on Dr. Rhode's achievement of certain objective and subject criteria established by our board of directors or the compensation committee of our board of directors.

Equity Incentive Grant

Per Dr. Rhode's employment agreement, subject to the approval of our board of directors, Dr. Rhode will be entitled to a grant of stock options in accordance with the terms of the Company's 2021 Plan. The stock options will have an exercise price per share equal to the fair market value per share of our common stock on the date of grant.

Severance Benefits

If we terminate Dr. Rhode's employment without cause (as defined in his employment agreement), subject to his execution of a release of claims in favor of the Company, Dr. Rhode is entitled to receive certain severance benefits, as described below.

Potential Payments Upon Termination or Change in Control

Dr. Wong

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

Ms. Byam

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

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

Dr. Rhode

If we terminate Dr. Rhode's employment without cause (as defined in the employment agreement), subject to his execution of a release of claims in our favor, Dr. Rhode is entitled to receive (i) a lump sum cash

severance payment equal to 75% of his then-current annual base salary, and (ii) the vesting of all of his then unvested and outstanding equity awards that would have become vested had he remained in the employ of the Company for the 9 month period following his termination of employment; provided, however that if Dr. Rhode's termination occurs in connection with or within the 12 months following a change in control of the Company (as defined in the 2021 Plan), the equity awards will vest in full as of the date of his termination.

See *"Employee Benefit Plans-2019 Equity Incentive Plan"* below for information about the treatment of stock options granted to our executive officers under the 2019 Plan in connection with a change in control of our company.

Employee Benefit Plans

2021 Equity Incentive Plan

General

Our 2021 Equity Incentive Plan ("2021 Plan") was adopted by our board of directors and approved by our stockholders on June 21, 2021. The 2021 Plan became effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

The 2021 Plan is intended to (i) attract and retain the best available personnel to ensure our success and accomplish our goals; (ii) incentivize employees, directors and independent contractors with long-term equity-based compensation to align their interests with our stockholders, and (iii) promote the success of our business. The 2021 Plan is intended to replace the 2019 Plan, which our board of directors terminated effective as of when the 2021 Plan becomes effective.

Our 2021 Plan permits the grant of incentive stock options, nonstatutory stock options, stock appreciation rights ("SARs"), restricted stock, restricted stock units ("RSUs") and stock bonus awards (all such awards collectively, "stock awards").

Share Reserve

Subject to adjustments set forth in the 2021 Plan, the maximum aggregate number of shares of common stock that may be issued under the 2021 Plan is (i) 2,400,000 shares, plus (ii) the number of shares reserved for future issuance and not subject to outstanding awards under our 2019 Plan on the 2021 Plan's effective date that will be added to the 2021 Plan on such date (up to 464,486 shares), plus (iii) the number of shares subject to awards under the 2019 Plan that otherwise would have been returned to the 2019 Plan on account of the expiration, cancellation, forfeiture or repurchase of such awards following the effective date of the 2021 Plan (up to 653,355 shares). In addition, the number of shares reserved for issuance under the 2021 Plan will be increased automatically on the first day of each fiscal year beginning with the 2022 fiscal year, by an amount equal to the smallest of (a) 2% of the outstanding shares of common stock on the last day of the prior fiscal year, (b) 514,286 shares, or (c) such number of shares determined by our board of directors.

If all or any part of a stock award expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, or cancelled without having been fully exercised or forfeited, in any case, in a manner that results in us acquiring shares covered by the stock award at a price not greater than the price (as adjusted pursuant to the 2021 Plan) paid by the participant for such shares or not issuing any shares covered by the stock award, the unused shares covered by the stock award will, as applicable, become or again be available for stock award grants under the 2021 Plan. The payment of dividend equivalents in cash in conjunction with any outstanding stock awards shall not count against the share limit set forth in the 2021 Plan. Notwithstanding anything to the contrary contained herein, the following shares shall not be added to the shares authorized for grant under the 2021 Plan and shall not be available for future grants of stock awards: (i) shares subject to SARs that are not issued in connection with the stock settlement of the SARs on exercise thereof, (ii) shares purchased

on the open market with the cash proceeds from the exercise of stock options, and (iii) shares delivered (either by actual delivery or attestation) to us by a participant to satisfy the applicable exercise or purchase price of a stock award and/or to satisfy any applicable tax withholding obligation with respect to a stock award (including shares retained by us from the stock award being exercised or purchased and/or creating the tax obligation).

Assumption or Substitution of Awards

The Plan Administrator (as defined below), from time to time, may determine to substitute or assume outstanding awards granted by another company, in connection with an acquisition, merger or consolidation of such other company or otherwise, by either: (i) assuming such award under the 2021 Plan or (ii) granting an award under the 2021 Plan in substitution of such other company's award. Any awards that are assumed or substituted under the 2021 Plan will not reduce the number of shares authorized for grant under the Plan or authorized for grant to a participant in any fiscal year.

Administration

The 2021 Plan must be administered by our board of directors or a committee thereof, which committee will be constituted to satisfy applicable laws (the "Plan Administrator"). Awards granted to our officers or directors or to any other person whose transactions in our common stock are subject to Section 16 of the Exchange Act (an "Insider") must be approved by two or more "non-employee directors" of the board of directors (as defined in the regulations promulgated under Section 16 of the Exchange Act). Currently, our compensation committee serves as the Plan Administrator.

The Plan Administrator has the powers and discretion necessary and appropriate to administer the 2021 Plan and to control its operation. Subject to the 2021 Plan's restrictions, the Plan Administrator's powers include, but are not limited to, determining the fair market value of our common stock, selecting service providers to whom stock awards may be granted, approving any form of stock award agreement used under the 2021 Plan, modifying or amending stock awards, and taking such other actions and making all other determinations necessary for administering the 2021 Plan. The Plan Administrator's decisions are final and binding on all participants and other persons holding stock awards.

However, to the extent permitted by applicable laws and listing requirements, our board of directors or a committee thereof may delegate to one or more of our officers who may be (but are not required to be) Insiders, the authority to (i) designate employees who are not Insiders to be recipients of stock awards and determine the number of shares subject to stock awards granted to such designated employees, subject to certain restrictions that are set forth in the 2021 Plan and (ii) take any and all actions on behalf of our board of directors or a committee thereof other than any actions that affect the amount or form of compensation of Insiders or have material tax, accounting, financial, human resource or legal consequences to us or our affiliates.

Stock Options

Each stock option must be designated in the stock award agreement as either an incentive stock option (which is entitled to potentially favorable tax treatment) or a nonstatutory stock option. However, notwithstanding such designation, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by a participant during any calendar year exceeds $100,000, such stock options must be treated as nonstatutory stock options. Incentive stock options may only be granted to employees.

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 10 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 5 years from the date of grant or such shorter term as may be provided in the stock award agreement.

The per share exercise price for the shares to be issued pursuant to exercise of a stock option will be determined by the Plan Administrator, subject to the following: in the case of an incentive stock option (i) granted to an employee who, at the time the incentive stock option is granted, owns stock representing more than 10% of the voting power of all classes of our stock or the stock of any of our affiliates, the per share exercise price will be no less than 110% of the fair market value per share on the date of grant, and (ii) granted to any other employee, the per share exercise price will be no less than 100% of the fair market value per share on the date of grant. In the case of a nonstatutory stock option, the per share exercise price will be no less than 100% of the fair market value per share on the date of grant. Notwithstanding the foregoing, stock options may be granted with a per share exercise price of less than 100% of the fair market value per share on the date of grant pursuant to a corporate reorganization, liquidation, or other transaction, described in, and in a manner consistent with, Section 424(a) of the Internal Revenue Code of 1986, as amended (the "Code").

At the time a stock option is granted, the Plan Administrator will fix the period within which the stock option may be exercised and will determine any conditions that must be satisfied before the stock option may vest or be exercised. The Plan Administrator will also determine the acceptable form of consideration for exercising a stock option, including the method of payment. In the case of incentive stock options, the Plan Administrator will determine the acceptable form of consideration at the time of grant.

If a participant ceases to be a service provider other than for "cause" (as defined in the 2021 Plan), the participant may exercise his or her stock option within such period of time as is specified in the stock award agreement to the extent that the stock option is vested on the date of termination (but in no event later than the expiration of the term of such stock option). In the absence of a specified time in the stock award agreement, to the extent vested as of a participant's termination, the stock option will remain exercisable for 12 months following a termination for death or "disability" (as defined in the 2021 Plan), and three months following a termination for any other reason. Any outstanding stock option (including any vested portion thereof) held by a participant will immediately terminate in its entirety upon the participant being first notified of his or her termination for cause and the participant will be prohibited from exercising his or her stock option from and after the date of such notification.

Stock Appreciation Rights (SARs)

The Plan Administrator determines the terms and conditions of each SAR, provided that the exercise price for each SAR must be no less than 100% of the fair market value of the underlying shares of our common stock on the date of grant. Upon exercise of a SAR, a participant will receive payment from us in an amount determined by multiplying the difference between the fair market value of a share on the date of exercise over the exercise price by the number of shares with respect to which the SAR is exercised. SARs may be paid in cash, in shares of equivalent value, or in some combination thereof, as determined by the Plan Administrator. SARs are exercisable at the times and on the terms established by the Plan Administrator.

Restricted Stock and RSUs

Restricted stock awards are grants of shares of common stock that are subject to various restrictions, including restrictions on transferability and forfeiture provisions. Shares of restricted stock will vest and the restrictions on such shares will lapse in accordance with terms and conditions established by the Plan Administrator. Each RSU is a bookkeeping entry representing an amount equal to the fair market value of one share of our common stock. Upon meeting the applicable vesting criteria, a participant will be entitled to receive a payout for his or her earned RSUs as determined by the Plan Administrator in the form of cash, shares, or a combination thereof.

In determining whether restricted stock or RSUs should be granted, and/or the vesting schedule for such stock awards, the Plan Administrator may impose whatever conditions on vesting as it determines to be appropriate.

During the period of restriction, participants holding restricted stock may exercise full voting rights and will be entitled to receive all dividends and other distributions paid, in each case with respect to such shares unless the Plan Administrator determines otherwise. Such dividends or distributions will be subject to the same restrictions, including without limitation restrictions on transferability and forfeitability, as the shares of restricted stock with respect to which they were paid.

During the vesting period, participants holding RSUs will hold no voting rights by virtue of such RSUs. The Plan Administrator may, in its sole discretion, award dividend equivalents in connection with the grant of RSUs that may be settled in cash, in shares of equivalent value, or a combination thereof.

Stock Bonus Awards

A stock bonus award is an award of shares to a participant without a purchase price that is not subject to any restrictions. The Plan Administrator will determine the number of shares to be awarded to the participant under a stock bonus award. A stock bonus award may be paid in cash, whole shares, or a combination thereof, based on the fair market value of the shares subject to the stock bonus award on the date of payment, as determined in the sole discretion of the Plan Administrator.

Performance Awards

The Plan Administrator may grant stock options, SARs, restricted stock and RSUs that are subject to the satisfaction of specified performance criteria. The Plan Administrator determines the terms surrounding performance awards, including the required levels of performance with respect to specified business criteria (including any adjustment(s) thereto that will be applied in determining the achievement of such performance criteria), the corresponding amounts payable upon achievement of such levels of performance, and the termination and forfeiture provisions; provided that all performance criteria must be determined when the achievement of such criteria remains substantially uncertain.

The Plan Administrator in its discretion may apply performance goals to a participant with respect to a stock award including one or more of the following: (i) sales or non-sales revenue; (ii) return on revenue; (iii) operating income, (iv) income or earnings including operating income, (v) income or earnings before or after taxes, interest, depreciation and/or amortization, (vi) income or earnings from continuing operations, (vii) net income, (viii) pre-tax income or after-tax income, (ix) net income excluding amortization of intangible assets, depreciation and impairment of goodwill and intangible assets and/or excluding charges attributable to the adoption of new accounting pronouncements, (x) raising of financing or fundraising, (xi) project financing, (xii) revenue or revenue backlog, (xiii) gross margin, (xiv) operating margin or profit margin, (xv) capital expenditures, cost targets, reductions and savings and expense management, (xvi) return on assets (gross or net), return on investment, return on capital, or return on stockholder equity, (xvii) cash flow, operating cash flow, free cash flow, cash flow return on investment (discounted or otherwise), net cash provided by operations, or cash flow in excess of cost of capital, (xviii) performance warranty and/or guarantee claims, (xix) stock price or total stockholder return, (xx) earnings or book value per share (basic or diluted), (xxi) economic value created, (xxii) pre-tax profit or after-tax profit, (xxiii) strategic business criteria, consisting of one or more objectives based on meeting specified market penetration or market share, completion of strategic agreements such as licenses, joint ventures, acquisitions, and the like, geographic business expansion, objective customer satisfaction or information technology goals, intellectual property asset metrics, (xxiv) objective goals relating to divestitures, joint ventures, mergers, acquisitions and similar transactions, (xxv) objective goals relating to staff management, results from staff attitude and/or opinion surveys, staff satisfaction scores, staff safety, staff accident and/or injury rates, compliance, headcount, performance management, or completion of critical staff

training initiatives, (xxvi) objective goals relating to projects, including project completion, timing and/or achievement of milestones, project budget, technical progress against work plans, and (xxvii) enterprise resource planning.

The performance goals of stock awards may also take into account other criteria (including subjective criteria). Performance goals may differ from participant to participant, performance period to performance period and from stock award to stock award. Any criteria used may be measured, as applicable, (i) in absolute terms, (ii) in relative terms (including, but not limited to, any increase (or decrease) over the passage of time and/or any measurement against other companies or financial or business or stock index metrics particular to us), (iii) on a per share and/or share per capita basis, (iv) against our performance as a whole or against that of any of our affiliate(s), or particular segment(s), business unit(s) or product(s) of ours or an individual project company, (v) on a pre-tax or after-tax basis, (vi) on a GAAP or non-GAAP basis, and/or (vii) using an actual foreign exchange rate or on a foreign exchange neutral basis.

Non-Employee Director Limitations

Stock awards granted during a single fiscal year under the 2021 Plan or otherwise, taken together with any cash fees paid during such fiscal year for services on the board of directors, will not exceed $1,000,000 in total value for any non-employee director in his or her first year of service as a non-employee director and $500,000 in total value for any other non-employee directors (calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes). Such applicable limit will include the value of any stock awards that are received in lieu of all or a portion of any annual committee cash retainers or other similar cash-based payments. Stock awards granted to an individual while he or she was serving in the capacity as an employee or while he or she was an independent contractor but not a non-employee director will not count for purposes of these limits.

Leaves of Absence /Transfer Between Locations/Time Commitment Change

The Plan Administrator has the discretion to determine at any time whether and to what extent the vesting of stock awards will be suspended during any leave of absence; provided that in the absence of such determination, vesting of stock awards will continue during any paid leave and will be suspended during any unpaid leave (unless otherwise required by applicable laws). A participant will not cease to be an employee in the case of (i) any leave of absence approved by the participant's employer or (ii) transfers between our locations or between us and any of our affiliates. If an employee holds an incentive stock option and such leave exceeds three months, then, for purposes of incentive stock option status only, such employee's service as an employee will be deemed terminated on the first day following such three month period and the incentive stock option will thereafter automatically treated for tax purposes as a nonstatutory stock option in accordance with applicable laws, unless reemployment upon the expiration of such leave is guaranteed by contract or statute, or unless provided otherwise pursuant to a written company policy.

If a participant's regular level of time commitment in performing services to us or an affiliate of ours is reduced after an stock award is granted, the Plan Administrator has the discretion, subject to applicable laws, to (i) proportionately reduce the number of shares or cash amount subject to stock awards that vest or become payable after such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the vesting schedule of the stock award. If the Plan Administrator makes such a reduction, the participant will no longer have any rights to the portion of the stock award that is so reduced.

Nontransferability of Stock Awards

Unless determined otherwise by the Plan Administrator, a stock award may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the participant, only by the participant. If the Plan

Administrator makes a stock award transferable, such stock award will contain such additional terms and conditions as the Plan Administrator deems appropriate; provided that in no event may any stock award be transferred for consideration to a third-party financial institution.

Clawback/Recovery

The Plan Administrator may specify in a stock award agreement that the participant's rights, payments, and/or benefits with respect to a stock award will be subject to reduction, cancellation, forfeiture, and/or recoupment upon the occurrence of certain specified events, in addition to any applicable vesting, performance or other conditions and restrictions of the stock award. Notwithstanding any provisions to the contrary under the 2021 Plan, a stock award granted under the 2021 Plan will be subject to any clawback policy as may be established and/or amended from time to time by us. The Plan Administrator may require a participant to forfeit or return to and/or reimburse us for all or a portion of the stock award and/or shares issued under the stock award, any amounts paid under the stock award, and any payments or proceeds paid or provided upon disposition of the shares issued under the stock award, pursuant to the terms of such company policy or as necessary or appropriate to comply with applicable laws.

Adjustment

In the event of a stock split, reverse stock split, stock dividend, combination, consolidation, recapitalization or reclassification of the shares, subdivision of the shares, a rights offering, a reorganization, merger, spin-off, split-up, repurchase, or exchange of our common stock or other securities of ours or other significant corporate transaction, or other change affecting our common stock occurs, the Plan Administrator, in order to prevent dilution, diminution or enlargement of the benefits or potential benefits intended to be made available under the 2021 Plan, will, in such manner as it may deem equitable, adjust the number, kind and class of securities that may be delivered under the 2021 Plan and/or the number, class, kind and price of securities covered by each outstanding stock award; provided that all such adjustments will be made in a manner that does not result in taxation under Section 409A of the Code.

Dissolution or Liquidation

In the event of the proposed winding up, dissolution or liquidation of us, the Plan Administrator will notify each participant as soon as practicable prior to the effective date of such proposed transaction. To the extent it has not been previously exercised or settled, a stock award will terminate immediately prior to the consummation of such proposed action.

Corporate Transaction

In the event of (i) a transfer of all or substantially all of our assets, (ii) a merger, consolidation or other capital reorganization or business combination transaction of us with or into another corporation, entity or person, (iii) the consummation of a transaction, or series of related transactions, in which any person becomes the beneficial owner directly or indirectly, of more than 50% of our then outstanding capital stock, or (iv) a "change in control" (as defined in the 2021 Plan) each outstanding stock award (vested or unvested) will be treated as the Plan Administrator determines, which determination may provide for one or more of the following: (a) the continuation of such outstanding stock awards (if we are the surviving corporation), (b) the assumption of such outstanding stock awards by the surviving corporation or its parent, (c) the substitution by the surviving corporation or its parent of new stock options or other equity awards for such stock awards, (d) the cancellation of such stock awards in exchange for a payment to the participants equal to the excess of (1) the fair market value of the shares subject to such stock awards as of the closing date of such corporate transaction over (2) the exercise price or purchase price paid or to be paid (if any) for the shares subject to the stock awards; provided that such payment may be subject to the same conditions that apply to the consideration that will be paid to holders of shares in connection with the transaction (subject to applicable laws), (e) the full or partial acceleration

of vesting, exercisability payout accelerated expiration of an outstanding stock award, lapse of our right to repurchase or reacquire shares acquired under a stock award or lapse of forfeiture rights with respect to shares acquired under a stock award, (f) the opportunity for participants to exercise their stock options and/or SARs prior to the occurrence of the corporate transaction and the termination (for no consideration) upon the consummation of such corporate transaction of any stock options not exercised prior thereto, or (g) the cancellation of such outstanding stock awards in exchange for no consideration.

Change in Control

A stock award may be subject to additional acceleration of vesting and exercisability upon or after a change in control (as defined in the 2021 Plan) as may be provided in the stock award agreement for such stock award or as may be provided in any other written agreement between us or any of our affiliates and the participant, but in the absence of such provision, no such acceleration will occur (unless otherwise determined by the Plan Administrator in connection with a corporate transaction).

Amendment, Termination and Duration of the 2021 Plan

The 2021 Plan will continue in effect for a term of 10 years measured from the board approval date, unless terminated earlier under the terms of the 2021 Plan. The Plan Administrator may at any time amend, alter, suspend or terminate the 2021 Plan pursuant to the listing standards of any national securities exchange or association on which our securities are listed or as otherwise required by applicable laws.

2019 Equity Incentive Plan

General. Our board of directors adopted, and our stockholders approved, our 2019 Equity Incentive Plan (the "2019 Plan") on March 14, 2019. The 2019 Plan was last amended on August 4, 2020. Our 2019 Equity Incentive Plan, or 2019 Plan, will be terminated effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, and no new awards will be granted under our 2019 Plan following this offering, but previously granted awards will continue to be subject to the terms and conditions of the 2019 Plan and the stock award agreements pursuant to which such awards were granted.

Share Reserve. Under our 2019 Plan, we have reserved an aggregate of 4,000,000 shares. In general, if options granted under our 2019 Plan are canceled or terminated or otherwise forfeited by a participant, then those option shares will again become available for awards under the 2019 Plan.

Plan Administration. Our board of directors has administered the 2019 Plan before this offering. Our board of directors has delegated its authority to administer the 2019 Plan to our compensation committee following this offering.

Eligibility. Employees, members of our board of directors who are not employees, and consultants are eligible to participate in our 2019 Plan.

Types of Award. Our 2019 Plan provides for incentive and nonstatutory stock options to purchase shares of our common stock, restricted stock awards, and restricted stock units.

Stock Options. Our board of directors or the compensation committee granted incentive and/or non-statutory stock options under our 2019 Plan, provided that incentive stock options were only granted to employees. The exercise price of such options was generally equal to at least the fair market value of our common stock on the date of grant. The term of an option did not exceed 10 years; provided, however, that an incentive stock option held by a participant who owns more than 10% of the total combined voting power of all classes of our stock, or of certain of our subsidiary corporations, did not have a term in excess of 5 years, and had an exercise price of at least 110% of the fair market value of our common stock on the grant date. The administrator determined the methods of payment of the exercise price of an option, which included cash, shares

or other property acceptable to the administrator. Subject to the provisions of our 2019 Plan, the administrator determined the remaining terms of the options (e.g., vesting). After the termination of service of an employee, director or consultant, the participant may exercise his or her option, to the extent vested, for the period of time stated in his or her option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for 3 months following the termination of service. However, in no event may an option be exercised later than the expiration of its term.

Share Awards. The purchase price, if any, for shares awarded under the 2019 Plan was not less than 100% of the fair market value of our common stock on the award grant date. Restricted shares and restricted stock units vest at the times determined by the administrator.

Non-transferability of Awards. Unless the administrator provides otherwise, our 2019 Plan generally does not allow for the transfer of awards and only the recipient of an option may exercise such an award during his or her lifetime.

Certain Adjustments. In the event of certain corporate events or changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2019 Plan, the administrator will make adjustments to one or more of the number, kind, and class of securities that may be delivered under the 2019 Plan and/or the number, kind, class, and price of securities covered by each outstanding award.

Effect of a Change in Control. Our 2019 Plan defines a change in control as (a) a transfer of substantially all of the Company's assets to any person other than an affiliate or (b) an acquisition or similar transaction in which any person becomes the beneficial owner, directly or indirectly, of more than 50% of the combined voting power of our outstanding voting securities, excluding certain related party transactions and transactions in connection with an offer to the public pursuant to a registration statement filed with the Securities and Exchange Commission. The 2019 Plan provides that in the event of a change in control, our administrator may, but is not obliged to (i) accelerate, vest, or cause the restrictions to lapse with respect to all or any portion of any award; (ii) cancel awards and cause to be paid to the holders of vested awards the value of such awards, if any; (iii) provide for the issuance of substitute awards or the assumption or replacement of such awards; or (iv) provide written notice to participants that for a period of at least 30 days prior to the change in control, such awards shall be exercisable, to the extent applicable, as to all shares of common stock subject thereto and upon the occurrence of the change in control, any awards not so exercised shall terminate and be of no further force and effect.

Equity awards under the 2019 Plan may be subject to additional acceleration of vesting upon or after a change in control as provided in the award agreement or as may be provided in any other written agreement between us and the participant. On December 21, 2019, our board of directors amended all outstanding equity awards to provide full accelerated time-vesting upon a change in control for participants who have provided at least one year of continuous service through the closing of the change in control.

Amendment or Termination. Our board of directors may amend or terminate the 2019 Plan at any time. If our board of directors amends the plan, it does not need to ask for stockholder approval of the amendment unless required by applicable law. No further awards will be made under our 2019 Plan after this offering.

Executive Incentive Bonus Plan

Our board of directors approved our Executive Incentive Bonus Plan ("Bonus Plan") to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

General

The purpose of the Bonus Plan is to motivate and reward our eligible officers and employees, including our named executive officers, for their contributions toward the achievement of certain performance goals. The

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

Targets and Performance Criteria

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

Eligibility and Clawback

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

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

Perquisites, Health, Welfare, and Retirement Benefits

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability, accidental death and dismemberment insurance and supplemental insurance plans, in each case on the same basis as all of our other employees. We provide a 401(k) plan to our employees, including our current named executive officers, as discussed in the section below entitled "—401(k) Plan."

We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances.

401(k) Plan

We maintain a tax-qualified retirement plan (401(k) plan) that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation subject to applicable annual Code limits. Employees are immediately and fully vested in their contributions. The 401(k) plan permits us to make matching contributions and profit sharing contributions to eligible participants, although we have not made any such contributions to date. We intend for our 401(k) plan to qualify under Sections 401(a) and 501(a) of the Code so that contributions by employees to the 401(k) plan, and earnings on those contributions, are not taxable to employees until withdrawn from the 401(k) plan.

Pension Benefits

None of our named executive officers participate in or have an account balance in any qualified or non-qualified defined benefit plan sponsored by us.

Nonqualified Deferred Compensation

We have not offered any nonqualified deferred compensation plans or arrangements or entered into any such arrangements with any of our named executive officers

Limitation of Liability and Indemnification Matters

Following this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation that will be in effect upon the completion of this offering will authorize us to indemnify our directors, officers, employees, and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws that will be in effect upon the completion of this offering will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws that will be in effect upon the completion of this offering will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines, and settlement amounts incurred by any of these individuals in connection with any action, proceeding, or investigation. We believe that these amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

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

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In addition to the compensation arrangements, including employment and termination of employment arrangements and indemnification agreements described in "Executive Compensation," the following is a description of each transaction since our inception in April 2018 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeds $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any immediate family member of or person sharing the household with any of these individuals, had or will have a direct or indirect material interest.

Equity Financings

Series A Preferred Stock Financing

In April 2018, we entered into a stock purchase agreement with Hing C. Wong, Ph.D., our Chief Executive Officer and the sole member of our board of directors pursuant to which we agreed to issue and sell shares of Series A redeemable preferred stock to Dr. Wong and his spouse, Bee Yau Huang. In April and November 2018, and February 2019, we sold an aggregate of 6,316,691 shares of our Series A redeemable preferred stock at a purchase price of $0.88 per share for an aggregate purchase price of approximately $5.6 million. Each share of our Series A redeemable preferred stock will convert into one share of our Class A Common Stock upon the closing of this offering in accordance with our Amended and Restated Certificate of Incorporation, filed on August 5, 2020 (the "August 2020 Certificate of Incorporation"). The price of these shares of Series A redeemable preferred stock was determined by the sole member of our board of directors. The terms of these purchases were the same for all purchasers of our Series A redeemable preferred stock.

Series B Preferred Stock Financing

In June, July, September, and October 2019, we sold an aggregate of 12,012,617 shares of our Series B redeemable preferred stock at a purchase price of $1.05 per share for an aggregate purchase price of approximately $12.6 million. Each share of our Series B redeemable preferred stock will convert into one share of our Class A Common Stock upon the closing of this offering in accordance with the August 2020 Certificate of Incorporation. The price of these shares of Series B redeemable preferred stock was determined by our board of directors.

The following table summarizes the Series B redeemable preferred stock purchased by our directors, executive officers and beneficial holders of more than 5% of our capital stock. The terms of these purchases were the same for all purchasers of our Series B redeemable preferred stock.

Name of stockholder	Shares of Series B Preferred Stock	Total purchase price
Hing C. Wong(1)	2,954,285	$3,102,000
Medmira Capital Ltd. (2)	2,857,142	3,000,000
DeepWork HCW Partners LLC (3)	2,009,524	2,110,001
Axone Ventures HCW LP	1,904,762	2,000,000
Golden Triangle Ventures, LLC (4)	953,571	1,001,250

(1) Includes 1,525,714 shares purchased by Dr. Wong and Ms. Bee Yau Huang.
(2) Medmira Capital Ltd. is a greater than 5% stockholder, and Dr. Peter Sun, a former member of our board of directors, serves as Chief Executive Officer of Medmira Capital Ltd.

(3) Ms. I-Ting Kathy Chiu, a former member of our board of directors, is a Managing Partner and founder of DeepWork Capital, LLC, an affiliate of DeepWork HCW Partners LLC.
(4) Mr. Fred A. Middleton, a former member of our board of directors, is the sole member of Golden Triangle Ventures, LLC, the purchaser of these shares.

Series C Preferred Stock Financing

In September, October, and November 2020, we sold an aggregate of 5,439,112 shares of our Series C redeemable preferred stock at a purchase price of $2.06 per share for an aggregate purchase price of approximately $11.2 million. Each share of our Series C redeemable preferred stock will convert into one share of our Class A Common Stock upon the closing of this offering in accordance with the August 2020 Certificate of Incorporation. The price of these shares of Series C redeemable preferred stock was determined by our board of directors.

The following table summarizes the Series C redeemable preferred stock purchased by our directors, executive officers, and beneficial holders of more than 5% of our capital stock. The terms of these purchases were the same for all purchasers of our Series C redeemable preferred stock.

Name of stockholder	Shares of Series C Preferred Stock	Total purchase price
Pacific Treasure Global Limited	1,704,545	$3,499,999
Hing C. Wong and Bee-Yau Huang(1)	1,071,428	2,200,000
Medmira Capital Ltd.(2)	730,519	1,499,999
DeepWork HCW Partners LLC(3)	662,307	1,359,937
Golden Triangle Ventures, LLC(4)	48,701	100,000

(1) Dr. Hing C. Wong is our founder, Chief Executive Officer and a member of our board of directors. Represents shares purchased by Dr. Wong and Ms. Bee Yau Huang.
(2) Medmira Capital Ltd. is a greater than 5% stockholder, and Dr. Peter Sun, a former member of our board of directors, serves as Chief Executive Officer of Medmira Capital Ltd.
(3) Ms. I-Ting Kathy Chiu, a former member of our board of directors, is a Managing Partner and founder of DeepWork Capital, LLC, an affiliate of DeepWork HCW Partners LLC.
(4) Mr. Fred A. Middleton, a former member of our board of directors, is the sole member of Golden Triangle Ventures, LLC, the purchaser of these shares.

Investors' Rights, Voting and Right of First Refusal Agreements

In connection with our redeemable preferred stock financings, we entered into investors' rights, voting, and right of first refusal and co-sale agreements containing voting rights, and rights of first refusal, among other things, with certain holders of our redeemable preferred stock and certain holders of our common stock. The parties to these agreements include entities affiliated with our former directors, Ms. Chiu, Mr. Middleton, and Dr. Sun. These stockholder agreements will terminate upon the completion of this offering. See the section titled "Principal Stockholders" for additional information regarding beneficial ownership of our capital stock.

Potential Insider Participation

Certain of our directors and existing stockholders or their affiliates, including our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer and Vice President of Clinical Operations, have agreed to purchase an aggregate of approximately 1,480,625 shares of our common stock in this offering at the initial public offering price. See the footnotes to the table in the section titled "Principal Stockholders" for additional information regarding the amount of shares of our common stock that our director and existing

stockholders have agreed to purchase in this offering. The underwriter will receive the same underwriting discount on any shares purchased by these parties as they will on any other shares sold to the public in this offering.

Review, Approval or Ratification of Transactions with Related Parties

We have adopted a written related-party transactions policy stating that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common stock, and any members of the immediate family of and any entity affiliated with any of the foregoing persons are not permitted to enter into a material related-party transaction with us without the review and approval or ratification, as applicable, of our audit committee or the disinterested members of our audit committee in the event it is inappropriate for any member of our audit committee to review such transaction due to a conflict of interest. The policy provides that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our common stock or with any of their immediate family members or affiliates in which the amount involved exceeds $120,000 must be presented to our audit committee or the disinterested members of our audit committee in the event it is inappropriate for any member of our audit committee to review such transaction due to a conflict of interest for review, consideration, and approval or ratification, as applicable. In approving or rejecting any such proposal, we expect that our audit committee or the disinterested members of our audit committee in the event it is inappropriate for any member of our audit committee to review such transaction due to a conflict of interest will consider the relevant facts and circumstances available and deemed relevant to the committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related party's interest in the transaction. Notwithstanding the foregoing, if any related-party transaction, or series of related-party transactions, is of the type that has "standing pre-approval" by the audit committee, even if aggregate amount involved will exceed $120,000, including, but, not limited to, any compensation paid to our executive officer if the compensation is required to be reported in the our proxy statement or Annual Report on Form 10-K pursuant to Item 402 of Regulation S-K, such transaction(s) shall be deemed to be pre-approved by the audit committee.

Although we have not had a written policy for the review and approval of transactions with related parties, our board of directors has historically reviewed and approved any transaction where a director or executive officer had a financial interest, including all of the transactions described above. Prior to approving such a transaction, the material facts as to a director's or executive officer's relationship or interest as to the agreement or transaction were disclosed to our board of directors. Our board of directors has taken this information into account when evaluating the transaction and in determining whether such transaction was fair to our company and in the best interest of all of our stockholders.

PRINCIPAL STOCKHOLDERS

The following table and footnotes set forth information regarding the beneficial ownership of our common stock as of June 30, 2021 and as adjusted to reflect the sale of the common stock offered by us under this prospectus by:

- each of our directors and named executive officers;
- all of our current directors and executive officers as a group; and
- each person who is known to us to beneficially own more than 5% of our common stock.

Except as otherwise noted, the address of each person listed in the table is c/o HCW Biologics Inc., 2929 N Commerce Parkway, Miramar, FL 33025. The table includes all shares of common stock issuable within 60 days of June 30, 2021 upon the exercise of options and other rights beneficially owned by the indicated stockholders on that date. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting and investment power with respect to shares. To our knowledge, except under applicable community property laws or as otherwise indicated, the persons named in the table have sole voting and sole investment control with respect to all shares beneficially owned. The applicable percentage of ownership for each stockholder is based on 28,724,020 shares of common stock outstanding as of most recent period above, together with applicable options for that stockholder. Shares of common stock issuable upon exercise of options and other rights beneficially owned were deemed outstanding for the purpose of computing the percentage ownership of the person holding these options and other rights, but are not deemed outstanding for computing the percentage ownership of any other person.

Certain of our directors and existing stockholders or their affiliates, including our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer and Vice President of Clinical Operations, have agreed to purchase an aggregate of approximately 1,480,625 shares of our common stock in this offering at the initial public offering price. The following table does not reflect any potential purchases by these parties.

	Shares Beneficially Owned Prior to the Offering		Shares Beneficially Owned After the Offering	
	Shares	%	Shares	%
5% or More Stockholders:				
Medmira Capital Ltd.(1)	3,587,661	12.5	3,587,661	10.5
DeepWork HCW Partners LLC(2)	2,671,831	9.3	2,671,831	7.8
Axone Ventures HCW LP(3)	1,904,762	6.6	1,904,762	5.5
Pacific Treasure Global Limited(4)	1,704,545	5.9	1,704,545	5.0
Fred A. Middleton(5)	1,430,843	5.0	1,430,843	4.2
Named Executive Officers and Directors:				
Hing C. Wong, Ph.D(6).	14,628,120	50.9	14,628,120	42.6
Peter Rhode, Ph.D(7)	34,285	*	34,285	*
Rebecca Byam(8)	27,000	*	27,000	*
Scott T. Garrett(9)	—	*	—	*
Rick S. Greene	—	*	—	*
All directors and executive officers as a group(10) (7 persons)	14,746,404	51.3	14,746,404	43.0

* Less than one percent of the outstanding shares of common stock.

(1) Peter Sun, Gang Li and Sean Hu are the managing members of Medmira Capital Ltd. and may be deemed the beneficial owners of the securities held by Medmira Capital Ltd. The business address of Medmira Capital Ltd. is Unit 38, 10/F Block D_Mai Tak Industry Building, No. 221 Wai Yip Street, Kwun Tong KLN, Hong Kong.

(2) DeepWork Capital, LLC is the managing entity of DeepWork HCW Partners LLC. Mitchel Laskey, Benjamin J. Patz and I-Ting Kathy Chiu are the managing members of DeepWork HCW Partners LLC and may be deemed the beneficial owner of the securities held by DeepWork HCW Partners LLC. The business address of DeepWork Capital, LLC is 1030 N. Orange Ave. Ste# 101, Orlando, Florida 32801.

(3) Axone HCW Operation LLC is the managing entity of Axone Ventures HCW LP. Fan Zhang has sole voting and investment power with respect to the common stock held by Axone Ventures HCW LP. Mr. Zhang may be deemed to beneficially own the shares held by Axone Ventures HCW LP. The business address of Axone HCW LP is 4340 Von Karman Avenue, Suite 250, Newport Beach, CA 92660. Axone Ventures HCW LP has agreed to purchase 437,500 shares of our common stock in the offering at the initial public offering price.

(4) Chor Woon Carol Yu and Lai Ching Tang are the managing members of Pacific Treasure Global Limited and may be deemed to beneficially own the shares held by Pacific Treasure Global Limited. The business address of Pacific Treasure Global Limited is Vistra Corporate Services Centre, Wickhams Cay II, Road Town, Tortola, VG1110, British Virgin Islands.

(5) Consists of (a) 428,571 shares of common stock held directly by Mr. Middleton and (b) 1,002,272 shares of common stock issuable upon the conversion of shares of the redeemable preferred stock held by Golden Triangle Ventures, LLC. Fred A. Middleton is the managing member of Golden Triangle Ventures, LLC and has sole voting and investment power with respect to the common stock held by Golden Triangle Ventures LLC. Mr. Middleton may be deemed to beneficially own the shares held by Golden Triangle Ventures, LLC. The business address of Golden Triangle Ventures, LLC is 1780 S. El Camino Real, Suite 203, San Mateo, California 94402.

(6) Consists of (a) 11,128,000 shares held directly by Dr. Hing C. Wong and (b) 3,500,119 shares held by Dr. Hing C. Wong and Ms. Bee Yau Huang. Dr. Wong and Ms. Huang have agreed to purchase 627,500 shares of our common stock in the offering at the initial public offering price.

(7) Dr. Rhode has agreed to purchase 12,500 shares of our common stock in the offering at the initial public offering price.

(8) Ms. Byam has agreed to purchase 25,000 shares of our common stock in the offering at the initial public offering price.

(9) An entity affiliated with Mr. Garrett has agreed to purchase 125,000 shares of our common stock in the offering at the initial public offering price.

(10) This group has agreed to purchase in the aggregate 821,250 shares of our common stock in the offering at the initial public offering price.

DESCRIPTION OF CAPITAL STOCK

Description of Capital Stock

The following is a description of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws as each will be in effect as of the completion of this offering, and of specific provisions of Delaware law. The following description is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation, our amended and restated bylaws and the Delaware General Corporation Law ("DGCL"). Copies of our amended and restated certificate of incorporation and amended and restated bylaws have been filed as exhibits to the registration statement of which this prospectus is a part.

General

Our authorized capital stock consists of 250,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of redeemable preferred stock, par value $0.0001 per share.

As of June 30, 2021, there were 28,724,020 shares of our common stock outstanding, held by 57 stockholders of record, and no shares of redeemable preferred stock outstanding, assuming the conversion of 23,768,420 outstanding shares of our redeemable preferred stock into shares of our common stock, which will occur upon the completion of this offering. Our board of directors is authorized, without stockholder approval except as required by the listing standards of Nasdaq, to issue additional shares of our capital stock.

Common Stock

Voting Rights

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

Dividends

Subject to preferences that may be applicable to any then outstanding redeemable preferred stock, holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by the board of directors out of legally available funds. For more information, see the section of this prospectus captioned "Dividend Policy."

Liquidation

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

Rights and Preferences

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

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued pursuant to this offering, when paid for, will be fully paid and nonassessable.

Preferred Stock

Our board of directors has the authority, without further action by the stockholders, to issue up to shares of redeemable preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences, and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of redeemable preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of redeemable preferred stock could have the effect of delaying, deferring or preventing change in our control or other corporate action. We have no present plan to issue any shares of redeemable preferred stock.

Options

As of June 30, 2021, we had outstanding options under the 2019 Plan to purchase an aggregate of 579,858 shares of our common stock, with a weighted-average exercise price of $0.16 per share.

Warrants

As of June 30, 2021, we had no outstanding warrants to purchase shares of our common stock.

Anti-Takeover Effects of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Our amended and restated certificate of incorporation and our amended and restated bylaws, which will be in effect upon the completion of this offering, will contain certain provisions that could have the effect of delaying, deterring or preventing another party from acquiring control of us. These provisions and certain provisions of Delaware law, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate more favorable terms with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us.

Undesignated Preferred Stock

As discussed above, our board of directors will have the ability to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Limits on Ability of Stockholders to Act by Written Consent or Call a Special Meeting

Our amended and restated certificate of incorporation will provide that our stockholders may not act by written consent, which may lengthen the amount of time required to take stockholder actions. As a result, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws.

In addition, our amended and restated bylaws will provide that special meetings of the stockholders may be called only by the chairperson of the board, the Chief Executive Officer or our board of directors. Stockholders may not call a special meeting, which may delay the ability of our stockholders to force consideration of a proposal or for holders controlling a majority of our capital stock to take any action, including the removal of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws will establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of our board of directors. These provisions may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Board Classification

Upon the closing of the offering, our board of directors will be divided into three classes, one class of which is elected each year by our stockholders. The directors in each class will serve three-year terms. For more information on the classified board, see "Management—Board of Directors." A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time-consuming for stockholders to replace a majority of the directors on a classified board.

No Cumulative Voting

Our amended and restated certificate of incorporation and amended and restated bylaws will not permit cumulative voting in the election of directors. Cumulative voting allows a stockholder to vote a portion or all of its shares for one or more candidates for seats on the board of directors. Without cumulative voting, a minority stockholder may not be able to gain as many seats on our board of directors as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board's decision regarding a takeover.

Amendment of Charter and Bylaws Provisions

The amendment of the above provisions of our amended and restated certificate of incorporation will require approval by holders of at least two-thirds of our outstanding capital stock entitled to vote generally in the election of directors. The amendment of our bylaws will require approval by the holders of at least two-thirds of our outstanding capital stock entitled to vote generally in the election of directors.

Choice of Forum

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, or employees to us or our stockholders; (3) any action asserting a claim against us or our stockholders arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce, or determine the validity of our certificate of incorporation or bylaws; (5) any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; or (6) any action asserting a claim governed by the internal affairs doctrine. The provisions would not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the U.S. federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

Delaware Anti-Takeover Statute

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

- prior to the date of the transaction, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, calculated as provided under Section 203; or
- at or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

The provisions of Delaware law and the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, as amended upon the completion of this offering, could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests.

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, NY 11219, and its telephone number is (718) 921-8124.

Listing

Our common stock has been approved for listing on the Nasdaq Global Market under the trading symbol "HCWB."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of certain contractual and legal restrictions on resale, sales of substantial amounts of our common stock in the public market after the restrictions lapse could adversely affect the prevailing market price and our ability to raise equity capital in the future.

Upon completion of the offering, we will have outstanding 35,650,520 shares of common stock (or 36,700,520 shares if the option to purchase additional shares is exercised in full). Of these shares, all of the shares sold in the offering (plus any shares issued upon exercise of the underwriters' option to purchase additional shares) will be freely tradable without restriction under the Securities Act, unless purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act, which generally includes officers, directors or 10% stockholders. The remaining shares outstanding are "restricted securities" within the meaning of Rule 144 under the Securities Act. These shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 promulgated under the Securities Act, which are summarized below. Sales of these shares in the public market, or the availability of such shares for sale, could adversely affect the market price of the common stock.

Our stockholders are subject to market stand-off provisions or lock-up agreements generally providing that they will not offer, sell, contract to sell or grant any option to purchase or otherwise dispose of our common stock or any securities exercisable for or convertible into our common stock owned by them for a period of 180 days after the date set forth on the cover page of this prospectus without the prior written consent of EF Hutton, division of Benchmark Investments, LLC, as representative of the underwriters. As a result of these contractual restrictions, notwithstanding possible earlier eligibility for sale under the provisions of Rules 144 and 701, shares subject to lock-up agreements will not be salable until such agreements expire or are waived by the underwriters' representative. Taking into account the market-standoff provisions and lock-up agreements, and assuming EF Hutton, division of Benchmark Investments, LLC, as representative of the underwriters, does not release stockholders from these agreements, the following shares will be eligible for sale in the public market at the following times:

- Beginning on the date on the cover page of this prospectus, only the shares sold in the offering will be immediately available for sale in the public market.
- Beginning on the 181st day after the date on the cover page of this prospectus, 28,650,520 additional shares will become eligible for sale in the public market, of which 18,323,780 shares will be held by affiliates and subject to volume and other restrictions of Rule 144, as described below.

In general, under Rule 144 as currently in effect, and beginning after the expiration of the lock-up agreements (180 days after the date on the cover page of this prospectus) of a person (or persons whose shares are aggregated) who has beneficially owned Restricted Shares for at least one year would be entitled to sell within any three-month period a number of shares that does not exceed the greater of: (i) one percent of the number of shares of common stock then outstanding (which will equal approximately 356,505 shares immediately after the offering, or 367,005 shares if the option to purchase additional shares is exercised in full); or (ii) the average weekly trading volume of the common stock during the four calendar weeks preceding the sale. Sales under Rule 144 are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us. Under Rule 144, a person who is not deemed to have been our affiliate at any time during the three months preceding a sale, and who has beneficially owned the shares proposed to be sold for at least one year, is entitled to sell such shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

As a result of the lock-up agreements, all of our employees holding common stock or stock options may not sell shares acquired upon exercise until the 181st day after the date on the cover page of this prospectus.

Beginning on the 181st day after the date on the cover page of this prospectus, any of our employees, officers, directors or consultants who purchased shares pursuant to a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701. Rule 701 permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. Rule 701 further provides that non-affiliates may sell such shares in reliance on Rule 144 without having to comply with the holding period, public information, volume limitation or notice provisions of Rule 144. In addition, we intend to file registration statements under the Securities Act as promptly as possible after the effective date to register shares to be issued pursuant to our employee benefit plans. As a result, any options exercised under the 2019 Plan or any other benefit plan after this offering will also be freely tradable in the public market, except that shares held by affiliates will still be subject to the volume limitation, manner of sale, notice, and public information requirements of Rule 144 unless otherwise resalable under Rule 701. As of March 31, 2021, there were outstanding options for the purchase of 653,355 shares, of which options 6,429 shares were exercisable. See “Risk Factors—Shares Eligible for Future Sale,” “Management—Stock Plans.”

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS

This section discusses the material U.S. federal income tax consequences of the ownership and sale, exchange or other taxable disposition of our common stock sold pursuant to this offering to a "non-U.S. holder" (as defined below). This discussion does not provide a complete analysis of all potential tax considerations. The information provided below is based upon provisions of the Internal Revenue Code of 1986, as amended (the "Code"), Treasury regulations promulgated thereunder, administrative rulings, and judicial decisions currently in effect. These authorities may change at any time, possibly on a retroactive basis, or the Internal Revenue Service (the "IRS"), might interpret the existing authorities differently. In either case, the U.S. federal income tax considerations of owning or disposing of our common stock could differ from those described below. As a result, we cannot assure you that the U.S. federal income tax considerations described in this discussion will not be challenged by the IRS or will be sustained by a court if challenged by the IRS.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address the tax considerations arising under the alternative minimum tax, the net investment income tax, the laws of any state, local or non-U.S. jurisdiction, or under U.S. federal gift and estate tax laws. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions;
- partnerships or entities or arrangements treated as partnerships or other pass-through entities for U.S. federal income tax purposes (or investors in such entities);
- corporations that accumulate earnings to avoid U.S. federal income tax;
- tax-exempt or governmental organizations or tax-qualified retirement plans;
- real estate investment trusts or regulated investment companies;
- controlled foreign corporations or passive foreign investment companies;
- persons who acquired our common stock pursuant to the exercise of an employee stock option or otherwise as compensation for services;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);
- certain former citizens or long-term residents of the United States;
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction; or
- persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes is a beneficial owner of our common stock, the tax treatment of a partner in the partnership or an owner of the entity will depend upon the status of the partner or owner and the activities of the partnership or entity. Accordingly, this discussion does not address U.S. federal income tax considerations applicable to partnerships that hold our common stock, and partners in such partnerships should consult their tax advisors.

Investors considering the purchase of our common stock should consult their own tax advisors regarding the application of the U.S. federal income, gift, and estate tax laws to their particular situations and the consequences of non-U.S., state or local laws, and tax treaties.

Non-U.S. Holder Defined

For purposes of this section, a "non-U.S. holder" is any holder of our common stock that is not a "U.S. person" or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States for U.S. federal income tax purposes;
- a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized under the laws of the United States, any state therein or the District of Columbia or otherwise treated as such for U.S. federal income tax purposes;
- a trust that (1) is subject to the primary supervision of a U.S. court and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable Treasury regulations to be treated as a U.S. person; or
- an estate whose income is subject to U.S. federal income tax regardless of source.

Distributions

We do not anticipate making any distributions on shares of our common stock in the foreseeable future. If we do make any distributions on shares of our common stock, however, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a non-U.S. holder's adjusted tax basis in shares of our common stock. Any remaining excess will be treated as gain realized on the sale, exchange or other taxable disposition of our common stock. See "Material U.S. Federal Income Tax Considerations for Non-U.S. Holders—Sale of Common Stock."

Subject to the discussion below regarding the Foreign Account Tax Compliance Act ("FATCA"), and backup withholding, any distribution made to a non-U.S. holder on our common stock that is not effectively connected with a non-U.S. holder's conduct of a trade or business in the United States will generally be subject to U.S. withholding tax at a 30% rate. The withholding tax might not apply, however, or might apply at a reduced rate, under the terms of an applicable income tax treaty between the United States and the non-U.S. holder's country of residence. You should consult your tax advisors regarding your entitlement to benefits under a relevant income tax treaty. Generally, in order for us or our paying agent to withhold U.S. tax at a lower treaty rate, a non-U.S. holder must certify its entitlement to treaty benefits. A non-U.S. holder generally can meet this certification requirement by providing an IRS Form W-8BEN, W-8BEN-E (or any successor form to the IRS Form W-8BEN or W-8BEN-E) to us or our paying agent. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent. The non-U.S. holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you may obtain a refund or credit from the IRS of any excess amounts withheld by filing an appropriate claim for a refund with the IRS in a timely manner.

Distributions received by a non-U.S. holder that are effectively connected with a U.S. trade or business conducted by the non-U.S. holder, and, if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, are attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States, are not subject to the 30% U.S. withholding tax. To obtain this exemption, a non-U.S. holder must provide us with an IRS Form W-8ECI properly certifying such exemption. Such effectively connected distributions, although not subject to U.S. withholding tax, are generally taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition to

the graduated tax described above, distributions received by corporate non-U.S. holders that are effectively connected with a U.S. trade or business of the corporate non-U.S. holder may also be subject to a "branch profits tax" equal to 30% of its effectively connected earnings and profits for the taxable year, as adjusted for certain items, although an applicable income tax treaty between the United States and the non-U.S. holder's country of residence might provide for a lower rate.

Sale of Common Stock

Subject to the discussion below regarding FATCA and backup withholding, non-U.S. holders will generally not be subject to U.S. federal income tax on any gains realized on the sale, exchange or other taxable disposition of our common stock unless:

- the gain (1) is effectively connected with the conduct by the non-U.S. holder of a U.S. trade or business and (2) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment (or, in the case of an individual, a fixed base) maintained by the non-U.S. holder in the United States (in which case the special rules described below apply);
- the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of the sale, exchange or other taxable disposition of our common stock, and certain other requirements are met (in which case the gain would be subject to a flat 30% tax, or such reduced rate as may be specified by an applicable income tax treaty, which may be offset by certain U.S.-source capital losses, even though the individual is not considered a resident of the United States, provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses); or
- the rules of the Foreign Investment in Real Property Tax Act ("FIRPTA"), treat the gain as effectively connected with a U.S. trade or business.

The FIRPTA rules may apply to a sale, exchange or other taxable disposition of our common stock if we are at the time of the sale, exchange, or other taxable disposition, or were within the shorter of the five-year period preceding the disposition and the non-U.S. holder's holding period, a "United States real property holding corporation," or USRPHC. In general, we would be a USRPHC if the fair market value of our "U.S. real property interests" comprised at least half of the fair market value of our business assets and our U.S. and non-U.S. real property interests. If we are or become a USRPHC, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as "U.S. real property interests" subject to the FIRPTA rules only if a non-U.S. holder actually owns or constructively holds more than 5% of our outstanding common stock at any time within the shorter of the five-year period preceding the disposition and the non-U.S. holder's holding period. Currently, we believe we are not, and do not anticipate becoming, a USRPHC.

If any gain from the sale, exchange or other taxable disposition of our common stock (1) is effectively connected with a U.S. trade or business conducted by a non-U.S. holder and, (2) if required by an applicable income tax treaty between the United States and the non-U.S. holder's country of residence, is attributable to a permanent establishment (or, in the case of an individual, a fixed base) maintained by such non-U.S. holder in the United States, then the gain generally will be subject to U.S. federal income tax at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. If the non-U.S. holder is a corporation, under certain circumstances, that portion of its earnings and profits that is effectively connected with its U.S. trade or business, subject to certain adjustments, generally would be subject to a "branch profits tax." The branch profits tax rate is equal to 30% of its effectively connected earnings and profits for the taxable year, as adjusted for certain items, although an applicable income tax treaty between the United States and the non-U.S. holder's country of residence might provide for a lower rate.

Backup Withholding and Information Reporting

Payments of dividends on our common stock will not be subject to backup withholding, provided the non-U.S. holder certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI (and we or our paying agent do not have actual knowledge or reason to know the holder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied), or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the non-U.S. holder, regardless of whether any tax was actually withheld. Copies of these reports may be made available to tax authorities in the country where the non-U.S. holder resides. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above or the non-U.S. holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting. The backup withholding rate is currently 24%.

Backup withholding is not an additional tax. Any amounts withheld from a payment to a holder of our common stock under the backup withholding rules can be credited against any U.S. federal income tax liability of the holder and may entitle the holder to a refund from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance Act ("FATCA")

FATCA imposes U.S. federal withholding tax of 30% on certain types of U.S. source "withholdable payments" (including dividends and the gross proceeds from the sale, exchange or other taxable disposition of U.S. stock) to "foreign financial institutions", which are broadly defined for this purpose, and other non-U.S. entities in connection with the failure to comply with certain certification and information reporting requirements regarding U.S. account holders or owners of such institutions or entities. The obligation to withhold under FATCA applies to any dividends on our common stock. While withholding under FATCA would have applied also to gross proceeds from the sale, exchange or other taxable disposition of our common stock paid after December 31, 2018 and to certain "passthru" payments received with respect to instruments held through foreign financial institutions after the date on which applicable final Treasury regulations are issued, recently proposed Treasury regulations eliminate FATCA withholding on payments of gross proceeds entirely and limit FATCA withholding on these "passthru" payments to those payments made two years after the date on which applicable final Treasury regulations are issued. Taxpayers generally may rely on these proposed Treasury regulations until final Treasury regulations are issued. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

The preceding discussion of U.S. federal income tax considerations is for general information only. It is not tax advice. Each prospective investor should consult its own tax advisor regarding the particular U.S. federal, state, local, and non-U.S. tax consequences of the sale, exchange or other taxable disposition of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

EF Hutton, division of Benchmark Investments, LLC (the "Representative") is acting as representative of the underwriters of the offering. We have entered into an underwriting agreement with the Representative (the "underwriting agreement"). Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the initial public offering price per share less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

	Number of Shares
EF Hutton, division of Benchmark Investments, LLC	4,687,500
Joseph Gunnar & Co. LLC	1,250,000
Revere Securities LLC	625,000
WestPark Capital, Inc.	437,500
Total	7,000,000

The underwriters are committed to purchase all of the shares of common stock offered by us, other than those covered by the over-allotment option to purchase additional shares of common stock described below, if they purchase any shares. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations, and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares of common stock subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public, and to reject orders in whole or in part.

Over-Allotment Option

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase up to an aggregate of additional shares of common stock (equal to 15% of the common stock sold in the offering) at the initial public offering price per share, less underwriting discounts and commissions, solely to cover over-allotments, if any. The purchase price to be paid per additional share of common stock shall be equal to the initial public offering price of one share, less the underwriting discount. If this option is exercised in full, the total price to the public will be $8,400,000 and the total net proceeds, before expenses, to us will be $7,812,000.

Discounts, Commissions, and Reimbursement

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

		Total	
	Per Share	Without Option	With Option
Initial public offering price	$ 8.00	$ 56,000,000	$ 64,400,000
Underwriting discounts and commissions (7%)	$ 0.56	$ 3,920,000	$ 4,508,000
Proceeds, before expenses, to us	$ 7.44	$ 52,080,000	$ 59,892,000

The underwriters propose to offer the shares to the public at the initial public offering price set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares to other securities dealers at such price less a concession of $0.28 per share. If all of the shares offered by us are not sold at the initial public offering price, the Representative may change the offering price and other selling terms by means of a supplement to this prospectus.

We have also agreed to pay all expenses relating to the offering, including: (a) all filing fees and expenses relating to the registration of the shares with the Commission; (b) all fees and expenses relating to the listing of the shares on Nasdaq; (c) all fees associated with the review of the offering by FINRA; (d) all fees, expenses and disbursements relating to the registration, qualification or exemption of shares offered under "blue sky" securities laws or the securities laws of foreign jurisdictions designated by the Representative, including the reasonable fees and expenses of the Representative's blue sky counsel; (e) all fees, expenses and disbursements relating to the registration, qualification or exemption of the shares under the securities laws of such foreign jurisdictions; (f) the costs of mailing and printing the offering materials; (g) transfer and/or stamp taxes, if any, payable upon our transfer of the shares to the Representative; and (h) the fees and expenses of our accountants; and (i) actual accountable expenses of the Representative not to exceed $150,000, which amount includes expenses for the Representative's legal counsel and road show expenses. We will also pay to the representative by deduction from the net proceeds of this offering, a non-accountable expense allowance equal to 0.35% of the gross proceeds received by us from the sale of our shares of common stock, exclusive of any shares that may be issued pursuant to exercise of the underwriters' over-allotment option.

We have paid a $100,000 advance to the Representative, which shall be applied against actual out-of-pocket-accountable expenses, which will be returned to us to the extent such out-of-pocket accountable expenses are not actually incurred in accordance with FINRA Rule 5110(f)(2)(C).

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount, and including the above-referenced advance to the Representative, will be approximately $4.6 million.

Pricing of the Offering

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters considered a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for the shares of our common stock, or that the shares will trade in the public market at or above the initial public offering price.

Discretionary Accounts

The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements

Our executive officers and directors, and certain of our stockholders have agreed not to, without the prior written consent of the Representative, directly or indirectly, offer to sell, sell, pledge or otherwise transfer or dispose of any of shares of our common stock (or enter into any transaction or device that is designed to, or could be expected to, result in the transfer or disposition by any person at any time in the future of our common stock, enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of our common stock, make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible into or exercisable or exchangeable for shares of common stock or any other of our securities or publicly disclose the intention to do any of the foregoing, subject to customary exceptions, for a period of 180 days from the date of this prospectus.

No Sales of Similar Securities

We have agreed not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our shares of common stock, whether any such transaction is to be settled by delivery of shares of common stock or such other securities, in cash or otherwise, without the prior written consent of the Representative, for a period of 360 days from the date of this prospectus.

Electronic Offer, Sale, and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members. The Representative may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us, and should not be relied upon by investors.

Listing

Our common stock has been approved for listing on the Nasdaq Global Market under the symbol “HCWB.”

Stabilization

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids, and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase securities so long as the stabilizing bids do not exceed a specified maximum and are engaged in for the purpose of preventing or retarding a decline in the market price of the securities while the offering is in progress.
- Over-allotment transactions involve sales by the underwriters of securities in excess of the number of securities the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of securities over-allotted by the underwriters is not greater than the number of securities that they may purchase in the over-allotment option. In a naked short position, the number of securities involved is greater than the number of securities in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing securities in the open market.

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of securities available for purchase in the open market as compared with the price at which they may purchase securities through exercise of the over-allotment option. If the underwriters sell more securities than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permit the Representative to reclaim a selling concession from a syndicate member when the securities originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, over-allotment transactions, syndicate covering transactions, and penalty bids may have the effect of raising or maintaining the market price of our securities or preventing or retarding a decline in the market price of our securities. As a result, the price of our securities in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our securities. These transactions may be effected on the Nasdaq Stock Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, underwriters, and selling group members may engage in passive market making transactions in our securities on Nasdaq in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker’s bid, then that bid must then be lowered when specified purchase limits are exceeded.

Offer Restrictions Outside the United States

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

Australia

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more

exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

Canada

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

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

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

China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (the "PRC") (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region, and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

European Economic Area — Belgium, Germany, Luxembourg and Netherlands

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements), and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);

- to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of our Company or any underwriter for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by our Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

France

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code monétaire et financier) and Articles 211-1, et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales, and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs non-qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1 and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

Israel

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the "ISA"), nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

Italy

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Societá e la Borsa, "CONSOB") pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

- to Italian qualified investors, as defined in Article 100 of Decree No. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ("Regulation no. 11971") as amended ("Qualified Investors"); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007, and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

Japan

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the "FIEL"), pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales, and distributions of securities in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

Switzerland

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

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority.

This document is personal to the recipient only and not for general circulation in Switzerland.

United Arab Emirates

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor have we received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by our Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

United Kingdom

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA")) has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to "qualified investors" (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to our company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the common stock offered hereby will be passed upon for us by Orrick, Herrington & Sutcliffe LLP, 405 Howard Street, San Francisco, California 94105. Certain legal matters in connection with this offering will be passed upon for the underwriters by Sheppard, Mullin, Richter & Hampton LLP.

EXPERTS

The audited financial statements included in this prospectus and elsewhere in the registration statement have been so included in reliance upon the report of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock covered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains an internet website that contains reports, proxy statements, and other information about issuers like us that file electronically with the SEC. The address of that website is www.sec.gov.

Upon the completion of this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy statements, and other information with the SEC. These periodic reports, proxy statements, and other information will be available for inspection and copying at the website of the SEC referred to above. We also maintain a website at https://hcwbiologics.com. Upon the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

HCW Biologics Inc.
Index to Financial Statements

Audited financial statements as of and for the years ended December 31, 2019 and December 31, 2020

Unaudited condensed interim financial statements as of and for the three months ended March 31, 2020 and March 31, 2021

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
HCW Biologics Inc.

Opinion on the financial statements

We have audited the accompanying balance sheets of HCW Biologics Inc. (a Delaware corporation) (the "Company") as of December 31, 2020 and 2019, the related statements of operations, changes in redeemable preferred stock and stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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 audits. 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 audits 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 audits 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2019.

Miami, Florida
April 16, 2021, except for reverse stock split described in Note 15 as to which the date is July 6, 2021

HCW BIOLOGICS INC.
Balance Sheets

	December 31, 2019	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,355,834	$ 8,455,834
Accounts receivable	—	2,500,000
Prepaid expenses	438,036	538,306
Other current assets	236,286	654,528
Total current assets	8,030,156	12,148,668
Investment	—	1,599,750
Property and equipment, net	2,001,613	1,615,426
Other assets	34,242	34,242
Total assets	$ 10,066,011	$ 15,398,086
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Liabilities		
Current liabilities:		
Accounts payable	$ 392,331	$ 155,343
Accrued liabilities and other liabilities	673,813	845,741
Total current liabilities	1,066,144	1,001,084
Commitments and contingencies (Note 14)		
Redeemable preferred stock:		
Series A, $0.0001 par value; 14,738,948 shares authorized and 6,316,691 issued at December 31, 2019; 14,738,948 shares authorized and 6,316,691 issued at December 31, 2020	5,792,302	6,140,792
Series B, $0.0001 par value; 34,261,053 shares authorized and 12,012,617 shares issued at December 31, 2019; 28,029,449 shares authorized and 12,012,617 issued at December 31, 2020	12,883,859	13,680,306
Series C, $0.0001 par value; nil shares authorized and issued at December 31, 2019; 18,181,818 shares authorized and 5,439,112 shares issued at December 31, 2020	—	11,294,301
Total redeemable preferred stock	18,676,161	31,115,399
Stockholders' deficit:		
Common stock:		
Class B convertible, $0.0001 par value; 10,000,000 shares authorized and 4,285,714 issued at December 31, 2019; 10,000,000 shares authorized and 4,285,714 issued at December 31, 2020	429	429
Class A, $0.0001 par value; 52,000,000 shares authorized and 431,828 shares issued at December 31, 2019; 74,950,215 shares authorized and 507,680 shares issued at December 31, 2020	43	51
Additional paid-in capital	—	—
Accumulated deficit	(9,676,766)	(16,718,877)
Total stockholders' deficit	(9,676,294)	(16,718,397)
Total liabilities, redeemable preferred stock and stockholders' deficit	$ 10,066,011	$ 15,398,086

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

HCW BIOLOGICS INC.
Statements of Operations

	For the Year Ended December 31,	
	2019	**2020**
Revenues:		
Revenues	$ —	$ 4,099,750
Total revenues	—	4,099,750
Operating expenses:		
Research and development	5,390,757	7,255,227
General and administrative	1,974,517	2,669,048
Total operating expenses	7,365,274	9,924,275
Loss from operations	(7,365,274)	(5,824,525)
Interest and other income, net	72,353	22,324
Net loss	$ (7,292,921)	$ (5,802,201)
Less: cumulative preferred dividends earned in the period	(489,610)	(1,271,675)
Net loss available for distribution to common stockholders	$ (7,782,531)	$ (7,073,876)
Net loss per share, basic and diluted	$ (1.82)	$ (1.49)
Weighted average shares outstanding, basic and diluted	4,286,528	4,739,285

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

HCW BIOLOGICS INC.
Statements of Changes in Redeemable Preferred Stock and Stockholders' Deficit

	Redeemable Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Paid-In Capital	Deficit	Deficit
Balance, December 31, 2018	5,413,714	$4,800,160	—	$ —	—	$ —	4,285,714	$ 429	$ 2,800	$ (1,958,987)	$ (1,955,815)
Issuance of Series A Preferred Stock at $0.38 per share for cash	902,977	800,640	—	—	—	—	—	—	—	—	—
Issuance of Series B Preferred Stock at $0.45 per share for cash, net of issuance costs of ($ 27,501)	—	—	12,012,617	12,585,751	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	3,257	—	289	—	289
Issuance of Class A Common Stock at $.06 per share for cash	—	—	—	—	—	—	428,571	43	59,900	—	60,000
Stock-based compensation	—	—	—	—	—	—	—	—	1,763	—	1,763
6% cumulative dividends on redeemable preferred stock	—	191,502	—	298,108	—	—	—	—	(64,752)	(424,858)	(489,610)
Net loss	—	—	—	—	—	—	—	—	—	(7,292,921)	(7,292,921)
Balance, December 31, 2019	**6,316,691**	**$5,792,302**	**12,012,617**	**$12,883,859**	**—**	**$ —**	**4,717,542**	**$ 472**	**$ —**	**$ (9,676,766)**	**$ (9,676,294)**

	Redeemable Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Paid-In Capital	Deficit	Deficit
Balance, December 31, 2019	6,316,691	$5,792,302	12,012,617	$12,883,859	—	$ —	4,717,542	$ 472	$ —	$ (9,676,766)	$ (9,676,294)
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	75,852	8	9,880		9,898
Issuance of Series C Preferred Stock at $0.88 per share for cash, net of issuance costs of ($ 23,799)	—	—	—	—	5,439,112	11,144,520	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	21,875	—	21,875
6% cumulative dividends on redeemable preferred stock	—	348,490	—	776,804	—	146,381	—	—	(31,755)	(1,239,920)	(1,271,675)
Accretion of issuance costs	—	—	—	19,643	—	3,400	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(5,802,201)	(5,802,201)
Balance, December 31, 2020	**6,316,691**	**$6,140,792**	**12,012,617**	**$13,680,306**	**5,439,112**	**$11,294,301**	**4,793,394**	**$ 480**	**$ —**	**$ (16,718,877)**	**$ (16,718,397)**

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

HCW BIOLOGICS INC.
Statements of Cash Flows

	Years Ended December 31,	
	2019	**2020**
Cash flows from operating activities:		
Net loss	$ (7,292,921)	$ (5,802,201)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	421,817	595,911
Stock-based compensation	1,763	21,875
Changes in operating assets and liabilities:		
Accounts receivable	—	(2,500,000)
Prepaid expenses and other assets	(662,221)	(2,118,264)
Accounts payable and other liabilities	766,394	(628,647)
Net cash used in operating activities	(6,765,168)	(10,431,326)
Cash flows from investing activities:		
Purchases of property and equipment	(1,460,255)	(186,682)
Payment for security deposits	164	—
Net cash used in investing activities	(1,460,091)	(186,682)
Cash flows from financing activities:		
Proceeds from PPP loan	—	563,590
Proceeds from issuance of preferred stock, net	13,386,391	11,144,520
Proceeds from issuance of common stock	60,289	9,898
Net cash provided by financing activities	13,446,680	11,718,008
Net changes in cash and cash equivalents	5,221,421	1,100,000
Cash and cash equivalents at the beginning of the period	2,134,413	7,355,834
Cash and cash equivalents at the end of the period	$ 7,355,834	$ 8,455,834
Non-cash operating, investing, and financing activities:		
In-kind payment for license fee	$ —	$ 1,599,750
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 19,458	$ —
Cumulative dividends earned and accrued in the reporting period	$ 489,610	$ 1,271,675

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

HCW BIOLOGICS INC.
Notes to the Financial Statements
December 31, 2019 and 2020

1. Organization and Summary of Significant Accounting Policies

Organization

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

Liquidity

Through December 31, 2020, the Company generated $4.1 million in revenue resulting from the Exclusive Worldwide License Agreement with Wugen Inc. ("Wugen License") signed on December 24, 2020. The Company had not generated any other revenue since inception. In the course of its development activities, the Company has sustained operating losses and expects to continue to incur operating losses for the foreseeable future. Since inception, substantially all the Company's activities have consisted of research, development, establishing large-scale cGMP production for clinical trials, and raising capital.

As of December 31, 2020, the Company had cash and cash equivalents of $8.5 million, excluding the $2.5 million reflected in Accounts receivable in the accompanying balance sheet. Since inception to December 31, 2020, the Company incurred cumulative net losses of $15.1 million. Management expects to incur additional losses in the future to conduct product research and development and acknowledges the need to raise additional capital to fully implement its business plan.

During the year ended December 31, 2019, the Company completed private placements in which the founder purchased Series A Preferred Stock, and the founder and other unrelated investors purchased Series B Preferred Stock. In addition, the Company sold Class A Common Stock at fair value. As a result of these transactions, the Company issued 2,106,948 shares of Series A Preferred Stock at $0.38 per share, 28,029,449 shares of Series B Preferred Stock at $0.45 per share, and 1,000,000 shares of Class A Common Stock at $0.06 per share. Gross proceeds from these private placements were $13.5 million. During the year ended December 31, 2020, the Company completed a private placement in which the founder and other unrelated investors purchased Series C Preferred Stock. The Company issued 12,691,270 shares of Series C Preferred Stock at $0.88 per share. Gross proceeds from this private placement were $11.2 million.

The Company intends to raise capital through additional equity financing, licenses with third parties which grant rights to the Company's proprietary molecules, co-development arrangements, and collaboration funding. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of some of its products. The Company expects that its cash and cash equivalents as of December 31, 2020, combined with the proceeds it received in 2020 from a forgivable government loan, as discussed in Note 6, will be sufficient to fund operating expenses and capital expenditure requirements for a period of at least one year from the issuance date of the financial statements.

Management's evaluation was based on relevant conditions, considered in the aggregate, and events that were known and reasonably knowable at the date that the financial statements were issued.

HCW BIOLOGICS INC.
Notes to the Financial Statements
December 31, 2019 and 2020

Summary of Significant Accounting Policies

Basis of Presentation

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

Segment Reporting

The Company has one operating segment. The Company's chief operating decision maker, its Chief Executive Officer, reviews financial information on an aggregate basis for allocating capital and evaluating performance.

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. Areas in which estimates are used in the preparation of financial statements include, but are not limited to, stock-based compensation expense, fair value of options, fair value of Class A Common Stock, and income tax uncertainties. 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.

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. Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 820, *Fair Value Measurement* ("Topic 820"), establishes a fair value hierarchy for those instruments measured at fair value that distinguishes between fair value measurements based on market data (observable inputs) and those based on the Company's own assumptions (unobservable inputs). This hierarchy maximizes the use of observable inputs and minimizes the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

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

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

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

Fair value measurements are classified based on the lowest level of input that is significant to the measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, which may affect the valuation of the assets and liabilities and their placement within the fair value hierarchy levels. The determination of the fair values, 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.

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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 investment. 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, 2020, all of the Company's revenue was entirely derived from the Wugen License. As of December 31, 2020, the Company holds an investment in Wugen Inc. ("Wugen") as reported in Investment and a receivable for the sale of non-financial assets to Wugen as reported in Accounts receivable.

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. 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.

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a pandemic, which continues to spread throughout the United States and the world. The spread of COVID-19 has caused significant volatility in the U.S. and international markets. There is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the U.S. and international economies and, as such, the Company is unable to determine if it will have a material impact to its operations. The ongoing COVID-19 pandemic has severely impacted many local economies around the globe. In many jurisdictions, organizations, and businesses have been forced to cease or limit operation for long or indefinite periods of time. Measure taken to contain the spread of the virus, including travel bans, quarantines, social distancing, and closures of non-essential services, have triggered significant disruptions to organizations worldwide, resulting in an economic slowdown. Global stock markets have also experienced great volatility and a significant weakening. Governments and central banks have responded with monetary and fiscal interventions to stabilize economic conditions. The duration and impact of the COVID-19 pandemic, as well as the effectiveness of government and central bank responses, remains unclear at this time. It is not possible to reliably estimate the duration and severity of these consequences, as well as their impact on the financial position and results of the Company for future periods. The Company has not experienced any significant business interruptions or losses related to the COVID-19 pandemic.

Property and Equipment, Net

Property and equipment is stated at cost less accumulated depreciation. Depreciation expense is calculated using the straight-line method over the estimated useful lives of the assets, which range from 3 to 7 years. 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. Upon retirement or sale of the assets, the cost and related accumulated depreciation and amortization are removed from the accompanying balance sheets and the resulting gain or loss is recorded to the statements of operations. Repairs and maintenance 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 loss 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. Impairment losses, if any, are recognized in earnings. There were no impairment losses for any of the periods presented.

Redeemable Preferred Stock

The Company applies the relevant accounting standards to distinguish liabilities from equity when assessing the classification and measurement of preferred stock. Preferred Stock subject to mandatory redemptions would be considered liabilities and measured at fair value. Conditionally redeemable preferred stock issued by the Company is considered mezzanine or temporary equity and is presented outside of the equity section of the accompanying balance sheets.

Cumulative Dividends on Preferred Stock

The Company's Preferred Stock earns a 6% cumulative dividend that compounds annually, whether or not declared by the Board of Directors. The Company considers cumulative dividends a legal obligation that should be recognized and accrued until such time as the dividends are declared and paid or liquidation occurs.

If Preferred Stock is classified as other than equity, this obligation will be presented within Redeemable preferred stock. If Preferred Stock is included within equity, this obligation will be treated as a long-term liability and presented within other liabilities in the accompanying balance sheet. As of December 31, 2019, and 2020, all of the Company's Preferred Stock is classified as other than equity, or mezzanine equity. Holders of Preferred Stock began to earn cumulative dividends on June 7, 2019, with the original issuance of Series B Preferred Stock. During the period from June 7, 2019 through December 31, 2019, Series A Preferred Stock, earned $191,502 in cumulative dividends; and Series B Preferred Stock earned $298,108 in cumulative dividends. During the year ended December 31, 2020, Series A Preferred Stock earned $348,490 in cumulative dividends; Series B Preferred Stock earned $776,804 in cumulative dividends; and Series C Preferred Stock earned $146,381 in cumulative dividends. No dividends were declared as of December 31, 2019 and 2020.

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 recognizes revenue when its customer or collaborator obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for

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those goods or services. To determine revenue recognition for arrangements that are within the scope of Topic 606, it 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 within the contract; and
v. recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of Topic 606 and it is probable of collection, the Company assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the Company's arrangements may consist of a license, or options to license, the Company's intellectual property and research, development, and manufacturing services. The Company may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

The Company determines the transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company then allocates the transaction price to each performance obligation based on the relative standalone selling price and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded as deferred revenue.

Amounts received prior to satisfying a performance obligation are recognized as deferred revenue in the Company's accompanying balance sheet. Deferred revenues expected to be recognized as revenue within the 12 months following the balance sheet date are classified as a current liability. Deferred revenues not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as non-current liabilities.

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During the year ended December 31, 2020, the entirety of the Company's revenues are related to the Wugen License. See Note 7 for further details regarding the Wugen License. Accounts receivables under the terms of the Wugen License are unsecured. Accordingly, the Company may be exposed to credit risk generally associated specific to the Wugen License. An allowance on the receivables will be recorded if circumstances indicate collection is doubtful for a particular receivables balance. To date, the Company has not experienced any losses related to these receivables.

Investment

The Company holds a minority interest in Wugen. The Company does not have significant influence over the operating and financial policies of Wugen. As a result, the Company has accounted for this investment using the measurement alternative whereby the investment is recorded at cost less impairment, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same investee. No impairment was recognized in the year ended December 31, 2020.

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 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. 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.

Patent Costs

Costs related to filing and pursuing patent applications are recorded as general and administrative expenses in the accompanying 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 accompanying statements of operations based on the function to which the related services are provided. Forfeitures are accounted for as they occur. 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. Because the Company's employee stock options have characteristics significantly different from those of publicly-traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models may not provide a reliable single measure of the fair value of the Company's employee stock options. 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 options that have service-based vesting, the Company expenses the fair value of the award on a straight-line basis over the requisite vesting period. For options that vest upon the achievement of performance milestones, the Company estimates the vesting period based on the evaluation of the probability of achievement of each respective milestone and the related estimated date of achievement. Stock-based compensation charges are non-cash charges and as such have no impact on the reported cash flows.

Deferred Offering Costs

The Company defers offering costs consisting of legal, accounting and other fees and costs directly attributable to its initial public offering ("IPO"). The deferred offering costs will be offset against the proceeds received upon the completion of the IPO. Deferred offering costs will be recorded under other non-current assets on the accompanying balance sheets. In the event the IPO is terminated, all of the deferred offering costs will be expensed within the Company's statements of operations. As of December 31, 2020 and 2019, there were no deferred offering costs recorded on the Company's balance sheets.

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 sheet.

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 loss 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.

Tax Credit Receivable

The Company is 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. The Company has applied approximately $239,000 and $250,000 of research and development credits to offset its federal payroll tax expenses for the years ended December 31, 2019 and 2020, respectively, due to its small business status. The remaining amounts for the years ended December 31, 2019 and 2020 are recorded 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 available for distribution to common stockholders, including both Class A and Class B Common Stock, by the 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 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"), 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.

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Recently Issued Accounting Pronouncements

In June 2016, FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments*, as clarified in subsequent amendments to the initial guidance (collectively, "Topic 326"). Topic 326 requires measurement and recognition of expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecast. The Company adopted Topic 326 using a modified retrospective approach which requires a cumulative effect adjustment as of the beginning of the reporting period in which the guidance is adopted. Topic 326 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company adopted Topic 326 effective January 1, 2020. The adoption did not have a material impact on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("Topic 842"), which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. For public entities, Topic 842 is effective for fiscal years beginning after December 15, 2018. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. Topic 842 is effective for the Company in the fiscal years beginning after December 15, 2020, with early adoption permitted. The Company is currently in the process of evaluating the impact of the adoption of Topic 842 on the Company's financial statements.

2. Property and Equipment, Net

Property and equipment, net consists of the following:

	At December 31,	
	2019	2020
Laboratory equipment	$ 1,770,144	$ 1,924,596
Office equipment	131,142	152,003
Furniture and fixtures	286,300	292,866
Leasehold improvements	345,174	349,976
	$ 2,532,760	$ 2,719,441
Less: Accumulated depreciation and amortization	(531,147)	(1,104,015)
Property and equipment, net	$ 2,001,613	$ 1,615,426

Depreciation and amortization expense for the year ended December 31, 2019 was $421,817 of which $250,399 is included in research and development expenses. Depreciation and amortization expense for the year ended December 31, 2020 was $572,867, of which $362,892 is included in research and development expenses.

3. Fair Value of Financial Instruments

The carrying amount of the Company's financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short-term maturities.

Money market funds included in cash and cash equivalents that are measured at fair value based on quoted prices that are derived from observable market data are classified as Level 1 inputs. No transfers between levels

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occurred during the periods presented. The following table presents the Company's assets which were measured at fair value at December 31, 2019 and 2020:

	At December 31, 2019:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 5,048,421	$ —	$ —	$ 5,048,421
Total	$ 5,048,421	$ —	$ —	$ 5,048,421

	At December 31, 2020:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 6,752,266	$ —	$ —	$ 6,752,266
Investment (Note 4):	—	—	1,599,750	1,599,750
Total	$ 6,752,266	$ —	$ 1,599,750	$ 8,352,016

4. Investment

In December 2020, the Company entered into an exclusive worldwide license agreement with Wugen, (the "Wugen License") for limited rights to develop, manufacture and commercialize cellular therapy products based on two of the Company's fusion protein molecules. As part of the consideration received for the Wugen License, the Company received shares of Wugen common stock, which was recognized at $1.6 million, the fair value of the securities as of December 24, 2020, the effective date for the Wugen License. This investment is valued using level 3 inputs, since there was no public market on which to trade these shares from the time they were received and through December 31, 2020. The fair value was determined based primarily on the pricing and terms of a recent third-party financing completed by Wugen. So long as there continues to be no public market for these securities, the Company will classify this asset as a Level 3 cost method investment.

5. Related Party Transactions

The Company was founded by Dr. Hing C. Wong, PhD., who was the sole investor and sole member of the Board of Directors as of December 31, 2018. Dr. Wong holds all Class B Common Stock and all Series A Preferred Stock issued by the Company. Each share of Class B Common Stock is convertible into one fully paid share of Class A Common Stock at the option of the holder. Conversion will occur automatically upon certain events, such as: (a) an IPO in which all shares of preferred stock convert to Class A Common Stock; (b) the resignation of Dr. Wong; or (c) the sale of the Company. He also participated in the Series C Preferred Stock financing which occurred in 2020 and the Series B Preferred Stock financing which occurred in 2019, on the same terms as third-party investors.

On December 9, 2019, a member of the Board of Directors purchased 428,571 shares of Class A Common Stock at fair value. He also owns and controls a fund which purchased Series B Preferred Stock on the same terms as all other investors. His investment is a non-controlling equity interest in the Company on a fully diluted basis in the aggregate as well as in each individual class of security purchased.

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6. Accrued Liabilities and Other Liabilities

The Company had Accrued liabilities and other liabilities of $673,813 as of December 31, 2019, primarily consisting of accrued liabilities of $638,999, and $845,741 as of December 31, 2020, primarily consisting of a loan of $567,311 and accrued liabilities of $273,907. In May 2020, HCW Biologics Inc. received an SBA Paycheck Protection Loan ("PPP loan") in the principal amount of $563,590. The Company qualified for a loan based on the criteria in Section 1102 of the CARES Act, that is, a multiple of 2.5 times allowable monthly expenses such as payroll, rent, and utilities. As of December 31, 2020, the Company reported $567,311 within Accrued liabilities and other liabilities on the balance sheet, consisting of $563,590 of principal and $3,721 of accrued and unpaid interest. See Note 15.

7. License Agreement

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 (10) 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 retained regulatory T cell-based cellular therapy, injectable rights, and manufacturing rights, not granted to Wugen under the terms of the Wugen License. The Company and Wugen will enter into two supply agreements under industry-standard terms, under which the Company will provide cGMP and non-cGMP grade materials, including a development supply agreement and a commercial supply agreement.

According to the terms of the agreement, Wugen will fund all future clinical development and commercialization activities for cellular therapy treatments for any indications utilizing the licensed fusion protein molecules covered by the Wugen License. In January 2021, two Phase 2 clinical trials related to treatment for relapsed / refractory acute myeloid leukemia based on one of the licensed molecules were initiated by Washington University and supported by Wugen.

The Company concluded that Wugen is a customer and the Wugen License is a functional license under the provisions of Topic 606. The Company identified the following performance obligations at the inception of the agreement:

- Provide Wugen with exclusive worldwide license rights for certain fusion proteins.
- Sell vials of HCW9201 clinical grade product available immediately.
- Transfer R&D know-how.
- Supply of cGMP and non-cGMP grade materials for development.
- Supply of cGMP grade materials for commercialization.

For the year ended December 31, 2020 the Company recognized $4.1 million for performance obligations satisfied in the period. This is the first time the Company has entered into an out-license arrangement and the first time the Company has established prices for its goods and services. Accordingly, the standalone selling price of the various performance obligations is uncertain, and the Company determined that an observable standalone selling price is not available for the identified performance obligations under the Wugen License. Where a standalone selling price is not directly observable, then the Company estimates the standalone selling price considering marketing conditions, entity-specific factors, and information about the customer that is reasonably

available. The process for determining a standalone selling price involves significant judgment and includes consideration of multiple factors, including assumptions related to the market opportunity and the time needed to commercialize a product candidate pursuant to the relevant license, estimated direct expenses and other costs.

The Company first determined the standalone selling price of $2.5 million for the vials of HCW9201 and the R&D know-how. The price was determined based on the cost of developing the know-how and the costs incurred in producing the vials. The standalone selling price for the license was determined using the residual approach and was priced at $1.6 million.

As of December 31, 2020, the Company and Wugen had not finalized the development supply agreement. Therefore, the Company will defer recognition of revenues and costs for supply of materials during development until the supply agreement is finalized. The commercial supply agreement will be entered into in the future, pursuant to the terms of the Wugen License.

The Wugen License 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 royalty is 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 our 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 our 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.

8. Redeemable Preferred Stock

In a series of closings that took place in 2019, the Company completed the private placement of Series B Preferred Stock. In total, 28,029,449 shares of Series B Preferred Stock were issued at $0.45 per share, for gross proceeds of $12.6 million and direct offering costs of $27,501, resulting in net proceeds of $12.6 million.

In a series of closings that took place in 2020, the Company completed the private placement of Series C Preferred Stock. In total, 12,691,270 shares of Series C Preferred Stock were issued at $0.88 per share, for gross proceeds of $11.2 million and direct offering costs of $23,799, resulting in net proceeds of $11.1 million.

During 2019, the Company had its final closing for the private placement of Series A Preferred Stock. In this closing, the Company issued 2,106,948 shares of Series A Preferred Stock at $0.38 per share, for gross proceeds of $800,640. Concurrent with the private placement of Series B Preferred Stock, the Company amended certain terms of the Series A Preferred Stock. These amendments had no impact the classification or carrying value of the Series A Preferred Stock.

Redemption of Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock (together, "Preferred Stock") may occur any time after the fifth anniversary from issuance, at the option of the holder so long as the holders of at least 50% of the interest in Series C Preferred Stock choose to exercise their right for redemption. The redemption amount will be paid in three annual installments following the redemption date.

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In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series C Preferred Stock have a liquidation preference over all other stockholders. The holders of Series B Preferred Stock have a liquidation preference that is subordinated to Series C Preferred Stock. Similarly, the holder of Series A Preferred Stock has a liquidation preference that is subordinated to Series B Preferred Stock. For certain events to qualify as a "deemed liquidation event," 66.67% of the outstanding shares of all Preferred Stock, voting together as a single class on an as converted basis, must approve. This includes change in control events such as a merger or sales of the Company.

So long as approximately 60% of the shares of Preferred Stock remain outstanding, the holders shall have protective rights that require a separate vote. These matters include liquidation and winding up of the Company, dividend declaration, repurchase of shares, and a change in the number of members of the Board of Directors.

Shares of Preferred Stock are convertible at the option of the holder in such number of shares of Class A Common Stock as determined by dividing the original issue price for each share by the conversion price in effect at the time of conversion. The terms of the Preferred Stock provide for an adjustment to the conversion price upon the occurrence of certain transactions or events, such as stocks splits, split-up, certain dividends, or distributions. Conversion rights terminate when Preferred Stock shareholders elect to redeem their shares. Each share of Preferred Stock is required to be automatically converted to Class A Common Stock when the Company closes on the sale of Class A Common Stock to the public at a price of at least $3.00 per share that raises at least $30 million in gross proceeds ("Qualified Public Offering"). Conversion rights terminate for all Preferred Stock upon a liquidation event or deemed liquidation event.

The Company evaluated the conversion feature to determine if there was an embedded derivative requiring bifurcation from the equity host. Based on this assessment, the Company determine bifurcation was not required since the conversion option is clearly and closely related to the equity host. The Company also considered if a Beneficial Conversion Feature was present, and concluded it was not.

Preferred Stock earns a 6% cumulative dividend which accrues whether or not declared by the Board of Directors. Such dividends will be paid only if declared by the Board of Directors or upon a liquidation or redemption event. Accrued and unpaid dividends which are not declared will be forfeited upon conversion of the Preferred Stock to Class A Common Stock. No dividends have been paid or declared as of the reporting date.

The Company evaluated whether Preferred Stock should be liability or equity classified and determined none of the Preferred Stock met the definition of a liability instrument. However, the Preferred Stock is subject to redemption under certain "deemed liquidation" events, as defined in the Company's Articles of Incorporation. As such, the Preferred Stock is considered contingently redeemable for financial accounting purposes. Since certain of the redemption features are outside the Company's control, the Preferred Stock and accrued and unpaid cumulative dividends that may be paid upon a liquidation event are presented as Redeemable preferred stock and treated as mezzanine or temporary equity.

HCW BIOLOGICS INC.
Notes to the Financial Statements
December 31, 2019 and 2020

9. Net Loss per Share

The following table summarizes the computation of the basic and diluted net loss per share:

	Year Ended December 31,	
	2019	2020
Numerator:		
Net loss	$ (7,292,921)	$ (5,802,201)
Less: cumulative preferred dividends earned in the period	(489,610)	(1,271,675)
Net loss available for distribution to common stock holders	$ (7,782,531)	$ (7,073,876)
Denominator:		
Weighted-average common shares outstanding	4,286,528	4,739,285
Net loss per share, basic, and diluted	$ (1.82)	$ (1.49)

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:

	As of December 31,	
	2019	2020
Redeemable preferred stock	18,329,308	23,768,420
Common stock options	586,714	742,114
Potentially dilutive securities	18,916,022	24,510,534

10. Stock-based Compensation

On March 14, 2019, the Company adopted the 2019 Equity Incentive Plan (“2019 Plan”). The 2019 Plan provides for the Company to grant equity awards, including equity awards, including incentive stock options or non-qualified stock options for the purchase of Class A Common Stock, to employees, members of the Board of Directors and advisors of the Company under terms and provisions established by the Board of Directors. The 2019 Plan initially reserved 857,142 shares of Class A Common Stock for issuance, and this reserve was increased on June 6, 2019 to 1,285,714 shares. As of December 31, 2019, 603,857 options were granted and outstanding to employees, consisting of 23,142 vested options and 580,715 unvested options. On August 4, 2020, the Company increased the reserve to 1,714,285 shares. As of December 31, 2020, 742,068 options were granted and outstanding, consisting of 91,114 vested and 650,954 unvested options.

The Company primarily grants employees incentive stock options, which have a maximum term of ten years from the date of grant. Generally, incentive stock options granted under the 2019 Plan have a four-year service-based vesting period. The exercise price for incentive stock options may not be less than 100% of the estimated fair value of the Company’s Class A Common Stock at the time of the grant. It is the Company’s policy to grant options with an exercise price equal to the fair value of a share of Class A Common Stock on the grant date.

HCW BIOLOGICS INC.
Notes to the Financial Statements
December 31, 2019 and 2020

The following summarizes the Company's stock option activity under the 2019 Plan for the year ended December 31, 2019 and December 31, 2020:

	Shares Issuable under Options	Weighted Average Exercise Price	Weighted Average Remaining Contract Term	Aggregate Intrinsic Value
Outstanding at December 31, 2018	—	$		$
Granted	603,857	0.13		
Exercised	(3,257)	0.09		
Forfeited or cancelled	(13,885)	0.10		
Outstanding at December 31, 2019	586,715	0.13	9.6 years	$ 5,500
Exercisable at December 31, 2019	19,885	0.09	9.3 years	$ 1,021
Outstanding at December 31, 2019	586,715	0.13	9.6 years	$ 5,500
Granted	263,999	0.20		
Exercised	(75,857)	0.13		
Forfeited or cancelled	(32,742)	0.12		
Outstanding at December 31, 2020	742,115	0.16	9.1 years	$ 39,078
Exercisable at December 31, 2020	91,114	0.15	9.0 years	$ 5,413

The aggregate intrinsic value is calculated based on the difference between the exercise price of the underlying stock options and the fair value of the Company's Class A Common Stock for stock options as of the reporting date.

The intrinsic value of stock options exercised during the years ended December 31, 2019 and 2020 was nil and $6,032, respectively.

The weighted-average fair value of options granted during the years ended December 31, 2019 and 2020 was $0.130 and $0.204 per share, respectively.

For stock options 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 stock option grants with performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable, or the performance condition has been achieved.

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.

Expected term—The expected term of stock options with service-based vesting 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 the Company has no trading history for its Common Stock due to its short history, 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.

HCW BIOLOGICS INC.
Notes to the Financial Statements
December 31, 2019 and 2020

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, 2019 and 2020, 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,	
	2019	2020
Expected term (years)	5.5	6.25
Expected volatility	65.60%	87.30%
Risk-free interest rate	1.60%	0.50%
Dividend yield	—	—
Fair value underlying common stock	$0.10	$0.18

For the year ended December 31, 2019, for options with service-based vesting conditions, the Company recognized $1,763 of employee stock-based compensation expense in general and administrative expenses in the accompanying statements of operations. For the year ended December 31, 2020, for options with service-based vesting conditions, the Company recognized $9,590 of employee stock-based compensation expense in research and development expenses and $12,285 of employee stock-based compensation in general and administrative expenses in the accompanying statements of operations.

As of December 31, 2019, the Company had an aggregate of $74,877 of unrecognized employee stock-based compensation cost for options with service-based vesting, which was expected to be recognized over a weighted average vesting period of 3.38 years. As of December 31, 2020, the Company had an aggregate of $103,045 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 5.12 years.

As of December 31, 2019 and 2020, there was no unrecognized employee stock-based compensation cost for options with performance-based vesting conditions, as no performance-based options were unvested. As of December 31, 2020, the Company recognized an aggregate of $6,750 of employee stock-based compensation cost for options with performance-based vesting conditions which vested immediately upon achieving the performance target.

11. 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, 2019 and 2020 was $93,185 and $146,436, respectively.

12. Collaborative Arrangements

In March 2020, the Company entered into two collaborative arrangements relating to IND-enabling activities. Pursuant to these agreements, the Company supplied materials for the studies and reimbursed the collaboration partner costs in connection with the projects. In turn, the partner will provide written reports and a body of scientific data for the results of the projects.

HCW BIOLOGICS INC.
Notes to the Financial Statements
December 31, 2019 and 2020

For the year ended December 31, 2019, the Company recorded approximately $274,500 of expenses related to an arrangement for the evaluation of certain of the Company's immunotherapeutic candidates completed in 2019, which are included in research and development expenses in the accompanying statement of operations. For the year ended December 31, 2020, the Company recorded approximately $95,400 of expenses related to these arrangements, which are included in research and development expenses in the accompanying statements of operations.

13. Income Taxes

The Company did not have a provision for income taxes (current or deferred tax expense) for tax years ended December 31, 2019 and 2020.

The following table summarizes the differences between the statutory federal income tax rate and the Company's effective income tax rate (percent data):

Rate Reconciliation	**2019**		**2020**	
Net loss before taxes	$(7,292,921)		$(5,802,201)	
Benefit at statutory rate	(1,531,513)	21.00%	(1,218,462)	21.00%
State tax benefit net of federal benefit	(305,811)	4.19%	(264,152)	4.55%
Permanent book/tax differences	4,021	(0.06%)	10,161	(0.18%)
Other adjustments	—	0.00%	(34,591)	0.60%
R&D credit payroll	50,154	(0.69%)	—	0.00%
R&D credit carryforward	—	0.00%	(46,608)	0.80%
Change in valuation allowance	1,794,217	(24.60%)	1,555,740	(26.81%)
Other	(11,068)	0.15%	(2,088)	0.40%
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, 2019 and 2020 are presented below:

	2019	**2020**
Deferred tax assets:		
Federal net operating loss carryforward	$ 1,903,292	$ 3,102,649
State net operating loss carryforward	407,932	658,595
Accrued expenses	—	24,585
Stock option compensation	—	2,821
Deferred rent	8,824	2,089
R&D credit	86,407	133,015
Net deferred tax assets	2,406,455	3,923,754
Deferred tax liabilities:		
Depreciable assets	(48,494)	(10,054)
Net deferred tax liabilities	(48,494)	(10,054)
Less: valuation allowance	(2,357,961)	(3,913,700)
Net deferred tax asset (after valuation allowance)	$ —	$ —

HCW BIOLOGICS INC.
Notes to the Financial Statements
December 31, 2019 and 2020

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, 2020, after consideration of all the evidence, both positive and negative, management has determined that a valuation allowance of $3.9 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, 2020, the valuation allowance increased by $1.6 million.

As of December 31, 2019, and 2020, the Company had available federal net operating loss ("NOL") carryforwards of $9.1 million and $14.8 million, respectively. The Company also has available state NOLs carryforwards of approximately $9.1 million and $15.2 million, as of December 31, 2019 and 2020, respectively. The Federal and State NOLs will carry forward indefinitely and be available to offset up to 100% of taxable income for taxable years before 2021 and 80% of taxable years staring after 2020.

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 March 27, 2020, the Coronavirus Aid, Relief and Economic Security ("CARES") Act was enacted and signed into law. The CARES Act, among other things, contains modifications on the limitation of business interest expense under Section 163(j), allow for NOL carryovers and carrybacks to offset 100% of taxable income for taxable years before 2021, and includes a technical correction to the Tax Cuts and Jobs Act with respect to Qualified Improvement Property ("QIP") where such property has a 15-year recovery period for purposes of the general depreciation system of Section 168(a). The Company evaluated the impact of the CARES Act, and aside from the 15-year QIP technical correction, it believes that none of other modifications or tax law changes will result in any material benefit or apply.

14. Commitments and Contingencies

Leases

The Company leased its operating facilities in Miramar, Florida under non-cancelable operating lease agreements and a short-term sublease agreement for additional office space, for the years ended December 31, 2019 and 2020. Rent expense is recognized for leases with increasing annual rents on a straight-line basis over the term of the lease. The amount of rent expense in excess of cash payments is classified as deferred rent. Lease incentives received are deferred and amortized over the term of the lease.

The future minimum payments for the lease and sublease agreements at December 31, 2020 were as follows:

Years ending December 31:

2021	$ 208,000
2022	36,000
Total Future Minimum Lease Payments	$ 244,000

HCW BIOLOGICS INC.
Notes to the Financial Statements
December 31, 2019 and 2020

Rental expense for the year ended December 31, 2019 was $184,538, of which $107,423 was included in research and development. Rental expense for the year ended December 31, 2020, including common area maintenance costs, recognized by the Company was approximately $183,943 of which $82,971 is included in research in development.

Manufacturing Commitment

During the year ended December 31, 2020, the Company entered into several agreements with a third-party global contract development and manufacturer of biologics for the manufacture of the Company's proprietary molecules for use in clinical trials. At December 31, 2019, the future minimum payments under the such agreements were $882,700. At December 31, 2020, future payment obligations under statements-of-work agreements were $3.9 million; of which approximately $403,000 was paid in January 2021.

Legal

As of April 16, 2021, management has no knowledge of any pending or unasserted claims against the Company.

15. Subsequent Events

On January 8, 2021, the Company received full loan forgiveness of $567,311 for the principal and accrued and unpaid interest related to the PPP loan.

Other than as disclosed above, the Company has evaluated all events or transactions that occurred after December 31, 2020 through April 16, 2021, the date the Company issued these financial statements. There were no other material events that impacted the financial statements or disclosures.

Reverse Stock Split

In June 2021, the Company's board of directors and stockholders approved an amendment to the Company's certificate of incorporation to effect a 3-for-7 reverse stock split, that was effective on June 25, 2021 (the "Reverse Stock Split"). The number of authorized shares and the par values of the common stock and redeemable preferred stock were not adjusted as a result of the Reverse Stock Split. The accompanying financial statements and notes to the financial statements give retroactive effect to the Reverse Stock Split for all periods presented.

HCW BIOLOGICS INC.
Condensed Balance Sheets

	December 31, 2020	March 31, 2021 (unaudited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,455,834	$ 6,856,138
Accounts receivable, net	2,500,000	1,300,000
Prepaid expenses	538,306	783,317
Other current assets	654,528	859,871
Total current assets	12,148,668	9,799,326
Investment	1,599,750	1,599,750
Property and equipment, net	1,649,668	1,528,912
Total assets	$ 15,398,086	$ 12,927,988
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT		
Liabilities		
Current liabilities:		
Accounts payable	$ 155,343	$ 323,496
Accrued liabilities and other current liabilities	845,741	1,023,331
Total current liabilities	1,001,084	1,346,827
Commitments and contingencies (Note 7)		
Redeemable preferred stock:		
Series A, $0.0001 par value; 14,738,948 shares authorized and 6,316,691 issued at December 31, 2020 and March 31, 2021	6,140,792	6,236,784
Series B, $0.0001 par value; 28,029,449 shares authorized and 12,012,617 issued at December 31, 2020 and March 31, 2021	13,680,306	13,898,206
Series C, $0.0001 par value; 18,181,818 shares authorized and 5,439,112 shares issued at December 31, 2020 and March 31, 2021	11,294,301	11,471,896
Total redeemable preferred stock	31,115,399	31,606,886
Stockholders' deficit:		
Common stock:		
Class B convertible, $0.0001 par value; 10,000,000 shares authorized and 4,285,714 issued at December 31, 2020 and March 31, 2021	429	429
Class A, $0.0001 par value; 74,950,215 shares authorized and 507,680 shares issued at December 31, 2020; 74,950,215 shares authorized and 596,386 shares issued at March 31, 2021	51	59
Accumulated deficit	(16,718,877)	(20,026,213)
Total stockholders' deficit	(16,718,397)	(20,025,725)
Total liabilities, redeemable preferred stock and stockholders' deficit	$ 15,398,086	$ 12,927,988

See accompanying notes to the unaudited condensed interim financial statements.

HCW BIOLOGICS INC.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
	2020	2021
Operating expenses:		
Research and development	$ 1,678,424	$ 2,329,812
General and administrative	718,568	1,082,360
Total operating expenses	2,396,992	3,412,172
Loss from operations	(2,396,992)	(3,412,172)
Interest and other income, net	21,478	568,176
Net loss	$ (2,375,514)	$ (2,843,996)
Less: cumulative preferred dividends earned in the period	(279,786)	(477,358)
Net loss available for distribution to common stockholders	$ (2,655,300)	$ (3,321,354)
Net loss per share, basic and diluted	$ (0.56)	$ (0.69)
Weighted average shares outstanding, basic and diluted	4,717,542	4,839,871

See accompanying notes to the unaudited condensed interim financial statements

HCW BIOLOGICS INC.
Condensed Statements of Changes in Redeemable Preferred Stock and Stockholders' Deficit
For the Three Months Ended March 31, 2020 and 2021
(Unaudited)

	Redeemable Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2019	6,316,691	$5,792,302	12,012,617	$12,883,859	—	$ —	4,717,542	$ 472	$ —	$ (9,676,766)	$ (9,676,294)
Stock-based compensation	—	—	—	—	—	—	—	—	76	—	76
6% cumulative dividends on redeemable preferred stock	—	86,646	—	193,140	—	—	—	—	(76)	(279,710)	(279,786)
Accretion of issuance costs	—	—	—	7,857	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(2,375,514)	(2,375,514)
Balance, March 31, 2020	**6,316,691**	**$5,878,948**	**12,012,617**	**$13,084,856**	**—**	**$ —**	**4,717,542**	**$ 472**	**$ —**	**$(12,331,990)**	**$ (12,331,518)**

	Redeemable Preferred Stock						Stockholders' Deficit				
	Series A		Series B		Series C		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2020	6,316,691	$6,140,792	12,012,617	$13,680,306	5,439,112	$11,294,301	4,793,394	$ 480	$ —	$ 16,718,877)	$ (16,718,397)
Issuance of Class A Common Stock upon exercise of stock options	—	—	—	—	—	—	88,702	8	13,364		13,385
Stock-based compensation	—	—	—	—	—	—	—	—	641	—	641
6% cumulative dividends on redeemable preferred stock	—	95,992	—	213,971	—	167,395	—	—	(14,005)	(463,353)	(477,358)
Accretion of issuance costs	—	—	—	3,929	—	10,200	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(2,843,996)	(2,843,996)
Balance, March 31, 2021	**6,316,691**	**$6,236,784**	**12,012,617**	**$13,898,206**	**5,439,112**	**$11,471,896**	**4,882,100**	**$ 488**	**$ —**	**$(20,026,213)**	**$ (20,025,725)**

See accompanying notes to the unaudited condensed interim financial statement

HCW BIOLOGICS INC.
Condensed Statements of Cash Flows
(Unaudited)

	Three Months Ended March 31,	
	2020	2021
Cash flows from operating activities:		
Net loss	$ (2,375,514)	$ (2,843,996)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	147,903	158,806
Gain on extinguishment of debt	—	(567,311)
Changes in operating assets and liabilities:		
Accounts receivable	—	1,200,000
Prepaid expenses and other assets	188,247	(150,356)
Accounts payable and other liabilities	57,916	713,055
Net cash used in operating activities	(1,981,448)	(1,489,802)
Cash flows from investing activities:		
Purchases of property and equipment	(100,857)	(23,279)
Net cash used in investing activities	(100,857)	(23,279)
Cash flows from financing activities:		
Proceeds from issuance of common stock	—	13,385
Offering costs	—	(100,000)
Net cash used in financing activities	—	(86,615)
Net changes in cash and cash equivalents	(2,082,305)	(1,599,696)
Cash and cash equivalents at the beginning of the period	7,355,834	8,455,834
Cash and cash equivalents at the end of the period	$ 5,273,529	$ 6,856,138
Non-cash operating, investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 8,983	$ —
Cumulative dividends earned and accrued in the reporting period	$ 279,786	$ 477,358
PPP loan forgiveness	$ —	$ 567,311
Offering costs	$ —	$ 200,000

See accompanying notes to the unaudited condensed interim financial statements.

HCW BIOLOGICS INC.
Notes to the Condensed Financial Statements
(Unaudited)

1. Organization and Summary of Significant Accounting Policies

Organization

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

Liquidity

On December 24, 2020, the Company entered into the Exclusive Worldwide License Agreement with Wugen Inc. ("Wugen License"). As a result of this transaction, as of December 31, 2020, the Company held a minority interest in Wugen carried at $1.6 million, the fair value on the effective date of the Wugen License, and Accounts receivable of $2.5 million. During the period ended March 31, 2021, the Company received payment of $1.25 million, and continued to hold a $1.25 million Accounts receivable as well as the minority investment as of March 31, 2021.

As of March 31, 2021, the Company had not generated any revenue from sales of its immunotherapeutic products. In the course of its development activities, the Company has sustained operating losses and expects to continue to incur operating losses for the foreseeable future. Since inception, substantially all the Company's activities have consisted of research, development, establishing large-scale cGMP production for clinical trials, and raising capital.

As of March 31, 2021 the Company had cash and cash equivalents of $6.9 million. Since inception to March 31, 2021, the Company incurred cumulative net losses of $17.9 million. Management expects to incur additional losses in the future to conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

HCW Biologics intends to raise capital through the issuance of additional equity financing and/or third-party collaboration funding. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of some of its products.

Summary of Significant Accounting Policies

Basis of Presentation

Unaudited Interim Financial Information

The accompanying unaudited condensed interim financial statements as of March 31, 2020 and for the three months ended March 31, 2020 and 2021 have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Act of 1933, as amended (the "Securities Act"). Accordingly, they do not include all of the information and notes required by U.S. GAAP for complete financial statements. These unaudited condensed financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company's financial position and the results of its operations and cash flows. The results for the three months ended March 31, 2021 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The condensed balance sheet at December 31,

HCW BIOLOGICS INC.
Notes to the Condensed Financial Statements
(Unaudited)

2020 has been derived from the audited financial statements at that date but does not include all disclosures required by U.S. GAAP for complete financial statements. Because all of the disclosures required by U.S. GAAP for complete financial statements are not included herein, these unaudited condensed financial statements and the notes accompanying them should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2020.

Revenue Recognition

The Company recognizes revenue when its customer or collaborator obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services.

To determine revenue recognition for arrangements that are within the scope of Topic 606, it 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 within the contract; and
v. recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of Topic 606 and it is probable of collection, the Company assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. The promised goods or services in the Company's arrangements may consist of a license, or options to license, the Company's intellectual property and research, development, and manufacturing services. The Company may provide options to additional items in such arrangements, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources, and (ii) is separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

The Company determines the transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. At contract inception for arrangements that include variable consideration, the Company estimates the probability and extent of consideration it expects to receive under the contract utilizing either the most likely amount method or expected amount method, whichever best estimates the amount expected to be received. The Company then considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The Company then allocates the transaction price to each performance obligation based on the relative standalone selling price and recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) control is transferred to the customer and the performance obligation is satisfied. For performance obligations which consist of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the

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combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded as deferred revenue.

The Company did not recognize any revenues for the three months ended March 31, 2020 or March 31, 2021.

Deferred Revenue

Deferred revenue represents amounts received in advance of the related performance obligation being satisfied. 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. The long-term portion of deferred revenue represents amounts to be recognized after one year. As of March 31, 2021, current deferred revenue includes amounts of $239,000 allocated to the development supply agreement performance obligation under the Wugen License that are included in Accrued liabilities and other liabilities. There were no long-term deferred revenues as of March 31, 2021, and no current or long-term deferred revenues prior to that period.

Investment

The Company holds a minority interest in Wugen. The Company does not have significant influence over the operating and financial policies of Wugen. As a result, the Company has accounted for this investment using the measurement alternative whereby the investment is recorded at cost less impairment, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same investee. No impairment was recognized in the year ended December 31, 2020 or the three months ended March 31, 2021.

Deferred Offering Costs

The Company defers offering costs consisting of legal, accounting and other fees and costs directly attributable to its initial public offering (“IPO”). The deferred offering costs will be offset against the proceeds received upon the completion of the IPO. Deferred offering costs will be classified as current or long term, depending on whether an IPO is expected to be completed within a one-year period. If offering expenses are paid prior to the completion of an IPO, they will be recorded in prepaid assets on the balance sheets until such time an IPO is completed. If an obligation is incurred but not settled prior to the IPO, the Company will recognize deferred offering costs as an accrued liability. In the event the IPO is terminated, all of the deferred offering costs will be expensed within the Company’s statements of operations. As of March 31, 2021, there was approximately $300,000 of current deferred offering costs, $100,000 of which are included within Prepaid expenses and $200,000 of which are included within Accrued liabilities and other liabilities on the accompanying condensed balance sheet. There were no long-term deferred offering costs as of March 31, 2021, and no deferred offering costs were recognized in any reporting periods prior to March 31, 2021.

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Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders, including both Class A and Class B Common Stock, by the 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 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"), 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.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("Topic 842"), which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. Topic 842 is effective for the Company in the fiscal years beginning after December 15, 2021, with early adoption permitted. The Company is currently in the process of evaluating the impact of the adoption of Topic 842 on the Company's financial statements and related disclosures.

2. Accrued Liabilities and Other Current Liabilities

In May 2020, HCW Biologics Inc. received an SBA Paycheck Protection Loan ("PPP loan") in the principal amount of $563,590. As of December 31, 2020, the Company had $845,741 of Accrued liabilities and other current liabilities, primarily consisting of the PPP loan of $567,311, including principal and accrued but unpaid interest, and accrued liabilities of $273,907. On January 8, 2021, the Company received full loan forgiveness of $567,311 for obligations related to the PPP loan. The Company accounted for the PPP loan as debt, and the loan forgiveness was accounted for as a debt extinguishment. The amount of loan and interest forgiven is recognized as a gain upon debt extinguishment and is reported within Interest and other income, net in the accompanying condensed statement of operations for the three months ended March 31, 2021.

3. Redeemable Preferred Stock

The Company's redeemable preferred stock is convertible into shares of Class A Common stock and earns cumulative dividends at a rate of 6% per annum and compound annually. The terms of the redeemable preferred stock provide for an adjustment to the conversion price upon the occurrence of certain transactions or events, such as stocks splits, split-up, certain dividends, or distributions. Cumulative dividends accrue whether or not declared by the Board of Directors. For the three months ended March 31, 2021, the Company accrued cumulative dividends of $477,358 which is included in the amounts reported for Redeemable preferred stock in the accompanying condensed balance sheet as of March 31, 2021. No dividends have been declared or paid as of March 31, 2021.

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4. Net Loss Per Share

The following table summarizes the computation of the basic and diluted net loss per share:

	Three Months Ended March 31,	
	2020	2021
Numerator:		
Net loss	$(2,375,514)	$ (2,843,996)
Less: cumulative preferred dividends earned in the period	(279,786)	(477,358)
Net loss available for distribution to common stock holders	$(2,655,300)	(3,321,354)
Denominator:		
Weighted-average common shares outstanding	4,717,542	4,839,871
Net loss per share, basic and diluted	$ (0.56)	$ (0.69)

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:

	As of March 31,	
	2020	2021
Redeemable preferred stock	18,329,308	23,768,420
Common stock options	586,687	653,355
Potentially dilutive securities	18,915,995	24,421,775

5. Fair Value of Financial Instruments

The carrying amount of the Company's financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short-term maturities.

Money market funds included in cash and cash equivalents that are measured at fair value based on quoted prices that are derived from observable market data are classified as Level 1 inputs. No transfers between levels occurred during the periods presented. The following table presents the Company's assets which are measured at fair value on a recurring basis at December 31, 2020 and March 31, 2021:

	At December 31, 2020:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$6,752,266	$ —	$ —	$6,752,266

	At March 31, 2021:			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$5,893,356	$ —	$ —	$5,893,356

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6. Income Taxes

The Company computes its quarterly income tax expense/(benefit) by using a forecasted annual effective tax rate and adjusts for any discrete items arising during the quarter. The Company did not have a provision for income taxes (current or deferred tax expense) as of March 31, 2021 and December 31, 2020. The Company will continue to maintain a 100% valuation allowance on total deferred tax assets. The Company believes it is more likely than not that the related deferred tax asset will not be realized. As a result, the Company's effective tax rate will remain at 0.00% because no items that are either estimated or discrete items would impact the tax provision.

7. Commitments and Contingencies

Leases

The Company leases its operating facilities in Miramar, Florida under non-cancelable operating lease agreements and a short-term sublease agreement for additional office space. Rent expense is recognized for leases with increasing annual rents on a straight-line basis over the term of the lease. The amount of rent expense in excess of cash payments is classified as deferred rent. Lease incentives received are deferred and amortized over the term of the lease.

The future minimum payments for the lease and sublease agreements at March 31, 2021 were as follows:

2021 (remaining 9 months)	$ 159,000
2022	36,000
Total future minimum lease payments	$ 195,000

Rental expense, including common area maintenance costs, recognized by the Company was $45,891 of which $20,658 is included in research and development and $48,140 of which $23,144 is included in research and development for the three months ended March 31, 2020 and 2021, respectively, in the accompanying condensed statements of operations.

Manufacturing Commitment

The Company entered into an agreement with a third-party global contract development and manufacturer of biologics for the manufacture of the Company's proprietary molecules for use in clinical trials. At March 31, 2020 and March 31, 2021, future payment obligations under statements-of-work agreements were $668,500 and $2.2 million, respectively. The difference between the two interim periods can be attributed to the ramp up to full cGMP manufacturing capabilities by March 31, 2021 for four different internally developed molecules.

Legal

As of May 26, 2021, management has no knowledge of any pending or unasserted claims against the Company.

Other

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a pandemic, which continues to spread throughout the United States and the world. The spread of COVID-19 has caused significant volatility in the U.S. and international markets. There is significant uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the U.S. and international economies and, as such, the Company is unable to determine if it will have a material impact to its operations.

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8. Subsequent Events

The Company has evaluated all events or transactions that occurred after March 31, 2021 through May 26, 2021, the date the Company issued these interim financial statements. There were no other material events that impacted the financial statements or disclosures.

Subsequent Events after May 26, 2021

The Company further evaluated subsequent events through July 6, 2021 and concluded that no subsequent event has occurred that requires disclosure except as noted below or elsewhere in these financial statements.

2021 Equity Incentive Plan

In June 2021, the Company's board of directors and stockholders approved an 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan will become effective immediately prior to the effectiveness of the registration statement for an Initial Public Offering of the Company's common stock. The 2021 Plan permits the grant of incentive stock options, nonstatutory stock options, stock appreciation rights ("SARs"), restricted stock, restricted stock units ("RSUs") and stock bonus awards (all such awards collectively, "stock awards"). A total of 2,400,000 new shares of common stock were approved to be initially reserved for issuance under the 2021 Plan. The number of shares reserved that are remaining in the 2019 Plan as of the effective date of the 2021 Plan will be added to the shares initially reserved under the 2021 Plan upon the effective date. In addition, the number of shares of common stock available for issuance under the 2021 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2022 (assuming the 2021 Plan becomes effective in 2021), in an amount equal to 2% of the outstanding shares of common stock on the last day of the prior fiscal year, or such number of shares determined by the Company's board of directors.

Reverse Stock Split

In June 2021, the Company's board of directors and stockholders approved an amendment to the Company's certificate of incorporation to effect a 3-for-7 reverse stock split, that was effective on June 25, 2021 (the "Reverse Stock Split"). The number of authorized shares and the par values of the common stock and redeemable preferred stock were not adjusted as a result of the Reverse Stock Split. The accompanying financial statements and notes to the financial statements give retroactive effect to the Reverse Stock Split for all periods presented.

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7,000,000 Shares

Common Stock

PROSPECTUS

Sole Book Running Manager

EF HUTTON
division of Benchmark Investments, LLC

Co-Manager

REVERE SECURITIES LLC