Risk Factors Comparison 2025-03-28 to 2024-04-01 Form: 10-K

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Our operations and financial results are subject to various risks and uncertainties, including those described below that could adversely affect our business, financial condition, results of operations, cash flows and the trading price of our common stock. It is not possible to predict or identify all such risks ; our operations could also be affected by factors, events or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. Therefore, while you should carefully consider the following risks, together with all of the other information in this Annual Report, including the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " our financial statements and the related notes thereto ~~. You~~ **, you** should not consider the following risks to be a complete statement of all the potential risks or uncertainties we could face. Summary of Key Risk Factors • We have incurred significant financial losses since our inception **,** and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability. • There is substantial doubt regarding our ability to continue as a going concern based on our cash and cash equivalents as of December 31, ~~2023~~ **2024** . We will need to raise additional funding, which may not be available on acceptable terms, if at all, to continue as a going concern and advance our current and any potential future product candidates. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations. Raising additional capital may dilute our existing shareholders, restrict our operations or cause us to relinquish valuable rights. • **The Company implemented remediation of material weaknesses identified in previous reporting periods. If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our common stock. •** We and our Chief Executive Officer **were** ~~are currently~~ involved in legal proceedings with Altor BioScience, LLC and NantCell (collectively, " Altor / NantCell ") ~~in~~ **. In July 2024, the parties entered a Settlement Agreement** which **removed some of** ~~Altor / NantCell have alleged, among other~~ -- **the uncertainties as to** ~~things, a claim of trade secret misappropriation and other~~ -- **the outcome** ~~related claims against us~~ and ~~breach~~ **cost** of ~~contract and fiduciary duty~~ **these proceedings. However** , ~~among other~~ -- **the** ~~claims, against~~ **Company has significant obligations that remain as a result of legal fees incurred but not paid for the defense of the Company as well as** our ~~chief~~ **Chief** ~~executive~~ **Executive** ~~officer~~ **Officer** ~~in arbitration~~ **. If we cannot negotiate acceptable payment plans to satisfy these obligations** , ~~and~~ an adverse result could have a negative material impact on our business and operations. • **As a result of the Settlement Agreement, the Company is unable to progress into Phase 2 clinical trials for HW9218, our lead product candidate for cancer indications. The Company is prepared to progress HCW9218 in Phase 2 clinical trials for non- oncology indications, however, we must secure supply of clinical materials to do so. As a condition of the Settlement Agreement, the Company transferred the master cell line for HCW9218 to ImmunityBio, who in turn agreed to enter a supply agreement with the Company by January 2025. As of the date of issuance of the Annual Report, there is no supply agreement in place. As a result the delay in securing supply, there is no assurance that the Company will be able to continue the clinical development of HCW9218 in non- oncology indications. • The Company has been out of compliance with three applicable rules with respect to its continued listing on The Nasdaq Stock Market, namely, Nasdaq Listing Rule 5450 (b) (2) (A) (the " MVLS Rule "), Nasdaq Listing Rule 5450 (a) (1) (the " Bid Price Rule ") and Nasdaq Listing Rule 5450 (b) (2 & 3) (C) (the " MVPHS Rule "). As a result, the Listing Staff of The Nasdaq Stock Market LLC (" Nasdaq ") delivered notices of its determination that the Company' s Common Stock was subject to delisting from the Nasdaq Global Market tier of Nasdaq. Nasdaq granted the Company a hearing before the Nasdaq Hearings Panel (the " Panel ") to appeal the delisting determination of the Nasdaq Listing Staff, which hearing was held on February 13, 2025, at which we presented our plan to regain compliance with all listing requirements. On March 3, 2025, the Panel granted our request to continue our listing on Nasdaq, subject to our demonstrating compliance with the Bid Price Rule on or before April 28, 2025 and our demonstrating compliance with all other Nasdaq Listing Rules on or before June 15, 2025. While the Company is exercising diligent efforts to maintain the listing of our Common Stock on Nasdaq, there can be no assurance that the Company will be able to regain or maintain compliance with the applicable Nasdaq Listing Rules. If the Company' s Common Stock were to be delisted from Nasdaq, it could have a material adverse effect on us and our stockholders. •** Our clinical trials may fail to demonstrate ~~substantial evidence of~~ 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. • Preliminary, topline or interim data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data. • The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time- consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates on a timely basis if at all, our business will be substantially harmed. • Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our product candidates are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all. • Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant

additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products. • We expect to rely on patents and other intellectual property rights to protect our technology, including product candidates and our immunotherapy platform technology, the prosecution, enforcement, defense, and maintenance of which may be challenging, time- consuming and costly. Failure to defend, protect or enforce these rights adequately, and costs and expenses associated with the same, could impact our financial condition and results of operations or otherwise harm our ability to compete and impair our business. • We rely on third parties to manufacture our product candidates. Any failure by a third- party manufacturer to produce acceptable drug substance for us or to obtain authorization from the FDA or comparable regulatory authorities may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory approvals or commercialize approved products. • Our information technology systems, or those used by our third- party contractors or consultants, may fail or suffer security breaches, which could adversely affect our business. Risks Related to our Financial Position and Need for Additional Capital We have incurred significant losses since our inception and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability. Since our inception, we have devoted most of our financial resources and all of our efforts to research and development, including preclinical studies and our clinical trials, and have incurred significant operating losses. **In addition, the Company and Dr. Wong, our Founder and Chief Executive Officer, were parties in an extended Arbitration, which was ongoing for over a year, during which time the Company incurred legal fees of nearly $ 28. 4 million for its own defense and the defense of Dr. Wong.** For the years ended December 31, ~~2022 and~~ 2023 **and 2024** , we reported a net loss of $ ~~14~~ **25** . ~~9~~ **0** million and $ ~~19~~ **30. 3 million, respectively. These losses are inclusive of reserve for credit losses and other expenses of $ 5. 3 million and $ 1. 3 million for the years ended December 31, 2023 and 2024, respectively. As of December 31, 2024, we had $ 4** . 7 million ~~, respectively. As of December 31, 2023, we had $ 3. 6 million~~ in cash and cash equivalents, in the balance sheet **of** ~~included in~~ our audited financial statements included elsewhere in this Annual Report. From inception to December 31, ~~2023~~ **2024** , we incurred cumulative net losses of $ ~~67~~ **98** . ~~8~~ **1** million. To date, we have financed our operations primarily through **the sale of our redeemable preferred stock (all of which converted to common stock upon the effective date of** our initial public offering, or ~~the~~ IPO **);** ~~, the sale of our redeemable preferred stock, and to a lesser extent,~~ payments received under our Wugen License for certain rights to two of our internally- developed molecules ~~and~~ **; proceeds from our IPO; a first lien mortgage of $ 6. 5 million;** proceeds from a Paycheck Protection Program (“ PPP ”) loan obtained through the Coronavirus Aid, Relief ~~,~~ and Economic Security Act (~~the “ CARES Act ”)~~ which was forgiven **); issuance of senior secured notes; and sale of common stock and warrants in private placements and direct registered offerings** . Based on our current operating plans, we believe that our cash and cash equivalents as of December 31, ~~2023~~ **2024** ~~, without considering any mitigating effects of financings that occurred after year end,~~ will not be sufficient for the Company to continue as a going concern for at least one year from the issuance date of the financial statements appearing elsewhere in this Annual Report. Our losses have resulted principally from expenses incurred in the research and development of our product candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure, as well as from the significant expenses we have incurred defending ourselves in current disputes with Altor / NantCell and advancing legal expenses of Dr. Wong, each as described further below. We expect to continue to incur significant operating losses for the foreseeable future. The only revenue we have generated to date relates to our Wugen License and the clinical material supply agreement. We have not generated any revenues from product sales. We anticipate that our expenses will increase substantially as we initiate preclinical and clinical studies, scale up our manufacturing process and capabilities to support our clinical studies and grow to scale. We have no products for which we have obtained marketing approval and have not generated any revenue from product sales. Even if we obtain marketing approval for, and are successful in commercializing, one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, accessing manufacturing capacity, establishing marketing capabilities, and ultimately selling any products. ~~.~~ We may never succeed in these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. There is substantial doubt about our ability to continue as a going concern. We will need to raise additional funding, which may not be available on acceptable terms, if at all to continue as a going concern and advance our product candidates. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations. Raising additional capital may dilute our existing shareholders, restrict our operations or cause us to relinquish valuable rights. There is substantial doubt regarding our ability to continue as a going concern based only on the cash and cash equivalents as of December 31, ~~2023~~ **2024** . We continuously evaluate whether there are conditions and events, considered in the aggregate, which raise substantial doubt about our ability to continue as a going concern within one year after the date that financial statements are issued. When substantial doubt exists based on this analysis, management evaluates whether the mitigating effect of our plans to raise capital or reduce costs sufficiently alleviates substantial doubt about our ability to continue as a going concern. We are at the clinical development stage of our Company with no commercial revenues from the products we are developing, and it is possible we will never generate revenue or profit from product sales. As of December 31, ~~2023~~ **2024** , we had cash and cash equivalents of $ ~~3~~ **4** . ~~6~~ **7** million ~~. Our management believes that such cash~~ and **there was substantial doubt**

about ~~cash equivalents will not be sufficient to fund~~ our ~~operating expenses and capital requirements~~ **ability to continue as a going concern** for ~~one year after~~ **at least 12 months from** the **issuance** date **of** the financial statements included elsewhere in this Annual Report ~~are issued~~, whether or not we curtail efforts with respect to certain of our current and future product candidates. We will require significant additional funding to advance any of our product candidates beyond the short term and to sustain our operations. We ~~intend to seek funds through collaborations, strategic alliances, or licensing arrangements with third parties. Such agreements may adversely impact retained rights to our assets, product candidates, future revenue streams and programs, especially those that require regulatory approval. We~~ may also seek to raise such capital through public or private equity, royalty financing or debt financing. Raising funds in the current economic environment may be challenging, and such financing may not be available in sufficient amounts or on acceptable terms, if at all. The terms of any financing may harm existing ~~shareholders~~ **stockholders**. The issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities may dilute the ownership of existing ~~shareholders~~ **stockholders**. Incurring debt would result in increased fixed payment obligations, and we may agree to restrictive covenants, such as limitations on our ability to incur additional debt or limitations on our ability to acquire, sell or license intellectual property rights that could impede our ability to conduct our business. Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. Since our inception in 2018, we have devoted a significant portion of our resources to identifying and developing our product candidates emerging from our internally- developed immunotherapy platform technology, our other research and development efforts, building our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully complete clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history. We **have identified certain material weaknesses in our internal control over financial reporting and if our remediation of such material weaknesses is not effective, or if we fail to develop and maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our common stock. Two of the material weaknesses were identified and reported in the Annual Report on Form 10- K for the year ended December 31, 2023. As the Company reported in a Current Report on Form 8- K filed with the SEC on May 1, 2024, we were a victim of a criminal scheme involving the impersonation of a purchaser of Secured Notes. The scheme resulted in the misdirection of approximately $ 1. 3 million held in Company accounts to a fraudulent account controlled by a third party and a default on a legally binding commitment to purchase Secured Notes. As a result of the default and the related misdirection of funds, management re- evaluated the effectiveness of our disclosure controls and procedures and internal control over financial reporting as of December 31, 2023. Based on this assessment, management identified material weaknesses in two areas, including the methods used to review, evaluate and accept financing proposals from investors and lenders and the process used to enter unusual significant transactions. As a result of the material weakness to protect the Company' s assets from fraud committed by third parties, there was a $ 1. 3 million loss recognized on the Company' s audited financial statements. As of September 30, 2024, the Company identified two additional material weaknesses in internal controls over financing reporting related to the classification of the Cogent Loan and accounting for the Secured Notes. On August 15, 2022, the Company entered into the 2022 Loan Agreement with Cogent Bank, pursuant to which we received $ 6. 5 million in proceeds to purchase a building. The loan is secured by a first priority lien on the building. As of September 30, 2024, certain subcontractors have filed mechanics liens related to unpaid invoices issued in connection with the Company' s construction and improvements on the building. The 2022 Loan Agreement contains a provision for a discretionary default in the event that the Company fails to pay sums due in connection with construction of any improvements. The Company did not identify and account for the loan as Short- term debt, net, to reflect that the lender has the right to accelerate the loan under a discretionary default provision as of September 30, 2024. The second material weakness identified as of September 30, 2024 related to accounting for complex transactions. This involved appropriately accounting for the Secured Notes and disclosing the amended terms that were executed during the third quarter of 2024. The Secured Notes were deemed to be a hybrid instrument, consisting of a debt host with embedded derivatives requiring bifurcation and accounting for separately. Prior to correcting the initial accounting treatment for the Secured Notes, as amended, the Company neglected to identify and account for the embedded derivatives. In addition, the disclosures for the Secured Notes would not have identified the embedded derivatives. The aggregation of these factors could have resulted in a material misstatement in the Company' s financial statements. For the reporting period ended September 30, 2024 and December 31, 2024, there was no impact to the financial statements related to correcting the accounting treatment for embedded derivatives. Another amended term for the Secured Notes is a fixed bonus payment that holders will receive if the Secured Notes are repaid on the Maturity Date. The Company determined that the fixed bonus payment should be accreted to the principal owed to holders over the term. As of and for the three and nine months ended September 30, 2024, the Company did not accrete the fixed bonus payment. Accretion during the reporting period ended September 30, 2024 did not materially misstate the amount owed to the holders. Accretion was reported in the year ended December 31, 2024 and reported within Depreciation expense. If the Company did not correct the accounting treatment for the accretion of the fixed bonus payment at maturity, we would understate our obligations. Over the term, this could have resulted in a material**

misstatement in the Company' s financial statements. In the year ended December 31, 2024, the Company implemented various steps to remediated these material weaknesses. In the second quarter of 2024, a remediation plan was adopted to strengthen controls and procedures used by the Company to review and accept financial proposals, particularly where there are upfront payments and other forms of payments made by the Company to third parties. These efforts include development of a process for assessment and communication, as well as involvement of additional key stakeholders, such as members of our Board of Directors. In the fourth quarter of 2024, the Company enhanced its controls to evaluate triggering events in debt and other financial instruments, to ensure the appropriate classification of obligations as current or noncurrent in the correct period. In addition, the Company strengthened controls to ensure timeliness in the determination of proper accounting and reporting for complex transactions by engaging consultants with technical accounting expertise to support the Company in our accounting analysis and conclusions for complex transactions. Also, the fourth quarter of 2024, the Company engaged advisors to support and assist in the review and augmentation of design and effectiveness of controls over financial reporting. As of December 31, 2024, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control- Integrated Framework. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2024, our disclosure controls and procedures were effective at a reasonable assurance level. However, we cannot assure you that any such actions we have or will take will prevent or avoid potential future material weaknesses. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our operating results or cause us to fail to meet our reporting obligations. The remediation efforts are intended both to address the identified material weakness and to enhance our overall financial control environment. This material weakness and any other failure to maintain effective internal control over financial reporting could result in a loss of confidence in the reliability of our financial statements which could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to avoid potential future material weaknesses. As we continue to evaluate and work to improve our internal control over financial reporting, we may take additional measures to address control deficiencies or determine to modify remediation measures. We cannot assure you that the measures we have taken to date, and may take in the future, will be sufficient to remediate the control deficiencies that led to the material weakness in internal control over financial reporting or that we will prevent or avoid potential future material weaknesses. Effective internal controls are necessary for us to provide reliable financial reports. These remediation measures may be time consuming and costly and there is no assurance that these initiatives will ultimately have the intended effects. We will require additional funding in order to complete development of our product candidates and commercialize our products, if approved. However, this additional financing may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts. Our operations have consumed significant amounts of cash since inception. **As of December 31, 2024, we held $ 4. 7 million of cash and cash equivalents and there was substantial doubt about our ability to continue as a going concern for at least 12 months from the issuance date of the financial statements included elsewhere in this Annual Report.** We expect our expenses to increase in connections with our ongoing **clinical development** activities, particularly as we continue to initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding for our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to: • delay, limit, reduce, or terminate preclinical studies, clinical trials, or other research and development activities, or eliminate one or more of our development programs altogether; • delay or terminate our plan to build and renovate our manufacturing facility; or • delay, limit, reduce, or terminate our efforts to establish manufacturing capacity, establish sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, or reduce our flexibility in developing or maintaining our sales and marketing strategy. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. We expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our technologies or product candidates, we will seek to finance our future cash needs through equity offerings, royalty- based or debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, stockholders' interests may be diluted, and the terms of these securities could include liquidation or other preferences and anti- dilution protections that could adversely affect our stockholders' rights. In addition, new debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that further limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, which could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our

management and may divert a disproportionate amount of their attention away from day- to- day activities, which may adversely affect their ability to oversee the development and potential future commercialization of our product candidates. If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. **On March 3, 2025, the Nasdaq Hearings Panel accepted our plan to regain compliance with all applicable continued listing rules of The Nasdaq Stock Market LLC (" Nasdaq "). There can be no assurance that the Company will be able to comply within the period of time granted by the Panel. If the Company does not execute our compliance plan or is delayed in doing so, the result could be the delisting of our Common Stock from Nasdaq. On March 3, 2025, the Company was granted an extension through April 28, 2025, to comply with the Bid Price Rule and through June 15, 2025 to comply with all Exchange Listing Rules by the Nasdaq Hearings Panel (the " Panel "). The Nasdaq Listing and Hearing Review Council may, on its own motion, determine to review any Panel decision within 45 calendar days after issuance of the written decision. If the Listing Council determines to review this Decision, it may affirm, modify, reverse, dismiss or remand the decision to the Panel. The Company will be immediately notified in the event the Listing Council determines that this matter will be called for review. As previously disclosed, the Company is currently out of compliance because the Company' s market value of listed securities (" MVLS ") closed below the $ 50, 000, 000 MVLS threshold required for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450 (b) (3) (A) (the " MVLS Rule "). In accordance with Nasdaq Listing Rule 5810 (c) (3) (C), the Company was provided a compliance period of 180 calendar days in which to regain compliance with the MVLS continued listing requirement, or until December 16, 2024 (the " Compliance Date "). The Company did not regain compliance with the MVLS Rule by the given deadline and, accordingly, the Listing Qualifications Staff (" Staff ") notified the Company that its securities were subject to delisting from Nasdaq unless the Company timely requested a hearing before the Panel (which we did). Additionally, on August 12, 2024, the Company received written notices from the Staff of Nasdaq which notified the Company that, for the 30 consecutive business days ended August 6, 2024, the Company' s security did not maintain a minimum bid price of $ 1 per share, in accordance with Nasdaq Listing Rule 5810 (c) (3) (A) (" Bid Price Rule "). Also on August 12, 2024, the Company received written notification from the Staff that for the 30 consecutive business days ended August 8, 2024, the Company' s market value of publicly held securities (" MVPHS ") closed below the $ 15, 000, 000 MVPHS threshold required for continued listing on the Nasdaq Global Market under Nasdaq Listing Rule 5450 (b) (2) (C) (the " MVPHS Rule "). The Company was granted a compliance period of 180 calendar days from the date of the notice (" Compliance Period ") for these delinquencies, in accordance with Nasdaq Listing Rule 5810 (c) (3) (A) for the Bid Price Rule and Nasdaq Listing Rule 5450 (b) (2) C) for the MVPHS Rule. The Company did not regain compliance with the Bid Price Rule by February 3, 2025 or the MVPHS Rule by February 4, 2025. Accordingly, by letter dated February 5, 2025, the Staff notified the Company that its securities were subject to delisting from Nasdaq unless the Company timely requested a hearing. The Company timely requested and received a hearing at which time it outlined its compliance plan before the Panel. The Panel accepted our compliance plan and granted us the above- referenced extensions. During the extension periods, the Company intends to implement its compliance plan and continue to actively monitor MVLS, the Bid Price and MVPHS while it considers all options available to it and to take other action, if necessary and as deemed appropriate by the Company' s Board, to remedy the deficiency, including potentially effecting a reverse stock split, entering into a $ 20. 0 million equity life of credit and converting at least $ 6. 6 million in senior secured notes to equity. On February 21, 2025, the Company filed its Definitive Proxy for a Special Meeting to obtain the requisite stockholder approvals to ensure it has the ability to take the certain of the actions that are part of its compliance plan. There can be no assurance that the Company will be able to comply within the period of time granted by the Panel. The Company' s balance sheet has liabilities that will require payment, and use of funds for this purpose will make less funding available for operations and clinical development. Included in the Company' s balance sheet in the accompanying audited financial statements are $ 17. 8 million of obligations included in accounts payable that represent amounts past due. These include $ 13. 5 million due for legal fees incurred as a result of mounting a defense for the Company and our Chief Executive Officer in a long- running arbitration proceeding that was settled on July 13, 2024. After year end, we received a $ 2. 0 million insurance payment which was used to offset obligations for legal fees for our Chief Executive Officer. Also included in outstanding obligations is $ 4. 3 million of obligations included in accounts payable for amounts owed for construction of a manufacturing facility that the Company is building at a property it owns in Miramar, Florida (the " Property "). As of December 31, 2024, certain subcontractors had filed mechanics liens related to unpaid invoices issued in connection with the facility. On December 16, 2024, BE & K Building Group, the prime contractor on the project, sent the Company a draft, unfiled lawsuit and requested the parties discuss payment. On January 22, 2025, the Company entered into a forbearance agreement with BE & K to allow the Company until March 31, 2025 to continue efforts to find the financing required to complete the construction and renovation of the Property. Pursuant to the forbearance agreement, the Company made an initial payment of $ 1. 0 million in partial satisfaction of amounts owing to BE & K and its subcontractors. The Company has continued to pursue financing alternatives to provide the funding needed to come current in past amounts due and complete the construction and renovation of the Property** Risks Related to our Business If we or any collaborators we work with in the future are unable to successfully develop and commercialize our product candidates, or experience significant delays in doing so, our business, financial condition, and results of operations will be materially adversely affected. Our ability to generate product and royalty revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a marketable product. Each of our

product candidates and any future product candidates we develop will require significant clinical development, management of clinical, preclinical, and manufacturing activities, regulatory approval in multiple jurisdictions, establishing manufacturing supply, including commercial manufacturing supply, and require us to build a commercial organization and make substantial investment and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. If we do not successfully execute or address these matters in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially adversely affect our business, financial condition, and results of operations. A key element of our strategy is to enter into out- licensing arrangements for certain rights to internally- developed molecules that we do not intend to develop into lead product candidates on our own or together with co-development partners. We may not be able to identify licensees, which could lower any return on our investments and increase our need for external funding. Since we have already generated over ~~30~~ **50** immunotherapeutic molecules, and plan to develop additional molecules, through our immunotherapy platform technology, our strategy includes funding operations in part through revenues derived from out- licensing molecules that are outside our oncological and anti- aging focus to third parties. Despite our efforts, we may be unable to enter into such licensing agreements. Supporting diligence activities conducted by potential licensors and negotiating the financial and other terms of a license agreement are long and complex processes with uncertain results, and we may fail to derive any revenues from these activities. ~~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~~ **not part of the Company' s in- house clinical development programs** , our revenues and return on our research and development activities would be negatively affected and we could be required to seek additional funding. **The success of our business development efforts, including license agreements, depends on our ability to realize the anticipate benefits of these transactions and is subject to numerous risks and uncertainties, many of which are outside of our control. Our potential licensors intend to develop alternative products or pursue alternative technologies either on their own or in collaboration with others, potentially resulting in our receiving no future milestone or royalty payments under any such licenses. We enter exclusive worldwide license arrangements pursuant to which licensors will develop certain immunotherapy products under which we may earn upfront license fees, additional milestone or royalty payments, but there can be no assurance that licensors will perform as required under the terms of the license agreements or will be successful in commercializing any products related to this license or that any such payments will ever be earned. We view our business development activities as an enabler of our strategy for clinical development activities and seek to generate growth by pursuing selected opportunities that have the potential to strengthen our clinical development program and provide a source of capital for our operations, including in- house development programs. The success of our business development activities is dependent on the availability of licensing partners, as well as being provided sufficient information that will enable us to accurately evaluate an opportunity. The success of our business development transactions also depends on our ability to realize the anticipated benefits of these transactions and is subject to numerous risks and uncertainties, many of which are outside of our control. Unsuccessful clinical trials, regulatory hurdles, new information and commercialization challenges, inability to raise the capital necessary to execute the clinical development program, among other factors, may adversely impact revenue and income contribution from business development transactions and may lead to an adverse impact on our business. While we seek to mitigate risks and liabilities through, among other things, due diligence, we may be exposed to risks and liabilities as a result of business development transactions. There is no assurance that we will be able to enter into strategic business relationships on favorable terms with desired positive outcomes that are accretive to our business.** We expect to continue to expand our capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. As of December 31, ~~2023~~ **2024** , we had ~~45~~ **36** full- time employees. We expect to experience continued growth in the number of our employees and the scope of our operations, particularly in the areas of drug development and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a public company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating additional employees; managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving our operational, financial and management controls, reporting systems, and procedures. We currently rely on certain independent organizations, advisors, and consultants to provide certain services, including strategic, financial, business development services, as well as certain aspects of regulatory approval, clinical management, manufacturing, and preparation for a potential commercial launch. There can be no assurance that the services of independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our

outsourced activities or if the quality or accuracy of the services provided by consultants or contract manufacturing organizations is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. Our business and operations are subject to risks related to climate change. The long- term effects of global climate change present risks to our business. Extreme weather or other conditions caused by climate change could adversely impact our supply chain and the operation of our business, which is geographically subject to higher incidents of climate events (such as hurricanes and other aggressive weather patterns). Such conditions could result in physical damage to our Miramar headquarters, clinical trial materials, clinical sites, or the facilities of our third- party manufacturing partners. These events could adversely affect our operations and our financial performance. The potential impacts of climate change may also include increased operating costs associated with additional regulatory requirements and investments in reducing energy, water use and greenhouse gas emissions. Risks Related to the Development and Clinical Testing of Our Product Candidates Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization. To obtain the requisite regulatory approvals to market and sell any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our investigational drug products are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials, and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications, patient population, and regulatory agency. Prior to obtaining approval to commercialize our product candidates and any future product candidates in the United States or abroad, we, our collaborators or our potential future collaborators must demonstrate with evidence from adequate and well- controlled clinical trials and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols, and the rate of dropout among clinical trial participants. If the results of our clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials, including adverse safety events in later trials that were not observed in prior trials, could limit the prospects for regulatory approval of that product candidate or other product candidates in any indications. Even if the trials are ~~successfully~~ completed **and successful**, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as demonstrating substantial evidence of efficacy even if positive results are observed in clinical trials **or having a positive benefit- risk profile**. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of our product candidates and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential. From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our company in general. From time to time, we may also disclose data from planned interim analyses of our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available and could result in volatility in the price of our common stock. Adverse differences between interim data and final data could significantly harm our business, operating results, prospects, or financial condition. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical

trials may fail to produce the same results or to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Our future clinical trial results may not be successful. To date, we have not completed any clinical trials required for the approval of our product candidates. We may experience delays in our clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time, or be completed on schedule, if at all. These clinical trials can be delayed, suspended, or terminated for a variety of reasons, including but not limited to delays in or failure to obtain regulatory authorization to commence a trial and IRB approval at each site, to reach agreement on acceptable terms with prospective clinical trial sites, or to recruit and enroll suitable patients to participate in a trial. In addition, the results of preclinical and early clinical trials of our product candidates may not be predictive of the results of our later- stage clinical trials. For example, while we may believe certain results in patients, such as stable disease, suggest encouraging clinical activity, stable disease is not considered a response for regulatory purposes in an endpoint assessing objective response rate. In addition, even if the regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or similar application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs. Clinical trials must be conducted in accordance with the FDA' s and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and **IRBs or** Ethics Committees ~~or IRBs~~ at the medical institutions where the clinical trials are conducted. We could encounter delays if a clinical trial is **put on hold by the FDA or other regulatory authorities,** suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted ~~,~~ **or** by the Data Review Committee or Data Safety Monitoring Board for such trial **.** ~~or~~ **For** ~~by~~ **example, in November 2024,** the FDA **placed a full clinical hold on the Phase 1 study of HCW9302 due to insufficient information regarding chemistry** , **manufacturing and controls, which prevented us from initiating the study until the FDA lifted the clinical hold in January 2025 after finding** ~~or~~ **our** ~~other regulatory authorities~~ **complete response to be satisfactory** . If we experience **further** delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business and results of operations. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP requirements and other regulations. Furthermore, we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions to conduct our clinical trials in compliance with GCP requirements. To the extent our collaborators fail to enroll participants for our clinical trials, fail to conduct the study in accordance with GCP, or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, and additional regulatory requirements, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening, and medical care. Our lead product candidate, ~~HCW9218~~ **HCW9302** , ~~is~~ **has been cleared by the FDA to initiate a first- in- human Phase 1 dose escalation clinical trial to evaluate HCW9302 in patients with moderate- to- severe alopecia areata, a common autoimmune disease in humans that** currently **has no curative FDA- approved treatments** ~~being evaluated in multiple clinical trials in cancer indications~~ . Our ability to advance **development of HCW9302** ~~HCW9218 through Phase 2 clinical trials~~ depends on timely completion of current clinical studies, successfully meeting those studies' objectives, including dose finding and / or optimization for the Phase 2 evaluation, and obtaining FDA authorization to proceed to ~~additional~~ Phase 2 trials. If the FDA does not allow our Phase 2 clinical trials to proceed, we may be required to undertake additional IND- enabling activities or dose finding activities, which would result in further delay and additional costs. If we experience delays in the progression and completion of our clinical trials **for HCW9302** , or if we terminate a clinical trial prior to completion, the commercial prospects of ~~HCW9218~~ **such product candidate** could be harmed, and our ability to generate revenues from ~~HCW9218~~ **the product candidate** may be delayed. In addition, any delays in our clinical trials would require us to store material which could expose us to inventory risk, increased costs, slow down in development and approval process, as well as jeopardize our ability to commence product sales and generate revenues. ~~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. Our other lead product candidate, HCW9302, is currently completing IND- enabling activities for an autoimmune indication. We rely on third- party providers for toxicology testing services for information required to be included in the submission of an IND. Any delays in completing toxicology studies and other IND- enabling activities 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 delays in commencing clinical trials could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates **. Any of these occurrences** ~~and impair our ability to commercialize our product candidates and~~ may harm our ~~business and results of operations. 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 delays in completion of internal procedures required to open a clinical site, patient enrollment taking longer than anticipated, patient withdrawal, or adverse events. For example, there were delays in commencing clinical trials of HCW9218 as a result of the ongoing pandemic and staffing shortages at clinical sites. 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. Patient enrollment depends on many factors, including but not limited to the size and nature of the patient population, the severity of the disease under investigation, and the availability of competing clinical trials, which 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~~ **many** of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates **, and may harm our business and results of operations** . We may become exposed to costly and damaging product liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the current and future use of product candidates by us and our partners in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, our partners, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our product candidates; injury to our reputation; withdrawal of clinical trial participants; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management' s time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any product candidate; and a decline in our share price. Although we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may be unable to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims, and our business operations could be impaired. Risks Related to Our Regulatory Environment The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post- marketing information and reports, and other possible activities relating to our product candidates are subject to extensive regulation. In the United States, marketing approval of a biologic requires the submission of a BLA to the FDA, and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product candidate. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing, and controls. Outside the United States, many comparable foreign regulatory authorities employ similar approval processes. We have not previously submitted a BLA to the FDA or similar regulatory approval filings to comparable foreign authorities for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval. Obtaining approval of a BLA can be a lengthy, expensive, and uncertain process, and as a company we have no experience with the preparation of a BLA submission or any other application for marketing approval. In addition, the FDA has the authority to require a REMS as part of a BLA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe- use criteria and requiring treated patients to enroll in a registry. We also would not be permitted to market our product candidates in countries outside of the United States until we receive marketing approval from applicable regulatory authorities in those countries. Our product candidates could fail to receive regulatory approval for many reasons including but not limited to flaws in trial design, dose selection, patient enrollment

criteria and failure to demonstrate an acceptable risk: benefit profile. In addition, data obtained from clinical trials is susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. The FDA and other regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our product candidates. As a result, we may be required to conduct additional preclinical studies, alter our proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which we hope to conduct clinical trials and develop and market our products, if approved. Further, even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. If we decide to pursue accelerated approval for any of our product candidates, it may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that it will receive marketing approval. If we are unable to obtain approval under an accelerated pathway, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, reduce the likelihood of obtaining and / or delay the timing of obtaining, necessary marketing approvals. In the future, we may decide to pursue accelerated approval for one or more of our product candidates. Under the FDA' s accelerated approval program, the FDA may approve a drug or biologic for a serious or life- threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Many cancer therapies rely on accelerated approval, and the treatment landscape can change quickly as the FDA converts accelerated approvals to full approvals on the basis of successful confirmatory trials. For drugs or biologics granted accelerated approval, post- marketing confirmatory trials are required to describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated and / or fully enrolled prior to approval. Moreover, the FDA may withdraw approval of any product candidate approved under the accelerated approval pathway if, for example: • the trial or trials required to verify the predicted clinical benefit of our product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with such product; • other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use; • we fail to conduct any required post- approval trial of our product candidate with due diligence; or • we disseminate false or misleading promotional materials relating to the relevant product candidate. In addition, the FDA may terminate the accelerated approval program or change the standards under which accelerated approvals are considered and granted in response to public pressure or other concerns regarding the accelerated approval program. Changes to or termination of the accelerated approval program could prevent or limit our ability to obtain accelerated approval of any of our clinical development programs. Recently, the accelerated approval pathway has come under scrutiny within the FDA and by Congress. The FDA has put increased focus on ensuring that confirmatory studies are conducted with diligence and, ultimately, that such studies confirm the benefit. For example, the FDA has convened its Oncologic Drugs Advisory Committee to review what the FDA has called dangling or delinquent accelerated approvals where confirmatory studies have not been completed or where results did not confirm benefit. In addition, the Oncology Center of Excellence has announced Project Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post- marketing processes, with the goal to enhance the balance **of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies** . The recent enactment of FDORA included provisions related to the accelerated approval pathway. Pursuant to FDORA, the FDA is authorized to require a post- approval study to be underway prior to approval or within a specified time period following approval. FDORA also requires the FDA to specify conditions of any required post- approval study and requires sponsors to submit progress reports for required post- approval studies and any conditions required by the FDA. FDORA enables the FDA to initiate enforcement action for the failure to conduct with due diligence a required post- approval study, including a failure to meet any required conditions specified by the FDA or to submit timely reports **. There is substantial uncertainty regarding the new Administration' s initiatives and how these might impact the FDA, its implementation of laws, regulations, policies and guidance and its personnel. Similar initiatives may also be directed toward other government agencies. These initiatives could prevent, limit or delay development and regulatory approval, and / or impact commercialization, of our product candidates, which would impact our business. FDA- regulated industries, such as ours, face substantial uncertainty regarding the regulatory environment we will face as we proceed with research and development, and possibly in future commercialization, efforts following the inauguration of President Trump in January 2025 (the " Administration "). Some of these efforts have manifested to date in the form of personnel measures that could impact the FDA' s ability to hire and retain key personnel, which could result in delays in or limitations on our ability to obtain guidance from the FDA on our product candidates in development and obtain the requisite regulatory approvals in the future. Moreover, the new Administration has proposed action to freeze or reduce the budget of the National Institutes of Health (" NIH ") as related to its funding for medical research, which could decrease the ability of facilities that rely**

on NIH funding to enroll and conduct clinical trials or increase the costs to us of conducting clinical trials. There remains general uncertainty regarding future activities. The new Administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development and sale of new therapeutic products. For example, on January 20, 2025, President Trump announced an executive order establishing the Department of Government Efficiency to maximize government efficiency and productivity. Pressures on and uncertainty surrounding the U. S. federal government' s budget and potential changes in budgetary priorities could adversely affect the funding for existing programs and grants and increase the costs to us of conducting clinical trials. Alternatively, state governments may attempt to address or react to changes at the federal level with changes to their own regulatory frameworks in a manner that is adverse to our operations. If we or our collaborators become negatively impacted by future governmental orders, regulations, policies or guidance as a result of the new Administration, there could be a material adverse effect on us and our business. If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post- approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co- marketers fails to comply with regulatory requirements, the regulators could take various actions. These include issuing warning letters or untitled letters, imposing fines on us, imposing restrictions on the product or its manufacture, and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our product labeling, or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition, and results of operations. In addition, if we have any product candidate approved, our product labeling, advertising, and promotion will be subject to regulatory requirements and continuing regulatory review. In the United States, the FDA and the Federal Trade Commission (" FTC "), strictly regulate the promotional claims that may be made about pharmaceutical products to ensure that any claims about such products are consistent with regulatory approvals, not misleading or false in any particular way, and adequately substantiated by clinical data. The promotion of a drug product in a manner that is false, misleading, unsubstantiated, or for unapproved (or off- label) uses may result in enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or the FTC. In particular, a product may not be promoted for uses that are not consistent with the uses approved by the FDA as reflected in the product' s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant sanctions and may result in false claims litigation under federal and state statutes, which can lead to consent decrees, civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid, and other federal and state healthcare programs. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be

changed, or the impact of such changes, if any. For example, the Oncology Center of Excellence within the FDA has advanced Project Optimus, which is an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well. This shift from the prior approach, which generally determined the maximum tolerated dose, may require sponsors to spend additional time and resources to further explore a product candidate' s dose- response relationship to facilitate optimum dose selection in a target population. Other recent Oncology Center of Excellence initiatives have included Project FrontRunner, a new initiative with a goal of developing a framework for identifying candidate drugs for initial clinical development in the earlier advanced setting rather than for treatment of patients who have received numerous prior lines of therapies or have exhausted available treatment options; Project **Confirm, which is an initiative to promote the transparency of outcomes related to accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation in approval and post- marketing processes, with the goal to enhance the balance of access and verification of benefit for therapies available to patients with cancer and hematologic malignancies; and Project** Equity, which is an initiative to ensure that the data submitted to the FDA for approval of oncology medical products adequately reflects the demographic representation of patients for whom the medical products are intended **. More recently, as part of FDORA, sponsors will be required to submit Diversity Action Plans (" DAPs ") for Phase 3 studies or other pivotal studies of new drugs. DAPs must include the sponsor' s goals for enrollment for such studies, disaggregated by age group, sex, and racial and ethnic demographic characteristics of clinically relevant study populations** ; **the sponsor' s rationale for such goals; and** ~~and~~ **an explanation of how the sponsor intends to meet such goals. Actions taken in the early days of the new presidential administration have created significant uncertainty as to whether** Project **Equity will continue** ~~Confirm, which is an~~ **and whether** ~~initiative to promote~~ the **statutory requirements** ~~transparency of outcomes~~ related to **DAPs will be implemented by FDA** ~~accelerated approvals for oncology indications and provide a framework to foster discussion, research and innovation~~ in ~~approval and post- marketing processes, with~~ the **near future** ~~goal to enhance the balance~~ . We are considering these and other policy changes as they relate to our programs. Our employees, independent contractors, principal investigators, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other misconduct. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, theft of trade secrets as well as patient privacy and other privacy laws and regulations. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, labeling, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations, and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. Further, defending against any such actions can be costly, time- consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Our current and future relationships with customers and third- party payors may be subject to applicable anti- kickback, fraud and abuse, transparency, health privacy, and other healthcare laws and regulations, which could expose us to significant penalties, including criminal, civil, and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, including physicians, and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as, market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations that may be applicable to our business include the following: • the federal Anti- Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; • the federal civil false claims laws, including the False Claims Act, which can be enforced by civil whistleblower or qui tam actions on behalf of the government, and criminal

false claims laws and the civil monetary penalties law, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal government program, or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government; • HIPAA, as amended by HITECH, and their implementing regulations, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates and their subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security, and transmission of such individually identifiable health information; • Analogous state laws and regulations such as state anti- kickback and false claims laws and analogous non- U. S. fraud and abuse laws and regulations, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third- party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance regulations promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, including price increases. State and local laws require the registration of pharmaceutical sales representatives. Efforts to ensure that our internal business processes and business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil and administrative sanctions, including exclusions from government funded healthcare programs, which could have a material adverse effect on our business, results of operations, financial condition and prospects. Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain. Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may not obtain or may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. Furthermore, government shutdowns could also impact the ability of regulatory authorities and government agencies to function normally and support our operations. For example, the U. S. federal government has shut down repeatedly since 1980, including for a period of 35 days beginning on December 22, 2018. During a shutdown, certain regulatory authorities and agencies, such as the FDA, have had to furlough key personnel and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, in the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. Previously, in March 2010, the ACA was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Healthcare reform initiatives ~~recently~~ culminated in the enactment of the IRA in August 2022, which, among other things, allows HHS to directly negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D **. The negotiated price may not exceed a statutory ceiling price** . Only high- expenditure single- source drugs that have been approved for at least 11 years for single- source biologics (7 years for **single- source** drugs) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. ~~Negotiations for~~ **For 2026, the first year in which negotiated prices become effective, CMS selected 10 high- cost** Medicare Part D products ~~take place~~ **in 2023, negotiations began** in 2024 **, and the negotiated maximum fair price for each product has been announced. These negotiations resulted in significant price reductions for the products from their 2023 list prices, ranging from 38 to 79 percent,** with ~~the negotiated~~ **an average** price **reduction of 59** ~~taking effect in 2026, and negotiations for Medicare Part B products will begin in 2026 with the negotiated price taking effect in 2028~~ . ~~In August 2023, HHS announced the ten~~ **4 percent. CMS has selected 15 additional** Medicare Part D drugs ~~and biologics that it selected~~ for ~~negotiations. HHS will announce the~~ negotiated maximum fair **pricing in** ~~prices by September 1, 2024~~ **2027 . For 2028** , ~~and~~ **an** ~~this price cap~~ **additional 15 drugs** , which ~~cannot exceed a statutory ceiling price~~ **may be covered under either Medicare Part B or Part D** , will **be selected** ~~go into effect on January 1~~ , **and for** ~~2026~~ **2029 and subsequent years, 20 Part B or Part D drugs will be selected** . A drug or biological product that has an orphan drug designation for only one rare disease

or condition will be excluded from the IRA' s price negotiation requirements, but will lose that exclusion if it receives designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The negotiated prices **have represented, and** will **continue to** represent **,** a significant discount from average prices to wholesalers and direct purchasers. The law also imposes rebates on Medicare Part D and Part B drugs whose prices have increased at a rate greater than the rate of inflation **, and in November 2024, CMS finalized regulations for these inflation rebates** . The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. These provisions may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high- expenditure single- source drugs and biologics have been challenged in multiple lawsuits brought by pharmaceutical manufacturers. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry. At the state level in the United States, legislatures are increasingly enacting laws and implementing regulations designed to control pharmaceutical and biologic product pricing, including price constraints, restrictions on certain product access, reporting on price increases and the introduction of high- cost drugs. In some states, laws have been enacted to encourage importation of lower cost drugs from other countries and bulk purchasing. For example, the FDA released a final rule in September 2020 providing guidance for states to build and submit plans for importing drugs from Canada, and FDA authorized the first such plan in Florida in January 2024 **, which has been extended until July 2025. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA** . In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drug products that we successfully commercialize or put pressure on our product pricing. We expect that the ACA, the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates. Risks Related to Commercialization of Our Product Candidates We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do. The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop, and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large pharmaceutical and biotechnology companies, academic institutions, government agencies, and other public and private research organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and marketing of products that compete with our product candidates. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. With the proliferation of new oncology drugs and therapies, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical, which could adversely impact our business, financial condition, or results of operations. Failure to successfully identify, develop, and commercialize additional product candidates could impair our ability to grow. Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of our product candidates in our current pipeline, we expect to continue to innovate and potentially expand our portfolio. Because we have limited financial and managerial resources, research programs to identify product candidates may require substantial additional technical, financial and human resources, whether or not any new potential product candidates are ultimately identified. Our success may depend in part upon our ability to identify, select, and develop promising product candidates and therapeutics. We may expend resources and ultimately fail to discover and generate additional product candidates suitable for further development. All product candidates are prone to risks of failure typical of biotechnology product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics indicating that it is unlikely to receive approval by the FDA, the EMA, and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize new product candidates we have identified and explored, our business, prospects, financial condition, and results of operations could be adversely affected. Even if approved, our products may not gain market acceptance, in which case we may not be able to generate product revenues, which will materially adversely affect our business, financial condition, and results of operations. Even if the FDA or any other regulatory authority approves the marketing of any product candidates that we develop on our own or with a collaborator, physicians, healthcare providers, patients, or the medical community may not accept or use them. Additionally, the product candidates that we are developing are based on our internally- developed

immunotherapy platform technology, which is a new technology. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any of our product candidates will depend on a variety of factors including but not limited to the terms of any approvals and the countries in which approvals are obtained, the number and clinical profile of competing products, and the availability of coverage and adequate reimbursement from insurers for our product candidates. If our product candidates fail to gain market acceptance, our ability to generate revenues to provide a satisfactory, or any, return on our investments may be materially and adversely impacted. Even if some product candidates achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues. We currently have no marketing, sales, or distribution infrastructure and we intend to either establish a sales and marketing infrastructure or outsource this function to a third party. Either of these commercialization strategies carries substantial risks to us. We currently have no marketing, sales, and distribution capabilities because all of our product candidates are still in clinical or preclinical development. If any of our product candidates are approved, we intend to either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in a legally compliant manner, or to outsource this function to a third party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we were to directly market or sell any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator' s willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator' s business strategy. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses, which would have a material adverse effect on our business, financial condition, and results of operations. Risks Related to Our Dependence on Third Parties We do not currently own or operate any cGMP manufacturing facilities nor do we have any in- house cGMP manufacturing capabilities. We rely on third- party contract manufacturers to produce sufficient quantities of materials required for the manufacture of our product candidates for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards, and intend to do so for the commercial manufacture of our products, if approved. If we are unable to arrange for such third- party manufacturing sources, or fail to do so on commercially reasonable terms, we may not be able to successfully produce sufficient supply of product candidate or we may be delayed in doing so. Such failure or substantial delay could materially harm our business. We rely on third parties for biological materials that are used in our discovery and development programs. These materials can be difficult to produce and occasionally have variability from the product specifications. Any disruption in the supply of these biological materials consistent with our product specifications could materially adversely affect our business. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. We may also have lower yields in manufacturing batches, which can increase our costs and slow our development timelines. Improper storage of these materials, by us or any third- party suppliers, may require us to destroy some of our biological raw materials or product candidates. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality control and assurance, volume production, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications), and the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates be manufactured according to cGMP and similar foreign standards relating to methods, facilities, and controls used in the manufacturing, processing, and packing of the product, which are intended to ensure that biological products are safe and that they consistently meet applicable requirements and specifications. If the FDA or a comparable foreign regulatory authority does not approve the manufacture of our product candidates at any of our proposed contract manufacturer' s facilities, or if any contract manufacturer fails to maintain a compliance status acceptable to the FDA or a comparable foreign authority, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. Any discovery of problems with a product, or a manufacturing facility used by us, may result in restrictions on the product or on the manufacturing facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. We may have little to no control regarding the occurrence of third- party manufacturer incidents. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed. In addition, the fact that we are dependent on our collaborators, our suppliers, and other third parties for the manufacture, filling, storage, and distribution of our product candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition, and results of operations. Any failure by our third- party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Pharmaceutical manufacturers are also subject to extensive post- marketing oversight by the FDA and comparable regulatory authorities in the jurisdictions where the product is marketed, which include periodic unannounced and announced inspections by the FDA to assess compliance with cGMP requirements. If an FDA inspection of a manufacturer' s facilities

reveals conditions that the FDA determines not to comply with applicable regulatory requirements, the FDA may issue observations through a Notice of Inspectional Observations, commonly referred to as a " Form FDA 483 ". If observations in the Form FDA 483 are not addressed in a timely manner and to the FDA' s satisfaction, the FDA may issue a warning letter or pursue other forms of enforcement action. Any failure by one of our contract manufacturers to comply with cGMP or to provide adequate and timely corrective actions in response to deficiencies identified in a regulatory inspection could result in enforcement action that could lead to a shortage of products and harm our business, including withdrawal of approvals previously granted, seizure, injunction or other civil or criminal penalties. The failure of a manufacturer to address any concerns raised by the FDA or foreign regulators or to maintain a compliance status acceptable to the FDA or foreign regulators could also lead to the delay or withholding of product approval by the FDA or by foreign regulators or could lead to plant shutdown. Certain countries may impose additional requirements on the manufacturing of drug products or drug substances, and on manufacturers, as part of the regulatory approval process for products in such countries. The failure by our third- party manufacturers to satisfy such requirements could impact our ability to obtain or maintain approval of our products in such countries. Supply sources could be interrupted from time to time and, if interrupted, there is no guarantee that supplies could be resumed within a reasonable time frame and at an acceptable cost or at all. We rely on our manufacturers to purchase from third- party suppliers the materials necessary to produce our product candidates for our clinical trials. The manufacturing capabilities of our suppliers have been impacted as a result of ongoing supply chain delays, and it may not be possible for us to timely manufacture our product candidates at desired levels. Reduced supply may also lead to increased costs for materials, which can adversely impact our business and results of operations There are a limited number of suppliers for raw materials that we use to manufacture our product candidates, and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. Reductions or interruptions in any of our third- party manufacturing processes as a result of supply chain delays caused global conflicts, public health emergencies (including a resurgence of a variant of the COVID- 19 pandemic or future pandemic) or other reasons could have a material adverse effect on our business, results of operations, financial condition and cash flows. We do not have any control over the process or timing of the acquisition of the raw materials we need to produce our product candidates by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event a new supplier must be used. The time and effort to qualify a new supplier could result in additional costs, diversion of resources, or reduced manufacturing yields, any of which would negatively impact our operating results. Although we will not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third- party manufacturer could considerably delay completion of our clinical trials, product testing, and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. We currently rely on, and expect to continue to rely on, third parties, including independent clinical investigators, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We currently rely, and expect to continue to rely on, third parties, including independent clinical investigators, to conduct our preclinical studies and clinical trials and to monitor and manage data for our preclinical and clinical programs. We will rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, our reliance on these third parties will not relieve us of our regulatory responsibilities, and we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, including GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators, and trial sites. If we fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Further, these investigators are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third- party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. There is a limited number of third- party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third- party laboratories, or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, or clinical investigators do not successfully carry out their

contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical or clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed. Switching or adding additional laboratories or investigators involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical- stage product candidate or any future product candidates. We may not realize the benefits of any existing or future co- development or out- licensing arrangement, and if we fail to enter into new strategic relationships, our business, financial condition, commercialization prospects, and results of operations may be materially adversely affected. Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. Therefore, for some of our product candidates, we may decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators. Collaborations are complex and time- consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms, or at all. If our strategic collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. In instances where we do enter into collaborations, we could be subject to a number of risks which may materially harm our business, commercialization prospects, and financial condition. For example, we may not be able to control the amount and timing of resources that is required of us to complete our development obligations or that the collaboration partner devotes to the product development or marketing programs, the collaboration partner may experience financial difficulties, or we may be required to relinquish important rights such as marketing, distribution, and intellectual property rights. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue, or specific net income that justifies such transaction. To date, we have relied on one third- party manufacturer for the cGMP production of our drug product candidates. The loss of this third- party manufacturer could negatively impact our ability to develop our product candidates and adversely affect our business. We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and currently rely on a single third- party vendor to manufacture supplies and process our product candidates. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. Although in the future we intend to develop our own manufacturing facility, we also intend to use third parties as part of our manufacturing process and may, in any event, never be successful in developing our own manufacturing facility. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. The lead time needed to establish relationships with new manufacturers can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new manufacturer. The time and effort to qualify a new manufacturer could result in additional costs, diversion of resources, or reduced manufacturing yields, any of which would negatively impact our operating results. Moreover, to meet anticipated demand, our third- party manufacturer may need to increase manufacturing capacity, which could involve significant challenges. This may require us and our vendor to invest substantial additional funds and hire and retain the technical personnel who have the necessary experience. Neither we nor our third- party manufacturer may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. Risks Related to Intellectual Property We expect to rely on patents and other intellectual property rights to protect our technology, including product candidates and our immunotherapy platform technology, the prosecution, enforcement, defense, and maintenance of which may be challenging and costly. Failure to protect or enforce these rights adequately could harm our ability to compete and impair our business. Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for technology related to our product candidates, including, but not limited to, our immunotherapy platform technology, product candidates, methods used to manufacture those product candidates, formulations thereof, and the methods for treating patients using those product candidates. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel platform technology and product candidates that are important to our business. The patent prosecution process is expensive and time- consuming, and we may not be able to prepare, file, and prosecute all necessary or desirable patent

applications at a reasonable cost or in a timely manner. In addition, during the patent prosecution process, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. The issuance, scope, validity, enforceability, and commercial value of our current or future patent rights are highly uncertain. It is possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Our pending and future patent applications may not result in the issuance of patents that protect our technology or product candidates, in whole or in part, or that effectively prevent others from commercializing competitive technologies and product candidates. The patent examination process may require us to narrow the scope of the claims of our pending and future patent applications, which may limit the scope of patent protection that may be obtained. Further, even if we obtain patents with sufficient scope to protect our technology or product candidates in their present forms, future technical changes to our technology or product candidates may render the patent coverage inadequate. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate or narrow the scope of a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties have initiated or may initiate opposition, interference, re- examination, post- grant review, inter partes review, nullification, or derivation actions in court or before patent offices, or similar proceedings challenging the validity, ownership, enforceability, or scope of such patents, which may result in the patent claims being narrowed, invalidated, or held unenforceable or circumvented. ~~For example, as described further below, we are engaged in legal proceedings with Altor / NantCell pursuant to which Altor / NantCell is seeking specific performance for assignment of and a constructive trust over certain of our patents, which if successful would materially impact our core intellectual property assets.~~ Because patent applications in the United States and other jurisdictions are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file any patent applications related to such inventions. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent is issued from such applications, and then only to the extent the issued claims cover the technology. Furthermore, even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that it used the invention in commerce before our filing date or that the other party benefits from a compulsory license. Additionally, our competitors or other third parties may be able to evade our patent rights by developing new biologics, biosimilars, or alternative technologies or products in a non- infringing manner. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned patent applications may in the future be co- owned with third parties. If we are unable to obtain an exclusive license to any such third- party co-owners' interest in such patents or patent applications, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our owned patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent application process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO, foreign patent offices, and patent courts or other authorities in granting patents and ruling on claim scope and validity are not always applied uniformly or predictably. Patent positions of life sciences companies can be uncertain and involve complex factual, scientific, and legal questions. Changes in either patent laws or their interpretation in any jurisdiction where we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights, and more generally may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our product candidates. We may become involved in lawsuits to protect or enforce our issued patents relating to one or more of our product candidates or our internally- developed platform, which could ultimately render our patents invalid or unenforceable and adversely affect our competitive position. Intellectual property litigation or other legal proceedings could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Competitors may infringe our patents or other intellectual property that relate to our immunotherapy platform technology and product candidates, their respective methods of use, manufacture, and formulations thereof. Third parties may in the future claim that our operations infringe their intellectual property rights. To defend against such claims, protect our competitive position and counter infringement or unauthorized use, we may from time to time need to resort to litigation to enforce or defend any patents or other intellectual property rights owned or licensed by us by filing infringement claims. We may be subject to further litigation in the future, involving claims that we have misappropriated or misused other parties' trade secrets or information. To the extent we gain greater market visibility, we face a higher risk of being the subject of intellectual property infringement claims, which is not uncommon with respect to the biopharmaceutical industry. As enforcement of intellectual property rights is difficult, unpredictable, time- consuming, and expensive, we may fail in enforcing our rights, in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole, in part, or on a claim- by- claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to

commercialize our product candidates or methods, or our immunotherapy platform technology, and then compete directly with us, without payment to us. Even if resolved in our favor, such litigation and other legal proceedings may cause us to incur significant expenses and would be likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities, and may impact our reputation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace ~~. We and our Chief Executive Officer are currently involved in legal proceedings with Altor / NantCell, in which Altor / NantCell has alleged, among other things, a claim of trade secret misappropriation and other related claims against us and breach of contract and fiduciary duty, among other claims, against our chief executive officer in arbitration, and an adverse result could have a negative material impact on our business and operations. On December 23, 2022, a lawsuit was filed by Altor BioScience, LLC and NantCell, Inc., collectively, Altor / NantCell, against the Company in U. S. District Court for the Southern District of Florida (the " Court "), alleging misappropriation of trade secrets under state and federal laws, inducement of breach of contract and breach of fiduciary duty, tortious interference with contractual relations, specific performance, conversion, unjust enrichment, specific performance for assignment of patents and patent applications, constructive trust, and replevin. The complaint against us is based on very similar allegations as those alleged by Altor / NantCell in an arbitration commenced in December 2022 against our Founder and Chief Executive Officer, Dr. Hing C. Wong, who was formerly employed by Altor / NantCell. Altor / NantCell alleges that Dr. Wong purportedly took Altor / NantCell' s confidential and trade- secret information and used it to form and build competing products for us. On January 31, 2023, the Company filed a motion to compel arbitration, a motion for the stay of the litigation, and a motion to dismiss the complaint (" motion to compel "). On April 18, 2023, the U. S. District Court for the Southern District of Florida (the " Court ") heard oral argument on the Company' s motion to compel and ordered the parties to provide supplemental briefing by April 28, 2023. Before the Court ruled on the Company' s motion to compel, on April 26, 2023, the parties stipulated that Altor / NantCell' s action against the Company would be consolidated with the Altor / NantCell arbitration demand against Dr. Wong. On April 27, 2023, the Court approved the parties' stipulation and ordered the parties to arbitration. On May 1, 2023, Altor / NantCell filed a demand against the Company before JAMS. On May 3, 2023, Altor / NantCell dismissed the federal court action without prejudice and the Court ordered the case dismissed without prejudice and closed the case. Altor / NantCell' s proceeding against the Company is now proceeding in arbitration before JAMS, with an arbitration hearing scheduled for May 20, 2024. On March 26, 2024, Altor / NantCell gave notice that they are filing a complaint (the " Complaint ") against the Company in the Chancery Court of the State of Delaware for the contribution of legal fees and expenses advanced to Dr. Wong, our founder and chief executive officer, in connection with the arbitration discussed above. Prior to the filing of the Complaint, Altor / NantCell had previously sought advancement from the Company and the Company agreed to advance 50 % of Dr. Wong' s legal fees going forward from December 2023. On January 8, 2024, Altor / NantCell reserved their right to pursue contribution against the Company for 50 % of the amount Altor / NantCell sent for advancement of expenses for Dr. Wong. In the Complaint, Altor / NantCell seek 50 % of the fees they have already advanced to Dr. Wong, a declaration that the Company has an obligation to contribute 50 % of the advancement of Dr. Wong' s expenses including 50 % of Dr. Wong' s expenses incurred in connection with the arbitration through final resolution of the matter, and costs and fees in bringing this action. We have incurred and expect to continue to incur significant expenses in connection with our defense in the arbitration proceedings with Altor / NantCell. Altor / NantCell has considerable resources available to it; we, on the other hand, are a company in the early stages of our clinical trials with comparatively few resources available to us to engage in costly and protracted litigation. These claims asserted against us have been and are expected to continue to be costly to defend and could limit our ability to use some technologies in the future. They have been, and will be, time consuming, have diverted and will divert our chief executive officer' s, management' s and scientific personnel' s attention, may be used by Altor / NantCell in an effort to generate negative publicity with our customers and investors, and may result in liability for substantial damages and reimbursements. For example, we have incurred and anticipate that we will continue to incur significant expense and substantial time in defending ourselves in the current disputes with Altor / NantCell and our advancement of legal expenses of Dr. Wong in connection therewith. There can be no assurance that we will not be required to pay damages or reimburse Altor / NantCell for the amounts they are seeking in connection with these matters. We anticipate that Altor / NantCell may continue to use options available to it through the arbitrator, including filing amended or new demands, other arbitration submissions, public statements and press releases, regardless of merit, in an attempt to disrupt our business and create uncertainty about our future prospects, which could create volatility in the trading price of our common stock or damage to our reputation. An adverse judgment in the Altor / NantCell arbitration proceedings could require us to pay damages, attorneys' fees, costs and expenses, or result in injunctive relief, or generate negative publicity, any of which could materially adversely affect our business, financial condition, results of operations, and prospects. We may also in the future be involved with other litigation. We expect that the number of such claims may increase as our scale and the level of competition in our industry segments grows~~ . Intellectual property rights of third parties could adversely affect our ability to develop or commercialize our product candidates, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our product candidates or any products, if approved, without infringing or otherwise violating the intellectual property and other proprietary rights of third parties. Our competitive position may suffer if patents issued to third parties or

other third- party intellectual property rights cover our methods or product candidates or elements thereof, our manufacture or uses relevant to our development plans, our product candidates or other attributes of our product candidates, or our immunotherapy platform technology. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third- party intellectual property right concerned, which can be expensive and time- consuming, or have to enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms at all. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. If we are sued for patent infringement, we would need to demonstrate that our product candidates or platform technology either do not infringe the patent claims of a relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. We may not have sufficient resources to bring these actions to a successful conclusion. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable, and time- consuming litigation and may be prevented from or experience substantial delays in marketing our product candidates. In addition, indemnity provisions in various agreements and our corporate documents potentially expose us to substantial liability for intellectual property infringement and other claims. In the ordinary course of business, we enter into agreements that may include indemnification provisions under which we agree to indemnify them for losses suffered or incurred as a result of claims of intellectual property infringement or other liabilities relating to or arising from our clinical trials, breach of warranties or other contractual obligations. In some cases, the indemnification will continue after the termination of the applicable agreement. In addition, in accordance with our bylaws and pursuant to indemnification agreements entered into with directors, officers and certain employees, we have indemnification obligations for claims brought against these persons arising out of certain events or occurrences while they are serving at our request in such capacities. For example, our founder and chief executive officer is subject to a claim from a former employer. We agreed to advance certain defense costs and other expenses, subject to an undertaking to repay us such amounts if, and to the extent that, it is ultimately determined that he is not entitled to indemnification, and his former employer is seeking reimbursement from us for advancements it has made on his behalf. The matter is ongoing. If these matters are resolved in favor of the former employer and if we are required to indemnify our founder and chief executive officer for a loss, we may be required to make an indemnity payment. While we maintain directors' and officers' liability insurance, such insurance may not be applicable, be adequate, or cover all liabilities that we may incur. Large indemnity payments, individually or in the aggregate, could have a material impact on our financial position. Our involvement in litigation, and in any interferences, post- grant proceedings, opposition proceedings, or other intellectual property proceedings inside and outside of the United States may divert management from focusing on business operations, and even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. We may need to obtain licenses of third- party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated. We own and are pursuing rights to the intellectual property, including patent applications relating to our immunotherapy platform technology and our product candidates. In the future, we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our platform technology and product candidates. The fusion components of our product candidates may have also been the subject of research by companies that could have filed patent applications on their specific construct and therapeutic methods. There can be no assurance any such patents will not be asserted against us or that we will not need to seek licenses from such third parties. We may not be able to secure such licenses on acceptable terms, if at all, and any such litigation would be costly and time-consuming. Should we be required to obtain licenses to any third- party technology, including any such patents required to manufacture, use, or sell our product candidates or any products, if approved, the growth of our business will likely depend in part on our ability to acquire, in- license, maintain, or use these proprietary rights. The inability to obtain any third- party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to successfully obtain a license to third- party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program and our business and financial condition could suffer. We are and may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances, where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. Disputes challenging our rights in or to patents or other intellectual property, such as the lawsuit as we are

currently facing in our legal proceedings with Altor / NantCell, have been and could be expensive and time consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own. In addition, interferences, post- grant proceedings, opposition proceedings, derivation proceedings, or other intellectual property proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co- ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. We may rely on trade secret and proprietary know- how, which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and product candidates, we may rely on trade secrets and / or confidential know- how to protect our technology, especially where patent protection is believed to be of limited value, to maintain our competitive position with respect to our research programs and product candidates. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know- how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know- how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees or by other third parties of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus adversely eroding our competitive position in our market. Further, monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our internally- developed technology will be effective. Enforcing a claim that a third party illegally obtained and is using trade secrets and / or confidential know- how is also expensive, time- consuming, and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, some courts inside and outside the United States are less willing or are unwilling to protect trade secrets or other proprietary information. Trade secrets can over time be disseminated within the biopharmaceutical industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our employees, consultants, contractors, collaborators, advisors, and other third parties to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our product candidates and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed. In addition, our competitors may independently develop substantially equivalent trade secrets, proprietary information, or know- how and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and / or confidential know- how. Under certain circumstances and to make it more likely that we have freedom to operate, we may also decide to publish some know- how to make it difficult for others to obtain patent rights covering such know- how, at the risk of potentially exposing our trade secrets to our competitors. We ~~are currently and~~ may be in the future subject to third- party claims asserting that our employees, consultants, contractors, collaborators, or advisors have misappropriated or wrongfully used or disseminated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees, including our senior management, were previously employed at universities or at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non- disclosure, and non-competition agreements in connection with such previous employment. Similarly, we work with consultants, contractors, collaborators, advisors, or other third parties who have worked with, and do currently work with, other companies, including our competitors or potential competitors, and have executed proprietary rights, non- disclosure, and non- competition agreements in connection with such other companies. Although we try to ensure that our employees, consultants, contractors, collaborators, advisors, or other third parties do not use or disclose the proprietary information or know- how of others in their work for us, we are and may become subject to claims that we or these employees or individuals that we work with have used or disclosed confidential information or intellectual property of others, including trade secrets or other proprietary information, or that we caused an individual to breach the terms of his or her non- competition or non- solicitation agreement with a current or former

employer or competitor ~~. For example, as described above, we are engaged in legal proceedings with Altor / NantCell, which alleges misappropriation of trade secrets, inducement of breach of contract and breach of fiduciary duty, among other claims against the company relating to our founder and chief executive officer' s former employment with Altor / NantCell~~ . Litigation may be necessary to defend against these claims and, even if we are successful, could result in substantial costs and could be a distraction to management, our employees, and our routine business. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to develop or commercialize our technology or product candidates. Such a license may not be available on commercially reasonable terms or at all. Moreover, any such litigation or the threat thereof may adversely affect our reputation and our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations, and financial condition. Risks Related to Data Privacy and Cybersecurity We collect and maintain information in digital form that is necessary to conduct our business, and we are dependent on our information technology systems and those of third parties to operate our business. In the ordinary course of our business, we collect, store, and transmit large amounts of confidential information, including intellectual property, proprietary business information, and personal information, and data to comply with cGMP, clinical and data integrity requirements. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise. We have also outsourced elements of our information technology infrastructure, and as a result a number of third- party vendors may or could have access to our confidential information. Despite the implementation of security measures, our information technology systems and data and those of our contractors and consultants are vulnerable to compromise or damage from computer hacking, malicious software, fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. While we continue to make investments to improve the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail, or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers, and others. Although to our knowledge we have not experienced any material cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to regulatory actions taken by governmental authorities, litigation under laws that protect the privacy of personal information, or other forms of legal proceedings, which could result in significant liabilities or penalties. Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price, stockholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums. We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us or our collaborators, from research institutions and our collaborators, and directly from individuals. We and our partners and vendors are subject to various federal, state, and foreign data protection laws and regulations (i. e., laws and regulations that address data privacy and security). If we fail to comply with these laws and regulations, we may be subject to litigation, regulatory investigations, enforcement notices, enforcement actions, fines, and criminal or civil penalties, as well as negative publicity and a potential loss of business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health- related and other personal information could apply to our operations or the operations of our partners. For example, most healthcare providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended HITECH. Under HIPAA, we could potentially face substantial criminal or civil penalties if we knowingly receive individually identifiable health information from a HIPAA- covered healthcare provider or research institution that has not satisfied HIPAA' s requirements for disclosure of individually identifiable health information, or otherwise violate applicable HIPAA requirements related to the protection of such information. Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute a violation of the Federal Trade Commission Act. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws (for example, the CCPA and the California Privacy Rights Act) requiring notification of affected individuals and state regulators in the event of a breach of personal information. Our clinical trial programs and research collaborations outside the United States may implicate international data protection laws, including in Europe the GDPR. If our privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices, and / or enforcement actions requiring us to change the way we use personal data and / or fines. In addition to statutory enforcement, a personal data breach can lead to negative publicity and a potential loss of business. Further, following the United Kingdom' s withdrawal from the E. U. effective as of December 31, 2020, we have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, which may have differing requirements. If we fail to comply with United Kingdom data protection laws, we may be subject to litigation, regulatory investigations, enforcement notices, and / or enforcement actions, as well as negative publicity and a potential loss of business. We are also subject to evolving EEA laws on data export, as we may transfer personal data from the EEA to other jurisdictions. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data

from the EEA to the United States. For example, on July 16, 2020, the CJEU invalidated the Privacy Shield, under which personal data could be transferred from the EEA to United States entities who had self- certified under the Privacy Shield scheme. Moreover, it is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature. As government authorities issue further guidance on personal data export mechanisms and / or start taking enforcement action, we could suffer additional costs, complaints, and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. These laws and regulations may apply, not only to us, but also to vendors that store or otherwise process data on our behalf, such as information technology vendors. If such a vendor misuses data we have provided to it, or fails to safeguard such data, we may be subject to litigation, regulatory investigations, enforcement notices, and / or enforcement actions, as well as negative publicity and a potential loss of business. Risks Related to Ownership of Our Common Stock Our stock price may be volatile or may decline regardless of our operating performance, resulting in substantial losses for investors. The market price of our common stock may be highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors described in this " Risk Factors " section and elsewhere in this Annual Report. 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. Additionally, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile. Also, broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of December 31, ~~2023~~ **2024**, our executive officers, directors and their respective affiliates beneficially owned approximately ~~45~~ **40. 6** % of our outstanding voting stock (excluding any stock options exercisable within 60 days of such date held by such persons). ~~Additionally, in February 2024, certain of our directors and officers, in the aggregate, acquired approximately 4 % of our outstanding voting stock in private placement of common stock, further~~ **Further ,** ~~increasing the beneficial ownership of~~ these stockholders **invested $ 2. 9 million in senior secured notes, which will be converted according to the Principal Terms agreed if approved by nonaffiliated stockholders at a Special Meeting of the Stockholders to be held on March 31, 2025**. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval **, in matters where they are eligible to vote**. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. We are an emerging growth company as well as a " smaller reporting company ", and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies or smaller reporting companies could make our common stock less attractive to investors. We are an " emerging growth company " as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including: • not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes- Oxley Act; • reduced disclosure obligations regarding executive compensation in our periodic reports and annual reports on Form 10- K; and • exemptions from the requirements of holding non- binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of: • the last day of the fiscal year in which we have more than $ 1. 235 billion in annual revenue; • the date we qualify as a " large accelerated filer, " with at least $ 700. 0 million of equity securities held by non- affiliates; • the date on which we have issued, in any three- year period, more than $ 1. 0 billion in non- convertible debt securities; or • December 31, 2026. Additionally, we are a " smaller reporting company " as defined in Item 10 (f) (1) of Regulation S- K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non- affiliates exceeds $ 250 million as of the end of that year' s second fiscal quarter, or (ii) our annual revenues exceeded $ 100 million during such completed fiscal year and the market value of our common stock held by non- affiliates exceeds $ 700 million as of the end of that year' s second fiscal quarter. We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded to emerging growth companies or smaller reporting companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these audited financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. If we fail to maintain proper and effective internal controls over financial reporting, our ability to produce accurate and timely financial statements could be impaired. Pursuant to Section 404 of the Sarbanes- Oxley Act, our management was required to report upon the effectiveness of our internal control over financial reporting beginning with the

annual report for our fiscal year ending December 31, 2022. When we lose our status as an " emerging growth company " and a " smaller reporting company, " and become an " accelerated filer " or a " large accelerated filer, " our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we have implemented and will continue to implement additional financial and management controls, reporting systems and procedures and we have hired and intend to continue to hire additional accounting and finance staff. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock. Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things: • establish a staggered board of directors (the " Board ") divided into three classes serving staggered three- year terms, such that not all members of the Board will be elected at one time; • authorize our Board to issue new series of redeemable preferred stock without stockholder approval and create, subject to applicable law, a series of redeemable preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock; • eliminate the ability of our stockholders to call special meetings of stockholders; • eliminate the ability of our stockholders to fill vacancies on our Board; • establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings; • permit our Board to establish the number of directors; • provide that our Board is expressly authorized to make, alter or repeal our amended bylaws; • provide that stockholders can remove directors only for cause and only upon the approval of not less than 66 2 / 3 of all outstanding shares of our voting stock; • require the approval of not less than 66 2 / 3 of all outstanding shares of our voting stock to amend our bylaws and specific provisions of our certificate of incorporation; and • limit the jurisdictions in which certain stockholder litigation may be brought. As a Delaware corporation, we are subject to the anti- takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two- thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of our company. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation, provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or any director, officer, or other employee arising pursuant to the Delaware General Corporation Law, (4) any action to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court' s having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. These provisions may limit an investor' s ability to bring a claim in a judicial forum that it finds favorable for disputes with our company, including by increasing the cost of such lawsuits, which may discourage such claims. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to

have waived our compliance with the federal securities laws and the rules and regulations thereunder, or maintain profitability. General Risk Factors Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Our operations and the global economy have been impacted by increasing interest rates and inflation. Likewise, the capital and credit markets may be adversely affected by the war in the Middle East, conflict between Russia and Ukraine, and the possibility of a wider European, Middle Eastern, or global conflict, global sanctions imposed in response thereto, or an energy crisis. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn. Our money market or other investments or bank deposits may be subject to market, interest and credit risk that may reduce in value. The value of our investments may decline due to increases in interest rates, downgrades of the bonds and other securities included in our money market or other investments and instability in the global financial markets that reduces the liquidity of securities included in our portfolio. In addition, we are aware of the closure of Silicon Valley Bank and appointment of the Federal Deposit Insurance Corporation as receiver. Furthermore, a possible recession, rising inflation, and the lingering effects of the COVID- 19 pandemic has and may continue to adversely affect the financial markets in some or all countries worldwide. Each of these events may cause us to record charges to reduce the carrying value of our money market or other investments or sell investments for less than our acquisition cost. Although we attempt to mitigate these risks through diversification of our investments and continuous monitoring of our portfolio' s overall risk profile, the value of our investments may nevertheless decline. Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel. Our success depends upon the continued contributions of our key management, scientific, and technical personnel, many of whom have been instrumental for us and have substantial experience with our product candidates and related technology. The loss of key managers and senior scientists could delay our research and development activities. Despite our efforts to retain valuable employees, members of our management, scientific, and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. In addition, the competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly- skilled scientific, technical, and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.