Risk Factors Comparison 2024-03-12 to 2023-03-07 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

An investment in our common stock is speculative and illiquid and involves a high degree of risk including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this report and our other reports filed with the Securities and Exchange Commission. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and financial condition. If any of the following risks actually materialize, our business, financial condition and / or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock. Summary of Risks Associated with Our Business Our business and an investment in our company is subject to numerous risks and uncertainties, including those highlighted in the section titled " Risk Factors " immediately following this summary. Some of these risks include: • We have never generated any product revenues; • We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability; • We will need substantial additional funding, and certain terms included in our financing transactions may restrict our ability to raise such capital at the times and in the manner we may require; • We expect that we will rely on third parties to assist us in conducting clinical trials for our drug candidates, and if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business would be substantially harmed; • Changes in geopolitical conditions, U. S.- China trade relations and other factors beyond our control may adversely impact our business and operating results; • We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates; • Clinical trials are very expensive, time- consuming, difficult to design and implement and involve an uncertain outcome; • If we are not able to obtain any required regulatory approvals for our drug candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited; • We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively; • We do not have our own manufacturing capabilities and will rely on third parties to produce clinical and commercial supplies of our product candidates; • We are, and will be, completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our drug candidates or fail to do so at acceptable quality levels or prices; • We have in- licensed a portion of our intellectual property, and if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property; and • We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock. Risk Related to our Company and our Business Risks Related to Our **Business,** Financial Position and Need for Capital We are a biopharmaceutical company with a limited operating history. We are a biopharmaceutical company with a limited operating history. All ~~of~~ our product candidates that we do not intend to out- license are in the discovery stage, pre- clinical, or clinical development stage. We must complete clinical studies and other development activity and receive regulatory approval of an NDA or BLA, before commercial sales of a product can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early- stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital- intensive business. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to: • successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound; • successfully manufacture our clinical products and establish commercial drug supply; • successfully complete the pre- clinical and clinical trials necessary to obtain regulatory approval for the marketing of our drug candidates; • secure market exclusivity and / or adequate intellectual property protection for our drug candidates; • attract and retain an experienced management and advisory team; • secure acceptance of our drug candidates in the medical community and with third **-** party payors and consumers; • launch commercial sales of our drug candidates, whether alone or in collaboration with others; and • raise sufficient funds in the capital markets to effectuate our business plan. If we cannot successfully execute any one of the foregoing, our business may not succeed, and your investment will be adversely affected. We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. We may never become profitable or, if we achieve profitability, be able to sustain profitability. We expect to incur substantial expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize any of our drug candidates. To date, we have not generated any revenue from our drug candidates, and we expect to incur significant expense to complete our pre- clinical and clinical program for our drug candidates in the ~~United States~~ **U. S.** and elsewhere. We may never be able to obtain regulatory approval for the marketing of our drug candidates in any indication in the ~~United States~~ **U. S.** or internationally. Even if we are able to commercialize our drug candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our net losses for the years ended

December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** were approximately $ **44, 603, 000 and $** 42, 347 ~~, 000 and $ 45, 640~~, 000, respectively. As of December 31, ~~2022~~ **2023**, we had an accumulated deficit of approximately $ ~~392. 1 million~~ **436, 684, 000**. We may elect to pursue FDA approval for our drug candidates, which will result in significant additional research and development expenses. As a result, we expect to continue to incur substantial losses for the foreseeable future, and these losses will increase. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital. Our cash, cash equivalents, or investments will only fund our operations for a limited time, and we will need to raise additional capital to support our development and commercialization efforts. We are currently operating at a loss and expect our operating costs will increase significantly as we incur further costs related to pre- clinical development and the clinical trials for our drug candidates. As of December 31, ~~2022~~ **2023**, we held cash, cash equivalents, and investments of approximately $ **20** ~~59. 2 million. We expect the cash~~, **906** ~~cash equivalents~~, **000. On May 31, 2023, we entered into Amendment No. 1 to the Open Market Sale Agreement originally dated August 6, 2020 (the " Open Market Sale Agreement ") with Jefferies LLC (" Jefferies ") pursuant to which Jefferies is serving as the sales agent to sell shares of our common stock through** ~~and~~ **an** ~~investments~~ **" at- the- market offering. " From May 31, 2023 through the date** of **this filing, we have sold** approximately $ ~~59~~ **21, 237, 000 in aggregate gross proceeds of shares of our common stock under the Open Market Sale Agreement. On January 30, 2024, we delivered written notice to Jefferies that we were suspending and terminating the prospectus supplement related to the shares issuable pursuant to the Open Market Sale Agreement. We will not make any sales pursuant to the Open Market Sale Agreement unless and until a new prospectus supplement is filed. On January 31, 2024, we entered into an underwriting agreement with Jefferies, as representative (the " Representative ") of the several underwriters (the " Underwriters "), relating to an underwritten public offering of 4, 325, 000 shares of our common stock, at a price to the public of $ 19. 00 per share (" January 2024 Public Offering"). The Underwriters were also granted a 30- day option to purchase up to an additional 648, 750 shares of common stock at the public offering price. On January 31, 2024, the Representative gave notice of the Underwriters' election to exercise the option to purchase additional shares, in full. On February** 2 ~~million at December 31~~, ~~2022 to be sufficient to meet our operating and capital requirements through the second quarter of~~ 2024, ~~based on planned expenditures~~ **we completed the public offering raising gross proceed of approximately $ 94, 500, 000 and net proceeds of $ 88, 500, 000 after deducting underwriting discounts and commissions and other estimated offering expenses payable by us**. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, and could increase our expenses and require that our assets secure such debt. Equity financing, if obtained, could result in dilution to our then existing stockholders and / or require such stockholders to waive certain rights and preferences. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. In addition, if we are unable to secure sufficient capital to fund our operations, we may choose to pursue, as an alternative, strategic collaborations that could require us to share commercial rights to our drug candidates with third parties in ways that we currently do not intend or on terms that may not be favorable to us. If we choose to pursue additional indications and / or geographies for our drug candidates or otherwise expand more rapidly than we presently anticipate we may also need to raise additional capital sooner than expected. Our Loan and Security Agreement contains restrictive and financial covenants that may limit our operating flexibility. On July 28, 2020, we entered into a Loan and Security Agreement (" the Loan and Security Agreement ") with our subsidiary, Corbus Pharmaceuticals, Inc., as borrower, us, as guarantor, and each lender party thereto (the " Lenders "), K2 HealthVentures LLC **(" " K2HV")**, an unrelated third party, as administrative agent for the Lenders, and Ankura Trust Company, LLC, an unrelated third party, as collateral agent for the Lenders, pursuant to which K2HV ~~may provide~~ **provided** us with **a** term ~~loans~~ **loan** ~~in an aggregate principal amount~~ of ~~up to~~ $ ~~50~~ **20**, 000, 000 **upon signing**. The Loan and Security Agreement is secured by a lien ~~covering substantially all~~ of our personal property, excluding intellectual property **, up to the outstanding balance of the term loan**. The Loan and Security Agreement contains customary representations, warranties, and covenants. including restrictive covenants by **us** ~~the Company~~ and Borrower limiting additional indebtedness, liens, mergers and acquisitions, dispositions, investments, distributions, subordinated debt, transactions with affiliates and fundamental changes. We therefore may not be able to engage in any of the foregoing types of transactions unless we obtain the consent of K2 HealthVentures or prepay the outstanding amount under the Loan and Security Agreement. The Loan and Security Agreement also contains certain financial covenants, including requirements to maintain unrestricted cash in the amount of $ 10, 000, 000 or the amount of all principal loans outstanding if certain regulatory and developmental milestones do not occur. The restrictions and covenants in the Loan and Security Agreement, as well as those contained in any future debt financing agreements that we may enter into, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. Our ability to comply with these covenants and restrictions may be affected by events beyond our control, and breaches of these covenants and restrictions could result in a default under the loan agreement and any future financing agreements that we may enter into. Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization Our success is dependent upon successful development of our drug candidates in our pipeline or that we may acquire. If we are unable to generate revenues from any product candidates, our ability to create stockholder value will be limited. We do not generate revenues from any FDA approved drug products. Our current business currently depends on the successful development, regulatory approval, and commercialization of our pre- clinical drug candidates, which may never occur. CRB- 701 is currently in a Phase 1 clinical trial being conducted by CSPC in China. **The FDA cleared our IND for CRB- 601 on January 9, 2024. We plan to**

commence clinical trials for both CRB- 701 and CRB- 601 in 2024. We are **also** completing pre- clinical testing for CRB- ~~601~~ **913** in the U. S. and we expect to file an IND in ~~2023~~ **2024** . We note that most drug candidates never reach the clinical development stage and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. **Drug development involves** ~~Notably, we advanced our product candidate lenabasum to~~ a ~~phase 3 study. In June 2021~~ **lengthy and expensive process with an uncertain outcome** , **and results** ~~we announced that the primary endpoint in our DETERMINE phase 3 study~~ of **earlier studies and trials may** ~~lenabasum for treatment of dermatomyositis was~~ not **be predictive** ~~met. We will continue to face risks related to the uncertainty~~ of **future trial results. Our pre- clinical and** clinical trials **may be unsuccessful, which would materially harm our business. Even if our initial trials are successful, we will be required to conduct additional trials to establish the safety and efficacy of our drug candidates before** ~~and~~ **an NDA or BLA can be filed with the FDA for marketing approval of any of our drug candidates. Drug testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome.** ~~success~~ **Success** in early phases of pre- clinical and clinical trials does not ensure that later clinical trials will be successful ~~. Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Our pre- clinical and clinical trials may be unsuccessful, which would materially harm our business. Even if our initial trials are successful, we will be required to conduct additional trials to establish the safety and efficacy of our drug candidates before an NDA or BLA can be filed with the FDA for marketing approval of any of our drug candidates. Drug testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre- clinical and clinical trials does not ensure that later clinical trials will be successful~~ , and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the drug testing process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the ~~United States~~ **U. S.** and other countries, which regulations differ from country to country. We are not permitted to market any of our drug candidates as prescription pharmaceutical products in the ~~United States~~ **U. S.** until we receive approval of an NDA or BLA from the FDA or in foreign markets until we receive the requisite approval from comparable regulatory authorities in such countries. In the ~~United States~~ **U. S.** , the FDA generally requires the completion of pre- clinical and clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA or BLA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA or BLA to the FDA and even fewer are eventually approved for commercialization. We have never submitted an NDA or BLA to the FDA or any comparable applications to other regulatory authorities. If our development efforts for our drug candidates, including regulatory approval, are not successful for our planned indications, or if adequate demand for our drug candidates is not generated, our business will be harmed. Receipt of necessary regulatory approval is subject to a number of risks, including the following: ~~•~~ pre- clinical testing may not yield results that justify progressing to clinical testing; ~~•~~ the FDA or comparable foreign regulatory authorities or institutional review boards, or IRBs, may disagree with the design or implementation of our clinical trials; ~~•~~ we may not be able to provide acceptable evidence of the safety and efficacy of our drug candidates; ~~•~~ the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, the European Medicines Agency, or EMA, or other comparable foreign regulatory authorities for marketing approval; ~~•~~ the dosing of our drug candidates in a particular clinical trial may not be at an optimal level; ~~•~~ patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidates; ~~•~~ the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA, or other submission or to obtain regulatory approval in the ~~United States~~ **U. S.** or elsewhere; ~~•~~ the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; ~~•~~ the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and ~~•~~ the FDA or comparable foreign regulatory authorities may decide that the clinical trial endpoints we have chosen, the statistical analysis plans that we use, or any other parameter that we rely on to show the safety and efficacy of our drugs, are not parameters that can be used to support approval of our products. Failure to obtain regulatory approval for any of our drug candidates for the foregoing or any other reasons will prevent us from commercializing such product candidate as a prescription product, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with the endpoints that we have chosen to use in our clinical trials, our assessment of the results of our clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidates. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre- clinical or other studies. In addition, varying interpretations of the data obtained from pre- clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third- party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of pre- clinical, clinical and / or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate' s safety and efficacy for each indication. Our drug candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the

type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for any of our drug candidates in any indication will prevent us from commercializing such product candidates, and our ability to generate revenue will be materially impaired. If we are not able to obtain any required regulatory approvals for our drug candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited. Drug 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. Our drug candidates are in various stages of discovery, pre- clinical, and clinical testing. Pre- clinical tests are performed at an early stage of a product' s development and provide information about a drug candidate' s safety and effectiveness on laboratory animals. Pre- clinical tests can last years. If a product passes its pre- clinical tests satisfactorily and we determine that further development is warranted, we would file an IND application for the product with the FDA, and if the FDA gives its approval, we would begin Phase 1 clinical tests. If Phase 1 test results are satisfactory and the FDA gives its approval, we can begin Phase 2 clinical tests. If Phase 2 test results are satisfactory and the FDA gives its approval, we can begin Phase 3 pivotal studies. Once clinical testing is completed and an NDA or BLA is filed with the FDA, it may take more than a year to receive FDA approval. The results of pre- clinical studies and early clinical trials may not be predictive of the results of later- stage clinical trials. We cannot assure you that the FDA will view the results as we do or that any future trials of our drug candidates will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre- clinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our drug candidates may not be successful. In all cases, we must show that a drug candidate is both safe and effective before the FDA, or drug approval agencies of other countries where we intend to sell the product, will approve it for sale. Our research and testing programs must comply with drug approval requirements both in the ~~United States~~ **U. S.** and in other countries, since we are developing our drug candidates with the intention to, or could later decide to, commercialize them both in the U. S. and abroad. A product may fail for safety or effectiveness at any stage of the testing process. A major risk we face is the possibility that none of our products under development will come through the testing process to final approval for sale, with the result that we cannot derive any commercial revenue from them after investing significant amounts of capital in multiple stages of pre- clinical and clinical testing. In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for our drug candidates. For example, our trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics, including demographic factors and health status. **Changes in product candidate manufacturing or formulation may result in additional costs or delay. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials. Approval may be delayed or denied because we cannot satisfy FDA' s Chemistry, Manufacturing and Control Requirements. Formulation and manufacturing of biologic products such as ours is complex and expensive. Our BLAs must include information about the chemistry and physical characteristics of our products, and we must demonstrate that we have a reliable process for manufacturing the products in commercial quantities in accordance with FDA' s current cGMP requirements. The manufacturing process must consistently produce quality batches of the biologic, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life. If we are unable to successfully complete any of these complex steps, approval of our biologic may be delayed or denied.** Even if we receive regulatory approval for our drug candidates, we still may not be able to successfully commercialize any of our products, and the revenue that we generate from sales, if any, may be limited. If approved for marketing, the commercial success of our drug candidates will depend upon their acceptance by the medical community, including physicians, patients and health - care payors. The degree of market acceptance of our drug candidates will depend on a number of factors, including: - demonstration of clinical safety and efficacy; - relative convenience, pill burden and ease of administration; - the prevalence and severity of any adverse effects; - the willingness of physicians to prescribe our drug candidates and of the target patient population to try new therapies; - safety, tolerability and efficacy of our drug candidates compared to competing products; - safety of competing products may impact our drug candidates; - the introduction of any new products that may in the future become available to treat indications for which our drug candidates may be approved; - new procedures or methods of treatment that may reduce the incidences of any of the indications in which our drug candidates may show utility; - pricing and cost- effectiveness; - the inclusion or omission of our drug candidates in applicable treatment guidelines; - the effectiveness of our or any future collaborators' sales and marketing strategies; - limitations or warnings contained in FDA- approved labeling; - our ability to

obtain and maintain sufficient third- party coverage or reimbursement from government health - care programs, including Medicare and Medicaid, private health insurers and other third- party payors; and - • the willingness of patients to pay out- of- pocket in the absence of third- party coverage or reimbursement. If any of our drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, health - care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third- party payors on the benefits of our drug candidates may require significant resources and may never be successful. In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our drug candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render our drug candidates not commercially viable. For example, regulatory authorities may approve our drug candidates for fewer or more limited indications than we request, may not approve the prices we intend to charge for our drug candidates, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve our drug candidates with labels that do not include the labeling claims necessary or desirable for the successful commercialization of a particular indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals, such as risk management plans and a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our drug candidates. Moreover, product approvals may be withdrawn for non- compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our drug candidates. Even if we obtain marketing approval for our drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our drug candidates could be subject to labeling and other restrictions and withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates. Even if we obtain ~~United States~~ **U. S.** regulatory approval of our drug candidates for an indication, the FDA may still impose significant restrictions on their indicated uses or marketing or the conditions of approval or impose ongoing requirements for potentially costly and time- consuming post- approval studies, including Phase 4 clinical trials, and post- market surveillance to monitor safety and efficacy. Our drug candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post- market information. These requirements include registration with the FDA, continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post- approval, continued compliance with the CSA and ongoing review by the DEA. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with ~~current Good Manufacturing Practices, or~~ cGMP ~~,~~ requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the ~~United States~~ **U. S.** and similar legal requirements in other countries. In the ~~United States~~ **U. S.** , the distribution of product samples to physicians must comply with the requirements of the U. S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U. S. Anti- Kickback Statute, U. S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific / educational grant programs. If we participate in the U. S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U. S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U. S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries. In addition, if any of our drug candidates are approved for an indication, our product labeling, advertising, and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product' s approved labeling. If we receive marketing approval for any of our drug candidates, physicians may nevertheless legally prescribe such products to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off- label uses, we may become subject to significant liability and government fines. 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 of permanent injunctions under which specified promotional conduct is changed or curtailed. If we or a regulatory agency discover 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 if we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions: ▪ restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; ▪ issuance of warning letters or untitled letters; ▪ injunctions or the imposition of civil or criminal penalties or monetary fines; ▪ suspension of any ongoing clinical trials; ▪ refusal to approve pending applications or supplements to approved applications filed by us, or

suspension or revocation of product license approvals; ▪ suspension of, or imposition of restrictions on, operations, including costly new manufacturing requirements; or ▪ product seizure or detention or refusal to permit the import or export of product. The occurrence of any event or penalty described above may inhibit our ability to commercialize our drug candidates and generate revenue. Adverse regulatory action, whether pre- or post- approval, can also potentially lead to product liability claims and increase our product liability exposure. **Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in post- approval regulatory action. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Undesirable side effects caused by product candidates could cause us, any partners with which we may collaborate or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or our potential partners, to cease further development of or deny approval of product candidates for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects. Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U. S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including: • regulatory authorities may withdraw their approval of the product; • regulatory authorities may require a recall of the product or we or our potential partners may voluntarily recall a product; • regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or field alerts to physicians and pharmacies; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS; • we may have limitations on how we promote the product; • we may be required to change the way the product is administered or modify the product in some other way; the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post- marketing testing and surveillance to monitor the safety or efficacy of the product; • the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post- marketing testing and surveillance to monitor the safety or efficacy of the product • sales of the product may decrease significantly; • we could be sued and held liable for harm caused to patients; and • our brand and reputation may suffer. Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us or our potential partners from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.** We have entered into, and may in the future enter into, collaboration agreements for the licensing, development, and ultimate commercialization of some of our drug candidates. In such cases, we will depend greatly on our third- party collaborators to license, develop and commercialize such drug candidates, and they may not meet our expectations. We may enter into co-development and commercialization partnerships for our drug candidates where appropriate. The process of identifying collaborators and negotiating collaboration agreements for the licensing, development, and ultimate commercialization of some of our drug candidates may cause delays and increased costs. We may not be able to enter into collaboration agreements on terms favorable to us or at all. Furthermore, some of those agreements may give substantial responsibility over our drug candidates to the collaborator. Some collaborators may be unable or unwilling to devote sufficient resources to develop our drug candidates as their agreements require. They often face business risks similar to ours, and this could interfere with their efforts. Also, collaborators may choose to devote their resources to products that compete with ours. If a collaborator does not successfully develop any one of our products, we will need to find another collaborator to do so. The success of our search for a new collaborator will depend on our legal right to do so at the time and whether the product remains commercially viable. If we enter into collaboration agreements for one or more of our drug candidates, the success of such drug candidates will depend in great part upon our and our collaborators' success in promoting them as superior to other treatment alternatives. We believe that our drug candidates can be proven to offer disease treatment with notable advantages over drugs in terms of patient compliance and effectiveness. However, there can be no assurance that we will be able to prove these advantages or that the advantages will be sufficient to support the successful commercialization of our drug candidates. We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make our drug candidates obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to our drug candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain. In the ~~United States~~ **U. S.** and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our drug candidates, restrict or regulate post- approval activities and affect our ability to profitably sell our drug candidates. Legislative and regulatory proposals have been made to

expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug 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. In the ~~United States~~ **U. S.** , under the Medicare Modernization Act, or MMA, Medicare Part D provides coverage to the elderly and disabled for outpatient prescription drugs by approving and subsidizing prescription drug plans offered by private insurers. The MMA also authorizes Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. The Part D plans use their formulary leverage to negotiate rebates and other price concessions from drug manufacturers. Also under the MMA, Medicare Part B provides coverage to the elderly and disabled for physician- administered drugs on the basis of the drug' s average sales price, a price that is calculated according to regulatory requirements and that the manufacturer reports to Medicare quarterly. Both Congress and the Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare program, from time to time consider legislation, regulations, or other initiatives to reduce drug costs under Medicare Parts B and D. For example, under the 2010 Affordable Care Act, drug manufacturers are required to provide a 50 % discount on prescriptions for branded drugs filled while the beneficiary is in the Medicare Part D coverage gap, also known as the " donut hole. " There have been legislative proposals to repeal the " non- interference " provision of the MMA to allow CMS to leverage the Medicare market share to negotiate larger Part D rebates. Further cost reduction efforts could decrease the coverage and price that we receive for our drug candidates and could seriously harm our business. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under the Medicare program may result in a similar reduction in payments from private payors. The 2010 Affordable Care Act is intended to broaden access to health insurance and reduce or constrain the growth of healthcare spending. Further, the Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also increased the amount of the rebates drug manufacturers must pay to state Medicaid programs, required that Medicaid rebates be paid on managed Medicaid utilization, and increased the additional rebate on " line extensions " (such as extended- release formulations) of solid oral dosage forms of branded products. The law also contains substantial provisions affecting fraud and abuse compliance and transparency, which may require us to modify our business practices with healthcare practitioners and incur substantial costs to ensure compliance. In addition, other legislative changes that affect the pharmaceutical industry have been proposed and adopted in the ~~United States~~ **U. S.** since the ACA was enacted. For example, the Inflation Reduction Act of 2022 included, among other things, a provision that authorizes CMS to negotiate a " maximum fair price " for a limited number of high- cost, single- source drugs every year, and another provision that requires drug companies to pay rebates to Medicare if prices rise faster than inflation. In addition, various states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability. Our future growth depends, in part, on our ability to enter into and succeed in markets outside of the ~~United States~~ **U. S.** , where we may choose to rely on third **-** party collaborations and will be subject to additional regulatory and commercial burdens, risks and other uncertainties. Our future profitability will depend, in part, on our ability to gain approval of and commercialize our drug candidates in non- U. S. markets. In some or all of these non- U. S. markets, we intend to enter into licensing and contractual collaborations with third parties to handle some or all of the tasks and responsibilities necessary to succeed. Our activities in non- U. S. markets are subject to additional risks and uncertainties, including: **-•** our ability to enter into favorable licensing and contractual arrangements with our partners; **-•** our ability to select partners who are capable of achieving success at the tasks they agree to perform; **-•** obtaining timely and sufficient favorable approval terms for our drug candidates; **-•** obtaining favorable pricing and reimbursement; **-•** our inability to directly control commercial activities because we are relying on third parties; **-•** the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements; **-•** different medical practices and customs in foreign countries affecting acceptance in the marketplace; **-•** import or export licensing requirements; **-•** longer accounts receivable collection times; **-•** longer lead times for shipping; **-•** language barriers for technical training; **-•** reduced protection of intellectual property rights in some foreign countries; **-•** foreign currency exchange rate fluctuations; and **-•** the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute. International sales of our drug candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, and trade restrictions and changes in tariffs, any of which may adversely affect our results of operations. If we market our drug candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties. The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so- called " off label " use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct may be subject to significant liability. Similarly, industry codes in the European Union and other foreign jurisdictions prohibit companies from engaging in off- label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U. S. Anti- Kickback Statute, U. S. False Claims Act and similar state laws. Because of the breadth of these laws and the

narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws. The U. S. Anti- Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti- kickback liability. Moreover, recent health - care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U. S. Anti- Kickback Statute and criminal health - care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U. S. Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the U. S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Over the past few years, pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off- label promotion that caused claims to be submitted to Medicare or Medicaid for non- covered, off- label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U. S. Anti- Kickback Statute and the U. S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer' s products from reimbursement under government programs, substantial criminal fines and imprisonment. We are, and will be, completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our drug candidates or fail to do so at acceptable quality levels or prices. We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredients of our drug candidates, or the finished drug products, for use in our clinical trials or for commercial product, if any. As a result, we will be obligated to rely on contract manufacturers if and when our drug candidates are approved for commercialization. We currently rely on ~~a single~~ contract ~~supplier~~ **suppliers** for **the** manufacturing ~~monoclonal antibodies~~ **of our drug candidates** . We have limited experience contracting third parties to manufacture ~~monoclonal antibodies~~ **our drug candidates** and **we** do not control the manufacturing processes of, and are completely dependent on, our ~~two~~ contract manufacturing partners for compliance with cGMPs for manufacture of all active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our drug candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved. Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market our drug candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market our drug candidates. If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our active pharmaceutical ingredient, or API, or our finished products or should cease doing business with us, we could experience significant interruptions in the supply of our drug candidates or may not be able to create a supply of our drug candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of our drug candidates might be negatively affected. Our inability to coordinate the efforts of our third- party manufacturing partners, or the lack of capacity available at our third- party manufacturing partners, could impair our ability to supply our drug candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of our drug candidates if we decided to

transfer the manufacture of our drug candidates to one or more alternative manufacturers in an effort to deal with the difficulties. Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability, and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of our drug candidates, increase our cost of goods sold and result in lost sales. We cannot guarantee that our manufacturing and supply partners will be able to manufacture our drug candidates at commercial scale on a cost- effective basis. If the commercial- scale manufacturing costs of our drug candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time. There are risks associated with scaling up manufacturing to commercial scale. If our contract manufacturers are unable to manufacture our drug candidates on a commercial scale, this could potentially delay regulatory approval and commercialization or materially adversely affect our results of operations. There are risks associated with scaling up manufacturing to commercial volumes including, among others, cost overruns, technical problems with process scale- up, process reproducibility, stability issues, and lot consistency. We have limited experience contracting with third parties to manufacture ~~monoclonal antibodies~~ **drug candidates** and will need to be able to successfully scale up and produce ~~a batch~~ **batches** of ~~CRB- 601~~ **our drug candidates** to commence clinical studies. We are dependent on our licensing partner, CSPC, to manufacture antibody drug conjugates and we do not have control over their chemistry, manufacturing, and control strategy for CRB- 701 to ensure successful development and supply of drug to commence clinical studies **or support commercial demand** . Even if we obtain regulatory approval for our drug candidates, there is no assurance that our contract manufacturers or licensing partners will be able to manufacture the approved products to specifications acceptable to the FDA or other regulatory authorities, to produce them in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of approved products for commercialization, either on a timely basis or at all, our commercialization efforts would be impaired, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. We expect that we will rely on third parties to assist us in conducting clinical trials for our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business would be substantially harmed. We expect to enter into agreements with third- party CROs to assist us in conducting and managing our clinical programs, including contracting with clinical sites to perform our clinical studies. We plan to rely on these parties for execution of clinical studies for our drug candidates and we will control only certain aspects of conducting the clinical studies. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, 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, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties. Although we intend to design the clinical trials for our drug candidates in consultation with CROs, we expect that the CROs will manage and assist us with the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, or if they breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of our drug candidates for the subject indications may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or our drug candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third- party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs 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 clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our financial results and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Any termination or suspension of or delays in the commencement or completion of any necessary studies of

our drug candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to: • the FDA failing to grant permission to proceed and placing the clinical study on hold; • subjects failing to enroll or remain in our trials at the rate we expect; • a facility manufacturing any of our drug candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross- contaminations of product in the manufacturing process; • any changes to our manufacturing process that may be necessary or desired; • subjects choosing an alternative treatment for the indications for which we are developing our drug candidates, or participating in competing clinical studies; • subjects experiencing severe or unexpected drug- related adverse effects; • reports of similar technologies and products raising safety and / or efficacy concerns; • third- party clinical investigators losing their ~~license~~ **licenses** or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGCP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner; • inspections of clinical study sites by the FDA or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications; • third- party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications; • one or more IRBs refusing to approve, suspending or terminating the study at an investigational site precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • deviations of the clinical sites from trial protocols or dropping out of a trial; • adding new clinical trial sites; • the inability of the CRO to execute any clinical trials for any reason; • government or regulatory delays or " clinical holds " requiring suspension or termination of a trial; and • delays related to the impacts of **pandemics** ~~COVID- 19~~, including slowdowns in enrollment or our ability **to** complete our clinical trials on our expected timeline. Product development costs for our drug candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, any IRBs, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of our drug candidates, our commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our drug candidates could be significantly reduced. We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates. We may seek orphan drug designation in the ~~United States~~ **U. S.** and in the European Union for our product candidates. Upon receipt of regulatory approval, orphan drug status will provide us with seven years of market exclusivity in the ~~United States~~ **U. S.** under the Orphan Drug Act. However, there is no guarantee that the FDA will grant orphan drug designation for any of our drug candidates for any future indication, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Moreover, there can be no assurance that another company also holding orphan drug designation for the same indication, or which may receive orphan drug designation in the future will not receive approval prior to us, in which case our competitor would have the benefit of the seven years of market exclusivity, and we would be unable to commercialize our product for the same indication until the expiration of such seven- year period. Even if we are the first to obtain approval for the orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during our seven- year period of exclusivity. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200, 000 individuals in the ~~United States~~ **U. S.** and for which there is no reasonable expectation that the cost of developing and making a drug available in the ~~Unites States~~ **U. S.** for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $ 400, 000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug' s orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant' s product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what

is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our drug candidates for any additional indications if we elect to seek such designation. Even if orphan designation is granted it may be withdrawn by the FDA for non- compliance with regulations. Third- party coverage and reimbursement and health - care cost containment initiatives and treatment guidelines may constrain our future revenues. Our ability to successfully market our drug candidates will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which our drug candidates are expected to be sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the ~~United States~~ **U. S.**, government- funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our drug candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third- party payors attempt to contain health - care costs in ways that are likely to impact our development of products including: • failing to approve or challenging the prices charged for health- care products; • introducing reimportation schemes from lower priced jurisdictions; • limiting both coverage and the amount of reimbursement for new therapeutic products; • denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third- party payors; and • refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval. Our collaboration partners are conducting and may intend to conduct additional clinical trials for certain of our drug candidates at sites outside the ~~United States~~ **U. S.**, and the FDA may not accept data from trials conducted in such locations or may require additional U. S.- based trials. Our collaboration partners are currently conducting and may intend in the future to conduct clinical trials outside the ~~United States~~ **U. S.**, particularly in China where CSPC is conducting a Phase 1 trial. Although the FDA may accept data from clinical trials conducted outside the ~~United States~~ **U. S.**, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted by qualified investigators in accordance with current good clinical practices, or GCPs, including review and approval by an independent ethics committee and receipt of informed consent from trial patients. The trial population must also adequately represent the U. S. population, and the data must be applicable to the U. S. population and U. S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical trial conducted outside of the ~~United States~~ **U. S.** must be representative of the population for which we intend to seek approval in the ~~United States~~ **U. S** . In addition, while these clinical trials are subject to applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also comply with all applicable U. S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the ~~United States~~ **U. S** . If the FDA does not accept the data from our clinical trials conducted outside the ~~United States~~ **U. S.**, it would likely result in the need for additional clinical trials, which would be costly and time- consuming and delay or permanently halt our ability to develop and market these or other drug candidates in the ~~United States~~ **U. S** . In addition, there are risks inherent in conducting clinical trials in jurisdictions outside the ~~United States~~ **U. S.** including: • regulatory and administrative requirements of the jurisdiction where the trial is conducted that could burden or limit our ability to conduct clinical trials; • foreign exchange fluctuations; • manufacturing, customs, shipment and storage requirements; • cultural differences in medical practice and clinical research; and • the risk that patient populations in such trials are not considered representative as compared to patient populations in the ~~United States~~ **U. S.** and other markets. Risks Relating to Our Intellectual Property Rights It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights. Our success will depend, in part, on maintaining and obtaining additional patent protection for our technologies, products and processes, successfully defending these patents against third- party challenges, and successfully enforcing these patents against third - party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable in our pending applications or, the enforceability of our existing and future patents. Our pending patent applications may never be approved by ~~United States~~ **U. S.** or foreign patent offices and the existing patents and patent applications relating to our product candidates may be challenged, invalidated, or circumvented by third parties and may not protect us against competitors with similar products or technologies. The degree of our current and future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical, or competitive to our product candidates, or important to our business. We cannot be certain that any patents or patent application owned by a third party will not have priority over patents and patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before ~~United States~~ **U. S.** or foreign patent offices. We also rely on trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants, and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third- party entity illegally obtained and is using any of our trade secrets is expensive and time - consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods, and know- how. If we fail to maintain or obtain

additional patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability. We may also rely on the trademarks we may develop to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us, or our business partners **,** will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks. We have in- licensed a portion of our intellectual property, and if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property. We are a party to license agreements with Jenrin, The Regents, and Milky Way BioPharma, LLC (" Milky Way ") pursuant to which we licensed exclusive worldwide rights to develop, manufacture and market drug candidates. **We** ~~These agreements are important to our business, and we~~ may enter into additional license agreements in the future. Certain of our in- licensed intellectual property covers, or may cover, potential cannabinoid and monoclonal antibody developmental candidates. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non- performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected. We **have determined to no longer pursue development of the assets under our license agreement with Milky Way, and on January 25, 2024, we sent a notice of termination without reason to Milky Way. Once the termination of the Milky Way license is effective, the assets subject to the license will no longer be company assets. We** are a party to a license agreement with CSPC pursuant to which we licensed the exclusive rights in the ~~United States~~ **U. S.** , Canada, the European Union (including the European Free Trade Area), the United Kingdom, and Australia to develop and market a drug candidate from CSPC. This agreement is important to our business, and we may enter into additional license agreements in the future. Certain of our in- licensed intellectual property covers, or may cover, potential antibodies, monoclonal antibody, and antibody drug conjugate developmental candidates. Our existing license agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If there is any conflict, dispute, disagreement or issue of non- performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected. Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts. Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third- party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third- party patents that may be infringed by any of our product candidates. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time- consuming and may: ~~•~~ result in costly litigation; ~~•~~ divert the time and attention of our technical personnel and management; ~~•~~ prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law; ~~•~~ require us to cease or modify our use of the technology and / or develop non-infringing technology; or ~~•~~ require us to enter into royalty or licensing agreements. Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent- related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market our product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign any product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition, and operating results. A number of companies, including several major pharmaceutical companies, have conducted research ~~on anti-inflammatory~~ **in the same therapeutic areas as our company** , ~~cancer, and anti- fibrosis therapies~~ which resulted in the filing of many patent applications ~~related to this~~ **in the same areas as our** research. If we were to challenge the validity of these or any issued ~~United States~~ **U. S.** patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued ~~United States~~ **U. S.** patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent' s claims. If we were to challenge the validity of these or any issued ~~United States~~ **U. S.** patent in an administrative trial before the Patent Trial and Appeal Board in the ~~United States~~ **U. S.** Patent and Trademark Office, we

would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and / or court would find in our favor on questions of infringement, validity, or enforceability. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is commonplace in our industry, we employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non- competition or non-solicitation obligations) or claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. We are, and may become, subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets that, regardless of merit, could result in significant expense and loss of our intellectual property rights. We have entered into and may in the future enter into non- disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third- party manufacturers, consultants, advisors, potential partners and other third parties. We may become subject to litigation where a third- party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from developing, marketing or otherwise commercializing our product candidates. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects ~~. On November 18, 2021, Venn Therapeutics, LLC (" Venn "), filed a complaint (the " Complaint ") against us in the U. S. District Court for the Middle District of Florida. The Complaint asserted claims for trade secret misappropriation under federal law and state law, a claim for breach of contract, and state law claims for unfair competition, misrepresentation, unjust enrichment, and intentional interference with advantageous business relations. On May 12, 2022, we entered into a binding term sheet (the " Settlement ") with Venn to resolve the claims by Venn against us, our Chief Executive Officer, and a former employee. Under the terms of the Settlement, we made a $ 5 million payment to Venn on May 26, 2022, and Venn dismissed with prejudice all claims against us, our Chief Executive Officer and a former employee~~ . We may be subject to claims challenging the inventorship of our patents and other intellectual property. Although we are not aware of any asserted third- party claims challenging inventorship on our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, strategic partners, commercial counterparties or other third parties associated with us or one of our predecessors in ownership have an interest in our patents or other intellectual property as an inventor or co- inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we cannot fully control the enforcement of these policies by third parties with which we contract, nor can we be certain that assignment agreements between us and our employees, between us and our counterparties, or between our counterparties and their employees or between our predecessors of ownership and their employees and counterparties, will effectively protect our interests as to any party who conceives or develops intellectual property that we regard as our own. Among other issues, the assignment of intellectual property rights may not be self- executing, the assignment agreements may be breached, or we may have disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. As we approach potential commercialization of our product candidates, we are more closely analyzing all facts that we believe might be used to assert an inventorship claim against us. Determinations like these involve complex sets of fact and applications of sometimes- unsettled patent law, resulting in inherent uncertainties regarding ownership rights. Determining the history of development of certain of our intellectual property is made more difficult by the fact that certain of our intellectual property was developed by other companies for other indications before being acquired by us. Consequently, we cannot be sure that we have all ~~of~~ the documentary records relevant to such an analysis ~~. In the course of our analysis, we identified a potential issue regarding incomplete inventorship on certain aspects of our lenabasum portfolio that were developed prior to our acquisition of lenabasum. Since identifying this potential issue, we reached agreement with the relevant third- party co- inventors and received assignments of such co- inventors' rights in and to the relevant patents~~ . If claims challenging inventorship are made against us, we may need to resort to litigation to resolve those claims. If we fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of valuable intellectual property rights or the right to assert those rights against third- parties marketing competing products. 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. General Company- Related Risks We will need to grow the size of our organization, and we may experience difficulties in managing this growth. As of December 31, ~~2022~~ **2023** , we had ~~33~~ **19** full- time employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial,

operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate, and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day- to- day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our drug candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth. Future capital raises may dilute our existing stockholders' ownership and / or have other adverse effects on our operations. If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced, and these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences, and privileges senior to those of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees, including Yuval Cohen, our Chief Executive Officer, ~~Rachael Brake, our Chief Scientific Officer, and~~ Sean Moran, our Chief Financial Officer **, and Dominic Smethurst, our Chief Medical Officer,** would adversely impact our business prospects. Our ability to compete in the highly competitive pharmaceuticals industry depends **,** in large part **,** upon our ability to attract highly qualified managerial, scientific, and medical personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in the price of our common stock that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies. Our management team has expertise in many different aspects of drug development and commercialization. However, we will need to hire additional personnel as we further develop our drug candidates. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We have entered into employment agreements with certain of our executive officers. However, these employment arrangements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results, or financial condition. In particular, we believe that the loss of the services of Yuval Cohen, Ph. D., our Chief Executive Officer, ~~Rachael Brake, Ph. D., our Chief Scientific Officer, and~~ Sean Moran, C. P. A., M. B. A., our Chief Financial **Officer, and Dominic Smethurst, MA MRCP, our Chief Medical** Officer, would have a material adverse effect on our business. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level, and senior managers as well as junior, mid- level, and senior scientific and medical personnel. Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we have to offer. If we are unable to continue to attract and retain high- quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates. We face a potential risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize our drug candidates. For example, we may be sued if any product we develop or any materials that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our drug candidates; • injury to our reputation; • withdrawal of clinical trial participants; • 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; • the inability to commercialize our drug candidates; and • a decline in the value of our stock. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We intend to obtain product liability insurance covering our clinical trials. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. We may acquire businesses, assets, or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions. We may acquire additional businesses, assets, or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in

developing, manufacturing, and marketing any new delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition. We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure 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. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic, and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. 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. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors, and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber- attacks or cyber- intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber- attacks or cyber- intrusion, including by computer hackers, foreign governments, and cyber- terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media, or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. Under the EU regulation and notably the General Data Protection Regulation, or GDPR, No. 2016 / 679, which entered into force on May 25, 2018 and is applicable personal data that we process in relation to our presence in the EU, the offering of products or services to individuals in the EU or the monitoring of the behavior of individuals in the EU, we have also a legal responsibility to report personal data breaches to the competent supervisory authority. The EU data protection regulation includes a broad definition and a short deadline for the notification of personal data breaches, which may be difficult to implement in practice and requires that we implement robust internal processes. Under this regulation, we **must** ~~have to~~ report personal data breaches to the competent supervisory authority within 72 hours of the time we become aware of a breach" unless the personal data breach is unlikely to result in a risk to the right and freedoms of natural persons" (Article 33 of the GDPR). In addition, the GDPR requires that we communicate the breach to the Data Subject if the breach is" likely to result in a high risk to the rights and freedoms of natural persons" (Article 34 of the GDPR). In order to fulfill these requirements, we have to implement specific internal processes to be followed in case of a personal data breach, which will allow us to (a) contain and recover the breach, (b) assess the risk to the data subjects, (c) notify, and possibly communicate the breach to the data subjects, (d) investigate and respond to the breach. The performance of these processes implies substantial costs in resources and time. Moreover, as we may rely on third parties that will also process as processor the data for which we are a data controller — for example, in the context of the manufacturing of our drug candidates or for the conduct of clinical trials, we must contractually ensure that strict security measures, as well as appropriate obligations including an obligation to report in due delay any security incident are implemented, in order to allow us fulfilling our own regulatory requirements. We would also be exposed to a risk of loss or litigation and potential liability for any security breach on personal data for which we are data controller. The costs of above- mentioned processes together with legal penalties, possible compensation for damages and any resulting lawsuits arising from a breach may be extensive and may have a negative impact on reputation and materially adversely affect our business, results of operations and financial condition. Changes in geopolitical conditions, U. S.- China trade relations and other factors beyond our control may adversely impact our business and operating results. Our operations and performance depend **,** in part **,** on global and regional economic and geopolitical conditions, given our current third- party license agreement with CSPC, which is headquartered in China. Changes in U. S.- China trade policies, and a number of other economic and geopolitical factors both in China and abroad could have a material adverse effect on our business, financial condition, results of operations or prospects. Such factors may include: • instability in political or economic conditions, such as inflation, recession, foreign currency exchange restrictions and devaluations, restrictive governmental controls on the movement and repatriation of earnings and capital, and actual or anticipated military or political conflicts, particularly in emerging markets; • expanded jurisdiction of the Committee for Foreign Investment in the ~~United States~~ **U. S.** (CFIUS); and • intergovernmental conflicts or actions, such as armed conflict, trade wars, retaliatory tariffs, and acts of terrorism or war. As a result of these events, our ability to obtain data or regulatory support from our China- based licensing

partner may be limited or adversely affected, and we may ourselves be subject to sanctions, diminished public perception and operational constraints. Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations. The disruptions to the global economy in 2020 and into 2021 have impeded global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have taken and may have to take steps to minimize the impact of these disruptions in lead times and increased costs by working closely with our suppliers and other third parties on whom we rely for the conduct of our business. Despite the actions we have undertaken or may have to undertake to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain will not have a material adverse effect on our business, financial condition and results of operations. Furthermore, inflation can adversely affect us by increasing the costs of clinical trials, the research and development of our product candidates, as well as administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected. Adverse global conditions, including economic uncertainty, may negatively impact our financial results. Global conditions, dislocations in the financial markets, any negative financial impacts affecting ~~United States~~ **U. S.** as a result of tax reform or changes to existing trade agreements or tax conventions, may adversely impact our business. In addition, the global macroeconomic environment could be negatively affected by, among other things, ~~COVID- 19 or other~~ pandemics or epidemics, instability in global economic markets, increased U. S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of Ukraine and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets. Risks Related to our Common Stock An active, liquid trading market for our common stock may not be sustained. Presently, our common stock is traded on The Nasdaq Capital Market, or Nasdaq, and an investment in our company may require a long- term commitment, with no certainty of return. If we are unable to maintain an active, liquid active trading market: • investors may have difficulty buying and selling or obtaining market quotations; • market visibility for shares of our common stock may be limited; and • a lack of visibility for shares of our common stock may have a depressive effect on the market price for shares of our common stock. The lack of an active market could impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration. We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on The Nasdaq Capital Market or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities. Although our common stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the exchange' s minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop or is sustained, our common stock may remain thinly traded. The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders: • the liquidity of our common stock; • the market price of our common stock; • our ability to obtain financing for the continuation of our operations; • the number of institutional and general investors that will consider investing in our common stock; • the number of investors in general that will consider investing in our common stock; • the number of market makers in our common stock; • the availability of information concerning the trading prices and volume of our common stock; and • the number of broker- dealers willing to execute trades in shares of our common stock. Our failure to maintain compliance with Nasdaq' s continued listing requirements could result in the delisting of our common stock **. Our common stock is currently listed for trading on The Nasdaq Capital Market. We must satisfy the continued listing requirements of The Nasdaq Stock Market LLC (" Nasdaq") to maintain the listing of our common stock on The Nasdaq Capital Market.** On ~~January 3~~ **November 10** , ~~2022~~ **2023** , we received a ~~letter (the " Notice~~ **notice** ~~")~~ from the Listing Qualifications Staff (the " Staff ~~) of the Nasdaq Stock Market, LLC (" Nasdaq~~ ") **of Nasdaq** indicating that ~~, based upon the closing bid price of our common stock for the last 30 consecutive business days,~~ we ~~are~~ **were** not in compliance with the **$ 2. 5 million minimum stockholders' equity** requirement ~~to maintain a minimum bid price of $ 1. 00 per share~~ for continued listing **of our common stock** on ~~the~~ **The** Nasdaq ~~Global~~ **Capital** Market, as set forth in Nasdaq Listing Rule 5550 (~~a~~ **b**) (~~2~~ **1**) (the " Minimum ~~Bid Price Requirement~~ **Stockholders' Equity Rule** ") **because our reported stockholders' equity of $ 311, 016 in our Quarterly Report on Form 10- Q for the period ended September 30, 2023 was below the required minimum of $ 2. 5 million, and because, as of November 9, 2023 we did not meet the alternative compliance standards relating to the market value of listed securities of $ 35 million or net income from continuing operations of $ 500, 000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years** . We **submitted** ~~were provided~~ a **plan of** compliance **to Nasdaq on December 26** ~~period of 180 calendar days from the date of the Notice~~ , ~~or~~ **2023. On January 8, 2024, the Staff notified us that that it granted an extension** until ~~July 5~~ **May 8** , ~~2022~~ **2024** ~~,~~ to regain compliance ~~with the minimum closing bid requirement~~ , **conditioned upon achievement** ~~pursuant to Nasdaq Listing Rule 5810 (c) (3) (A). On July 6, 2022, we transferred to The Nasdaq Capital Market, and we were afforded the remainder~~ of **certain milestones included in the plan of** ~~The Nasdaq Capital Market' s second 180 calendar day~~ compliance **previously submitted** ~~period, or until January 3, 2023,~~ to ~~regain compliance~~

~~with~~ the **Staff** ~~Minimum Bid Price Requirement. On December 20~~ , **including** ~~2022, we held~~ a **plan** ~~special meeting of stockholders at which our stockholders approved the adoption and approval of an amendment~~ to **raise additional capital** ~~our Charter to effect a reverse stock split of the shares of our common stock, issued and outstanding or held by the Company in treasury, at a specific ratio, ranging from 1: 4 to 1: 40, with the exact ratio to be determined by our board of directors without further approval or authorization of the Company' s stockholders~~ . On February ~~9~~ **8** , ~~2023~~ **2024** ~~, our board of directors approved a 1: 30 reverse stock split (the " Reverse Stock Split ") which became effective on February 14, 2023. On January 4, 2023~~ , we received **a** notice from the Staff ~~that due to our continued non- compliance with the Minimum Bid Price Requirement, it had determined to delist our securities from The Nasdaq Capital Market unless we timely request a hearing before the Nasdaq Hearings Panel (the " Panel "). We timely requested a hearing before the Panel and appeared before the Panel on February 23, 2023. On March 7, 2023, we received notice~~ that we had regained compliance with the **alternative continued listing standard because our market value of listed securities was $ 35 million or greater (the "** Minimum ~~Bid Price~~ **Market Value** Requirement **") for at least 10 consecutive business days and that the matter was closed** . There can be no assurance that we will continue to maintain compliance with the Minimum ~~Bid Price~~ **Stockholders' Equity Rule, the Minimum Market Value** Requirement **,** or ~~maintain compliance with the~~ other Nasdaq listing requirements. A delisting could substantially decrease trading in our common stock, adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws, adversely affect our ability to obtain financing on acceptable terms, if at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. Additionally, the market price of our common stock may decline further, and stockholders may lose some or all of their investment. The market price of our common stock may be significantly volatile. The market price for our common stock may be volatile and subject to wide fluctuations in response to factors including the following: • actual or anticipated fluctuations in our quarterly or annual operating results; • changes in financial or operational estimates or projections; • conditions in markets generally; • changes in the economic performance or market valuations of companies similar to ours; and • general economic or political conditions in the ~~United States~~ **U. S.** or elsewhere. In particular, the market prices of biotechnology companies like ours have been highly volatile due to factors, including, but not limited to: • any delay or failure to conduct a clinical trial for our product or receive approval from the FDA and other regulatory agencies; • developments or disputes concerning a company' s intellectual property rights; • technological innovations of such companies or their competitors; • changes in market valuations of similar companies; • announcements by such companies or their competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and • failure to complete significant transactions or collaborate with vendors in manufacturing a product. The securities market has from time- to- time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our common stock. Future sales of shares by existing stockholders could cause our stock price to decline. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of December 31, ~~2022~~ **2023** , we had outstanding options to purchase an aggregate of ~~617~~ **708** , ~~996~~ **762** shares of our common stock at a weighted average exercise price of $ ~~88~~ **63** . ~~99~~ **96** per share **, 17, 911 shares of common stock issuable upon the vesting of restricted stock units,** and warrants to purchase an aggregate of 50, 207 shares of our common stock at a weighted average exercise price of $ 283. 81 per share. The exercise of such outstanding options and warrants **and vesting of restricted stock units** will result in further dilution of your investment. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business. We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our investors have purchased their shares. **If we fail to maintain** ~~There may be limitations on the effectiveness~~ ~~----~~ **effective** ~~of our~~ internal controls, ~~and a failure of~~ **we may not be able to report financial results accurately** ~~our~~ ~~-~~ **or** ~~control systems to prevent error~~ **on a timely basis,** or **to detect** fraud ~~may~~ **, which could have a** ~~materially~~ ~~--~~ **material** ~~harm~~ **adverse effect on our business** ~~our~~ ~~-~~ **or** ~~company~~ **share price** . We are required, pursuant to Section 404 of the Sarbanes- Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation. **In May 2023, in connection with the preparation of our interim financial statements for the period ended March 31, 2023, we determined that our disclosure controls and procedures were not effective due to a material weakness. The material weakness related to our failure to maintain an effective control environment over the internal control activities to ensure the processing of and reporting of accruals associated with upfront payments and issue fees in licensing agreements were complete, accurate and timely. Based upon, and as of the date of, this evaluation, our Chief Executive**

Officer and our Chief Financial Officer concluded that the material weakness has been remediated and our disclosure controls and procedures as of December 31, 2023 are effective. We do not expect that our disclosure controls or internal control over financial reporting will prevent or detect all ~~error~~ **errors** or all fraud. We may in the future discover **other** weaknesses in our system of internal control over financial reporting that could result in a material misstatement of our financial statements. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we identify **additional** ~~one or more~~ material weaknesses in our internal controls, investors could lose confidence in the reliability of our financial statements, the market price of our stock could decline and we could be subject to sanctions or investigations by The Nasdaq Stock Market, the SEC or other regulatory authorities. Failure of our control systems to detect or prevent error or fraud could materially adversely impact us. We may be unable to complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock. We may not be able to complete our evaluation and testing of our internal control over financial reporting and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. If we are unable to assert that our internal control over financial reporting is effective, or, if applicable, our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC. We will also be required to disclose changes made in our internal control and procedures on a quarterly basis. If we identify a material weakness, our remediation efforts may not enable us to avoid a material weakness in our internal control over financial reporting in the future. Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price. Upon dissolution of our company, you may not recoup all or any portion of your investment. In the event of a liquidation, dissolution or winding- up of our company, whether voluntary or involuntary, the proceeds and / or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities and distributions required to be made to holders of any outstanding preferred stock will then be distributed to the stockholders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding- up of our Company. In this event, you could lose some or all of your investment. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Unused federal net operating losses for tax years beginning before January 1, 2018 may be carried forward to offset future taxable income, if any, until such unused net operating losses expire. Under legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or the Tax Act, as modified by legislation enacted on March 27, 2020, entitled the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, federal net operating losses incurred in tax years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020 is limited to 80 % of taxable income. In addition, as a result of our merger in April 2014 with Corbus Pharmaceuticals, Inc., our wholly- owned subsidiary, our ability to utilize our federal net operating loss, carryforwards and federal tax credit prior to that date may be limited under Sections 382 of the Internal Revenue Code. The limitations apply if an " ownership change, " as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect " five percent shareholders " increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an " ownership change " and, consequently, Section 382 limitations. As a result, if we earn net taxable income, our ability to use our pre- change net operating loss carryforwards and other tax attributes to offset ~~United States~~ **U. S.** federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. Legislation or other changes in U. S. tax law could adversely affect our business and financial condition. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. For example, the Tax Act ~~,~~ made significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 %; limitation of the tax deduction for interest expense to 30 % of adjusted earnings (except for certain small businesses); and, subject to certain changes in tax law made by the CARES Act as discussed above, limitation of the deduction of net operating losses generated in tax years beginning after December 31, 2017 to 80 % of taxable income, indefinite carryforward of net operating losses generated in tax years after 2018 and elimination of net operating loss carrybacks generated in tax years ending after December 31, 2017; changes in the treatment of offshore earnings regardless of whether they are repatriated; current inclusion in U. S. federal taxable income of certain earnings of controlled foreign corporations, mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50 % to 25 % of qualifying expenditures. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The impact of

this tax reform on holders of our common stock is also uncertain and could be adverse. This periodic report does not discuss any such tax legislation or the manner in which it might affect us or our stockholders in the future. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation. In addition, the CARES Act included certain changes in tax law intended to stimulate the U. S. economy in light of the COVID- 19 outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. Our certificate of incorporation, as amended, allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock. Our ~~board~~ **Board** of ~~directors~~ **Directors** has the authority to fix and determine the relative rights and preferences of preferred stock. We anticipate that our ~~board~~ **Board** of ~~directors~~ **Directors** will have the authority to issue up to 10, 000, 000 shares of our preferred stock without further stockholder approval. As a result, our ~~board~~ **Board** of ~~directors~~ **Directors** could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation and the right to receive dividend payments before dividends are distributed to the holders of common stock. In addition, our ~~board~~ **Board** of ~~directors~~ **Directors** could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders. **53**