

Risk Factors Comparison 2025-03-21 to 2024-03-21 Form: 10-K

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You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report and in our other public filings in evaluating our business. Investors should be aware that it is not possible to predict or identify all such factors and that the following is not meant to be a complete discussion of all potential risks or uncertainties. Additionally, our business is subject to general risks applicable to any company, such as economic conditions, geopolitical events, ~~climate change~~ **trade restrictions**, extreme weather and natural disasters. If known or unknown risks or uncertainties materialize, our business, financial condition, results of operations, cash flows, access to liquidity and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our ~~common~~ **Common** ~~stock~~ **Stock** would likely decline. The following discussion of risk factors contains forward- looking statements, as discussed in the Special Note Regarding Forward- Looking Statements section in this Annual Report on Form 10-K. Summary of Risk Factors Below is a summary of the principal factors that make an investment in our ~~common~~ **Common** ~~stock~~ **Stock** speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this Annual Report on Form 10- K and our other filings with the SEC before making an investment decision regarding our ~~common~~ **Common** ~~stock~~ **Stock**.

- There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations. We will need substantial additional financing to develop our product candidates and implement our operating plans, including to support one or more pivotal trials in 2025 and beyond. If we fail to obtain additional financing, we may be delayed or unable to complete the development and commercialization of our product candidates ;
- We have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain ;
- If we fail to develop and maintain proper and effective processes and operating procedures as a non- traditional government contractor, our ability to adhere to the **DoD Department of Defense** and related entity standards could impact our ongoing and future development financing awards from the U. S. government; • We are seeking to develop antibacterial agents using bacteriophage and synthetic phage technology, a novel approach, which makes it difficult to predict the time and cost of development. No bacteriophage products have been approved in the United States or elsewhere. • Results from **interim, “ topline, ” and preliminary data, or** preclinical studies and Phase 1 or 2 clinical trials of our product candidates or from single- patient expanded access treatments may not be predictive of the results of later stage clinical trials ; **and are subject to audit and verification procedures that could result in material changes in the final data.** • We must continue to develop manufacturing processes for our product candidates and any delay in or our inability to do so would result in delays in our clinical trials ;
- We rely on third parties to conduct our clinical trials **and to obtain materials or supplies necessary to conduct trials or to manufacture our product candidates** , and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates ;
- **We face potential risks associated with future changes in laws and policies, including the availability of government funding for grants, staffing and funding of regulatory agencies.** • **The use or anticipated use of artificial intelligence (“ AI ”) technologies, including generative AI, by us or third parties, may increase or create new operational risks.** • Our business operations and current and future relationships with clinical site investigators, healthcare professionals, consultants, third- party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. • Innoviva, our principal stockholder, beneficially owns greater than 50 % of our outstanding shares of ~~common~~ **Common** ~~stock~~ **Stock** , which causes us to be deemed a “ controlled company ” under the rules of the New York Stock Exchange (the “ NYSE ”). In addition, Innoviva’ s interests in our business may be different than our other stockholders.

Risks Related to Our Financial Condition and Need for Additional Capital There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations. We will need substantial additional financing to develop our product candidates and implement our operating plans. If we fail to obtain additional financing, we may be delayed or unable to complete the development and commercialization of our product candidates. The audited consolidated financial statements and accompanying notes thereto included disclosures that our recurring losses and negative cash flows from operations raise substantial doubt about our ability to continue as a going concern. Our **consolidated** financial statements as of December 31, ~~2023~~ **2024** and December 31, ~~2022~~ **2023** were prepared under the ~~assumption~~ **assumption** that we will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty. As of December 31, ~~2023~~ **2024** , we had unrestricted cash and cash equivalents of \$ ~~13.9~~ **5.3** million, and we have had recurring losses from operations and negative operating cash flows since inception. In March 2024, we received an additional loan from Innoviva of \$ 35. 0 million. Our outstanding **term** loans , **which comprise of \$ 60. 0 million of principal and \$ 9. 4 million of accrued interest** , mature in January ~~2025~~ **2026** and in June 2025. We will need to raise additional capital to support our operations and product development activities. Our ability to raise additional capital via equity or debt financing may be adversely impacted by potential worsening global economic conditions and the ~~recent~~ disruptions to, and volatility in, financial markets in the United States and worldwide. We may also seek funds through arrangements with collaborators, grant agencies or others that may require us to relinquish rights to the product candidates that we might otherwise seek to develop or commercialize independently. If we are unable to secure additional funds when needed or on acceptable terms, we may be required to defer, reduce or eliminate significant planned expenditures, restructure, curtail or eliminate some or all of our

development programs or other operations, dispose of technology or assets, pursue an acquisition of our company by a third party at a price that may result in a loss on investment for our stockholders, enter into arrangements that may require us to relinquish rights to certain of our product candidates, technologies or potential markets, file for bankruptcy or cease operations altogether. Any of these events could have a material adverse effect on our business, financial condition and results of operations. While we believe that our existing resources will be sufficient to fund our planned operations into fiscal year 2024 2025, we cannot provide assurances that our estimates will be accurate, that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. Our future funding requirements will depend on many factors, including: • the costs and timing of our research and development activities; • the progress and cost of our clinical trials and other research and development activities; • manufacturing costs associated with our targeted phage therapies strategy and other research and development activities; • the terms and timing of any collaborative, licensing, acquisition or other arrangements that we may establish; • whether and when we receive future Australian tax rebates, if any; • the costs and timing of seeking regulatory approvals; • the costs of filing, prosecuting, defending and enforcing any patent applications, claims, patents and other intellectual property rights; and • the costs of lawsuits involving us or our product candidates; **and • the continued availability of government funding for grants.** 45Any -- **Any** additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. Our ability to raise additional funds will depend, in part, on the success of our product development activities, including our targeted phage therapies strategy and any clinical trials we initiate, regulatory events, our ability to identify and enter into in- licensing or other strategic arrangements, and other events or conditions that may affect our value or prospects, as well as factors related to financial, **political**, economic and market conditions, many of which are beyond our control. There can be no assurances that sufficient funds will be available to us when required or on acceptable terms, if at all. We have incurred losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and our future profitability is uncertain. **Clinical 42Clinical** trials and activities associated with discovery research are costly. We do not expect to generate any revenue from the commercial sales of our product candidates in the near term, and we expect to continue to have significant losses for the foreseeable future. Our ability to generate meaningful revenue and achieve profitability depends on successfully completing the development of, and obtaining the regulatory approvals necessary to, commercialize our product candidates. If any of our product candidates fail in clinical trials or if any of our product candidates do not gain regulatory approval, or if any of our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our ability to generate future revenues from product sales depends heavily on our success in: • completing research and preclinical and clinical development of our product candidates; • seeking and obtaining regulatory and marketing approvals for product candidates for which we complete clinical trials; • developing a sustainable, scalable, reproducible, and transferable manufacturing process for our product candidates; • launching and commercializing product candidates for which we obtain regulatory and marketing approval, either by establishing a sales force, marketing and distribution infrastructure, or by collaborating with a partner; • obtaining market acceptance of any approved products; • addressing any competing technological and market developments; • implementing additional internal systems and infrastructure, as needed; • identifying and validating new product candidates; • negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter; • maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know- how; and • attracting, hiring and retaining qualified personnel. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency (“EMA”), or other foreign regulatory authorities to perform clinical trials and other studies in addition to those that we currently anticipate. Even if we are able **46to to** generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. As of December 31, **2023-2024**, our accumulated deficit was \$ **308-327. 8-7** million and we expect to incur losses for the foreseeable future. We have devoted, and will continue to devote for the foreseeable future, substantially all of our resources to research and development of our product candidates. Additional information regarding our results of operations may be found in our consolidated financial statements included in Item 8 in **the this** Annual Report and in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in Item 7 in this Annual Report. **If 43If** we fail to develop and maintain proper and effective processes and operating procedures as a non- traditional government contractor, our ability to adhere to the Department of Defense and related entity standards could impact our ongoing and future development financing awards from the U. S. government. On June 15, 2020, we entered into an agreement with the Medical Technology Enterprise Consortium (“MTEC Agreement”), pursuant to which we received a \$ 15. 0 million **grant award** and have entered into a **three-multi**- year program administered by the **DoD U. S Department of Defense** through MTEC **and managed by the Naval Medical Research Command (NMRC) – Naval Advanced Medical Development (NAMD)** with funding from the Defense Health Agency and Joint Warfighter Medical Research Program. On September 29, 2022, the MTEC Agreement was modified to increase the total **grant award** by \$ 1. 3 million to \$ 16. 3 million and extend the term into the third quarter of 2024. **In July 2024, the MTEC Agreement was modified to increase the total award by \$ 5. 3 million to \$ 21. 6 million and extend the term into the third quarter of 2025.** We **are using plan to use** the **grant award** to partially fund a Phase 1b / 2a, **multicenter**, randomized, double- blind, placebo- controlled, **dose -escalation clinical study that will assess the safety, tolerability and efficacy** of our **Armata’s therapeutic**- phage- based candidate, AP- SA02, for the treatment of **adults with S. aureus (“diSArm” study)** bacteremia. As an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we fail to maintain compliance with those obligations, we may be subject to potential liability and may result in the termination of our government contracts,

including the MTEC Agreement. Government contracts and grants normally contain additional requirements that may increase our costs of doing business and expose us to liability for failure to comply with these terms and conditions. These requirements **have historically included and may continue to** include, for example: • tracking of contract costs and maintenance of effective controls over tracking of such costs; • completion and submission of periodic reporting packages; • mandatory financial audits and potential liability for failing such audits; and • mandatory socioeconomic compliance requirements, including labor standards, non- discrimination, and affirmative action programs, and environmental compliance requirements. While we believe we are in compliance with all requirements under the MTEC Agreement, potential failure to maintain such compliance could result in reduction of the grant or termination of the contract, which could in turn negatively impact our business.

Risks Related to Our Business We are seeking to develop antibacterial agents using bacteriophage and synthetic phage technology, a novel approach, which makes it difficult to predict the time and cost of development. No bacteriophage products have been approved in the United States or elsewhere. We are developing our product candidates with bacteriophage and synthetic phage technology. We have not, nor to our knowledge has any other company, received regulatory approval from the FDA or equivalent foreign agencies for a pharmaceutical drug based on this approach. While in vitro studies have characterized the behavior of bacteriophages in cell cultures and there exists a body of literature regarding the use of phage therapy in humans, the safety and efficacy of phage therapy in humans has not been extensively studied in well- controlled modern clinical trials. Most of the prior research on phage- based therapy was conducted in the former Soviet Union prior to and immediately after World War II ~~47and~~ **and** lacked appropriate control group design or lacked control groups at all. Furthermore, the standard of care has changed substantially during the ensuing decades since those studies were performed, diminishing the relevance of prior claims of improved cure rates. We cannot be certain that our approach will lead to the development of approvable or marketable drugs. Developing phage- based therapies on a commercial scale will also require developing new manufacturing processes and techniques. We and our third- party collaborators may experience delays in developing manufacturing capabilities for our product candidates and may not be able to do so at the scale required to efficiently conduct the clinical trials required ~~to~~ **44to** obtain regulatory approval of our product candidates, or to manufacture commercial quantities of our products, if approved. In addition, the FDA or other regulatory agencies may lack experience in evaluating the safety and efficacy of drugs based on these approaches, which could lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. Results from **interim, “ top- line, ” and preliminary data, or** preclinical studies and Phase 1 or 2 clinical trials of our product candidates or from single- patient expanded access treatments may not be predictive of the results of later stage clinical trials **and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim, top- line or preliminary data from our preclinical studies and clinical trials, based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimates, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data when we publicly disclose such data. As a result, any interim, top- line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or top- line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, top- line and preliminary data should be viewed with caution until the final data are available. In addition, preliminary or interim data from ongoing clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between any preliminary or interim data we disclose and final data could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by investors or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, top- line or preliminary data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business, financial condition, results of operations and prospects**. Preclinical studies, including studies of our product candidates in animal disease models, may not accurately predict the result of human clinical trials of those product candidates. In particular, promising animal studies suggesting the efficacy of prototype phage products in the treatment of bacterial infections, such as P. aeruginosa and S. aureus, may not predict the ability of these products to treat similar infections in humans. Despite promising data in our completed Phase 1 clinical trials, our phage technology may be found not to be safe or efficacious in treating bacterial infections alone or in combination with other agents, when studied in later- stage clinical trials. In addition, we have used our bacteriophage technology in the area of targeted medicine under single- patient expanded access guidelines, which permit the use of phage therapy outside of clinical trials, in the United States and Australia. Despite prior single- patient expanded access successes, no assurance can be given that we will have similar single- patient expanded access treatment successes in the future. Single- patient expanded access is a term that is used to refer to the use of an investigational drug or therapy outside of a clinical trial to treat a patient with a serious or immediately life- threatening disease or condition who has no

comparable or satisfactory alternative treatment options. Regulators often allow single- patient expanded access on a case- by- case basis for an individual patient or for defined groups of patients with similar treatment needs. In some countries, such as Australia, the treating physician can administer ~~45~~ **administer** treatment under single- patient expanded access guidelines without pre- approval from the applicable regulatory authority. To satisfy FDA or foreign regulatory approval standards for the commercial sale of our product candidates, we must demonstrate in adequate and controlled clinical trials that our product candidates are safe and effective. Success in early clinical trials, including Phase 1 and Phase 2 trials, or in our single- patient expanded access program does not ensure that later clinical trials will be successful. Our initial results from early stage clinical trials or our single- patient expanded access program also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials and most product candidates that commence clinical trials are never approved for commercial sale. Delays in our clinical trials could result in us not achieving anticipated developmental milestones when expected, increased costs and delay our ability to obtain regulatory approval for and commercialize our product candidates. Delays in our ability to commence or enroll patients for our clinical trials could result in us not meeting anticipated clinical milestones and could materially impact our product development costs and delay regulatory approval of our ~~48~~ **product- product** candidates. Planned clinical trials may not be commenced or completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including: • delays in the development of manufacturing capabilities for our product candidates to enable their consistent production at clinical trial scale; • failures in our internal manufacturing operations that result in our inability to consistently and timely produce bacteriophages in sufficient quantities to support our clinical trials; • the availability of financial resources to commence and complete our planned clinical trials; • delays in reaching a consensus with clinical investigators on study design; • delays in reaching a consensus with regulatory agencies on trial design or in obtaining regulatory approval to commence a trial; • **changes in the FDA and foreign regulatory approval processes, staffing, resources or perspectives that may delay or prevent the approval of future products and result in lost market opportunity; • changes in regulations or judicial decisions, or new interpretations of existing laws, regulations or judicial decisions, related to health care availability, pricing or marketing practices, compliance with employment practices, method of delivery, payment for health care products and services, compliance with health information and data privacy and security laws and regulations, tracking and reporting payments and other transfers of value made to physicians and teaching hospitals, extensive anti- bribery and anti- corruption prohibitions, product serialization and labeling requirements and used product take- back requirements;** • delays in obtaining clinical materials; • slower than expected patient recruitment for participation in clinical trials; • failure by clinical trial sites, other third parties, or us to adhere to clinical trial agreements; • delays in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval; and • adverse safety events experienced during our clinical trials. **Completion** ~~46~~ **Completion** of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients, which is a function of many factors, including: • the therapeutic endpoints chosen for evaluation; • the eligibility criteria defined in the protocol; • the perceived benefit of the product candidate under study; • the size of the patient population required for analysis of the clinical trial' s therapeutic endpoints; • our ability to recruit clinical trial investigators and sites with the appropriate competencies and experience; • our ability to obtain and maintain patient consents; and • competition for patients from clinical trials for other treatments. Difficulties in enrolling patients in our clinical trials, could increase the costs or affect the timing or outcome of these clinical trials. This is particularly true with respect to diseases with relatively small patient populations. If we do not successfully commence or complete our clinical trials on schedule, the price of our ~~common~~ **Common stock** ~~Stock~~ may decline. ~~49~~ **We** ~~We~~ must continue to develop manufacturing processes for our product candidates and any delay in or our inability to do so would result in delays in our clinical trials. We are ~~continuing to developing~~ **develop** novel manufacturing processes for our ~~phase~~ **product** candidates at our ~~current~~ **facility** in ~~Los Angeles Marina Del Rey~~, California. ~~We are constructing~~ **Construction of** the new manufacturing facility in Los Angeles, California ~~was completed~~ **and plan to move manufacturing processes to this new facility** in the second half of 2024. The manufacturing processes for our product candidates, and the scale- up of such processes for clinical trials, are novel, and there can be no assurance that we will be able to complete this work in a timely manner, if at all. The manufacture of our product candidates requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers often encounter difficulties in production, particularly in scaling up for commercial production. These problems include difficulties with production costs and yields, quality control, including stability of the equipment and product candidates and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. If we were to encounter any of these difficulties, our ability to provide our products to patients in our clinical trials or to commercially launch a product would be jeopardized. Any delay or interruption could postpone the completion of our clinical trials, increase the costs associated with maintaining our clinical trial program, and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely. Any delay in the development or scale up of these manufacturing processes could delay the start of clinical trials and harm our business. In the event our facility in Los Angeles, California, does not receive a satisfactory cGMP inspection for the manufacture of our product candidates, we may need to fund additional modifications to our manufacturing process, conduct additional validation studies, or find alternative manufacturing facilities, any of which would result in significant cost to us as well as a delay of up to several years in obtaining approval for such product candidate. Our manufacturing facility will be subject to ongoing periodic inspection by the FDA for compliance with cGMP regulations. Compliance with these regulations and standards is complex and costly, and there can be no assurance that we will be able to comply. Any failure to comply with applicable regulations could result in sanctions being imposed (including fines, injunctions and civil penalties), failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of

product candidates or products, operating restrictions and criminal prosecution. **Any 47Any** of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our products, entail higher costs or result in our being unable to effectively commercialize our products. Furthermore, if we fail to deliver the required commercial quantities on a timely basis, pursuant to provided specifications and at commercially reasonable prices, we may be unable to meet demand for our products and would lose potential revenues. If we are unable to obtain FDA approval of our products, we will not be able to commercialize our products in the United States. We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our products in the United States, which will significantly impair our ability to generate any revenues. This regulatory review and approval process, which includes evaluation of pre-clinical studies and clinical trials of our product candidates as well as the evaluation of our manufacturing processes, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that our product candidates are both safe and effective for each indication for which approval is sought. Satisfaction of the approval requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the product. We do not know if or when we might receive regulatory approvals, including approval for an Investigational New Drug application (“IND application”), for any of our product candidates currently under development, other than for our product candidates AP-PA02 and AP-SA02, for which we received FDA clearance of our respective IND applications. Moreover, approvals that we obtain may not cover all of the clinical ~~50indications~~ **indications** for which we are seeking approval, or could contain significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use. In such event, our ability to generate revenues from such products would be greatly reduced and our business would be harmed. The FDA has substantial discretion in the approval process and may either refuse to consider any of our applications for substantive review or may form the opinion after review of our data that one or more of our applications are insufficient to approve our product candidates. If the FDA does not consider or approve any of our applications, it may require that we conduct additional clinical, pre-clinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our applications for approval, which might significantly harm our business and prospects. It is possible that none of our products or any product we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Any delay in obtaining, or an inability to obtain, applicable regulatory approvals would prevent us from commercializing our products, generating revenues and achieving and sustaining profitability. We may conduct clinical trials for our products or product candidates outside the United States and the FDA may not accept data from such trials. We completed an investigator-sponsored clinical trial of AP-SA01 at the University of Adelaide in Australia for CRS in December 2016. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U. S. population, and the data must be applicable to the United States population and U. S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U. S. laws and **regulations 48regulations**. There can be no assurance the FDA will accept data from trials conducted outside of the United States. Further, with respect to AP-SA01, we have changed the product formulation to AP-SA02 and any work related to AP-SA01 may not be relevant to the FDA or other international regulatory authorities. We are subject to significant regulatory approval requirements, which could delay, prevent or limit our ability to market our product candidates. Our research and development activities, preclinical studies, clinical trials and the anticipated manufacturing and marketing of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in Europe and elsewhere. There can be no assurance that our manufacturing facilities will satisfy the requirements of the FDA or comparable foreign authorities. We require the approval of the relevant regulatory authorities before we may commence commercial sales of our product candidates in a given market. The regulatory approval process is expensive and time-consuming, and the timing of receipt of regulatory approval is difficult to predict. Our product candidates could require a significantly longer time to gain regulatory approval than expected, or may never gain approval. We cannot be certain that, even after expending substantial time and financial resources, we will obtain regulatory approval for any of our product candidates. A delay or denial of regulatory approval could delay or prevent our ability to generate product revenues and to achieve profitability. Changes in regulatory approval policies during the development period of any of our product candidates, changes in, or the enactment of, additional regulations or statutes, ~~or~~ changes in regulatory review practices for a submitted product application, **or changes in regulatory staffing and funding** may cause a delay in obtaining approval or result in the rejection of an application for regulatory approval. ~~51Regulatory~~ **Regulatory** approval, if obtained, may be made subject to limitations on the indicated uses for which we may market a product. These limitations could adversely affect our potential product revenues. Regulatory approval may also require costly post-marketing follow-up studies. In addition, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping related to the product will be subject to extensive ongoing regulatory requirements. Furthermore, for any marketed product, its manufacturer and its manufacturing facilities will be subject to continual review and periodic inspections by the FDA or other regulatory authorities. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspensions of regulatory approvals, product recalls, product seizures, operating restrictions

and criminal prosecution. We rely on third parties to conduct our clinical trials and to obtain materials or supplies necessary to conduct trials or to manufacture our product candidates, and their failure to perform their obligations in a timely or competent manner may delay development and commercialization of our product candidates. We use third parties, such as clinical research organizations, to assist in conducting our clinical trials and for many aspects of our manufacturing process development of our product candidates. However, we may face delays outside of our control if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers. This risk is heightened for clinical trials conducted outside of the United States, where it may be more difficult to ensure that clinical trials are conducted in compliance with FDA requirements. Any third party that we hire to conduct clinical trials may also provide services to our competitors, which could compromise the performance of their obligations to us. If we experience significant delays in the progress of our clinical trials and in our plans to submit Biologics License Applications, the commercial prospects for product candidates could be harmed and our ability to generate product revenue would be delayed or prevented. Our business operations and current and future relationships with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties. Our business operations and current and future arrangements with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial ~~arrangements~~ **arrangements** and relationships through which we conduct our operations, including how we market, sell, and distribute our product candidates, if approved. Such laws include, but are not limited to, the U. S. Anti-Kickback Statute, U. S. civil and criminal false claims laws, the U. S. federal Beneficiary Inducement Statute, HIPAA, and state and local laws and regulations. Some of these laws may apply differently to, and may have different requirements for, and effects on, our business, rendering compliance complex and possibly burdensome. We cannot predict how future changes to these laws may impact our business. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, may not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties; damages; fines; exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other jurisdictions; integrity oversight and reporting obligations to resolve allegations of non-compliance; disgorgement; individual imprisonment; contractual damages; reputational harm; diminished profits; and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment, which could affect our ability to operate our business. Furthermore, defending against any of these actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any actions that may be brought against us, our business may be impaired. ~~52~~ **We** face potential liability related to the privacy of health information we may obtain from the patients in our clinical trials if we fail to comply with privacy laws. Most healthcare providers are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH, **as well as similar state laws governing the collection, use, and disclosure of health-related information**. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial **negative consequences – including** criminal penalties, **regulatory fines, reputational damage, and other harmful effects** – if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, if we receive sensitive personally identifiable information, including health information, we may be subject to state laws ~~requiring notification of affected individuals~~ **governing the use, security, and disclosure** ~~state regulators if a breach of personal~~ **such** information ~~occurs, which is a broader class of information than the health information protected by HIPAA~~. We cannot assure you that we, our CROs, our clinical trial sites, and our clinical trial principal investigators with access to personally identifiable and other sensitive or confidential information relating to the patients in our clinical trials will not breach contractual obligations, or that we or they will not experience data security breaches or attempts thereof. This could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations as discussed above, which could in turn adversely affect our business, financial condition, results of operations, and prospects. We **also** cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage, and transmission of such information. Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which could have a material adverse effect on our business, financial condition, results of operations, or prospects. The regulatory framework for the collection, use, safeguarding, sharing, transfer, and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, many jurisdictions have established their own data security and privacy frameworks. In the United States, there are a broad variety of data protection laws that are either currently in place or under way and a wide range of enforcement agencies ~~at~~ **50a** both the state and federal levels have the authority to review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission (“FTC”), and state Attorneys General have been aggressive in reviewing privacy and data security

protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act (the “CCPA”), which went into effect on January 1, 2020, provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. Additionally, the CCPA was amended by the California Privacy Rights Act, which significantly amends the CCPA and imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations, which could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in, or are being considered by, other states. The enactment of such laws in other states could result in potentially conflicting requirements, which would make compliance challenging and costly. The FTC and many state attorneys general continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers’ personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5 (a) of the Federal Trade Commission ~~53 Act~~ **Act**. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. We may also be subject to new state laws governing the privacy of consumer health data, including information concerning individual health conditions and treatment. The **collection, use, disclosure, transfer, or other processing of personal data privacy laws regarding individuals** in the European Union (the “EU”) **have also been significantly reformed. The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU**, including personal health data, is subject to the General Data Protection Regulation, (EU) 2016 / 679 (the “GDPR”). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR has expanded the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial patients and investigators. In addition, the GDPR ~~also~~ imposes strict rules on the transfer of personal data to countries outside the EU, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the European Economic Area should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information or impose substantial fines for violations of the GDPR, which can be up to 4 % of global revenues or € 20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own additional laws and regulations limiting the processing of personal data, including genetic, biometric, or health data. Furthermore, since the United Kingdom is no longer part of the EU, its data protection regulatory regime ~~is will be~~ independent of the EU. From January 1, 2021, companies have had to comply with ~~both~~ the GDPR and ~~also~~ the United Kingdom GDPR, which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in UK national law. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear. In addition, the longer term economic, legal, political, regulatory, and social framework to be put in place between the United Kingdom and the EU has had, and may continue to have, a material and adverse effect on global economic conditions and the stability of global financial markets and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors ~~could~~ **could** depress economic activity and restrict our access to capital, which could materially and adversely affect our business, financial condition, and results of operations. **We face potential risks associated with future changes in laws and policies, including the availability of government funding for grants, staffing and funding of regulatory agencies. In the United States, changes in the U. S. government between administrations have resulted in potential changes in regulations, fiscal policy, social programs, domestic and foreign relations and international trade policies. Our ability to respond to these developments or comply with any resulting new legal or regulatory requirements, including those involving economic and trade sanctions, could increase our costs of doing business, reduce our financial flexibility and otherwise have a material adverse effect on our business, financial condition and results of our operations. Our operations, including research, development, and clinical programs and trials, are largely dependent on government grants (for example, the MTEC Agreement, which is paid over the term of the award), meaning any substantial policy shift or executive action that restricts or diminishes the availability of these funds could materially harm our business. The use or anticipated use of artificial intelligence (“AI”) technologies, including generative AI, by us or third parties, may increase or create new operational risks. AI technologies offer numerous potential benefits, such as creating or increasing operational efficiencies, and we expect an increase in the use of AI and generative AI by us, third parties on our behalf, and other market actors, including our competitors. However, the deployment of such technologies also poses certain risks, including that the algorithms may be flawed, misused or otherwise function in an unexpected manner; data sets may be insufficient, of poor quality, or contain biased information; and inappropriate or controversial data practices by data scientists, engineers, and end- users could impair results. The relative newness of the**

technology, the speed at which it is being adopted, and the paucity of laws, regulations or standards expressly and specifically governing its use increases these risks. If the analyses that AI- based applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability and brand or reputational harm. Our competitors may also adopt AI or generative AI more quickly or more effectively than we do, which could cause competitive harm. Furthermore, use of AI- based software may lead to the release of confidential information which may impact our ability to realize the benefits of our intellectual property

Risks Related to Our Intellectual Property
If we are unable to obtain and maintain patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and product candidates may be adversely affected. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our technology and product candidates. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability. To protect our proprietary positions, we file patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive and time- consuming. We, our current licensees, or any future licensors and licensees may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We or our current licensees, or any future licensors or licensees may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. ~~54Therefore~~ **Therefore**, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with our best interests. It is possible that defects of form in the preparation or filing of our patents or patent applications ~~may~~ **may** exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised, and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and / or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. Any of these outcomes could impair our ability to prevent competition from third parties. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. For example, European patent law currently restricts the patentability of methods of treatment of the human body more than United States law does. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, recent changes in patent laws in the United States, including the America Invents Act of 2011, may affect the scope, strength and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights. We may not be aware of all third- party intellectual property rights potentially relating to our current and future product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, should we own any patents or patent applications in the future, we may not be certain that we were the first to file for patent protection for the inventions claimed in such patents or patent applications. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the U. S. Patent and Trademark Office ~~or (“USPTO”)~~ or become involved in derivation, ex- parte reexamination, or inter partes review proceedings in the USPTO or similar proceedings elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable and / or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and / or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of

proceedings, a court or other agency with jurisdiction may find our patents invalid and / or unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may ~~55result--~~ result in loss of exclusivity or freedom to operate, a patent being held unenforceable, and / or in one or more patent claims being narrowed or invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others ~~from 53from~~ using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Intellectual property disputes arise in several areas including with respect to patents, use of other proprietary rights and the contractual terms of license arrangements. Third parties may assert claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. If we are found to infringe a third- party' s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. In some cases, we may not be able to obtain patent protection for certain licensed technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and preclinical programs and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. ~~56Accordingly--~~ Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. ~~54If~~ If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent and trademark protection for our product candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties prior to beginning research or disclosing proprietary information. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. Despite these efforts and the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information due to our reliance on third parties, increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, our competitors may independently develop knowledge, methods and know- how equivalent to our trade secrets. Competitors could purchase our

products and replicate some or all the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Risks Related to Our Industry—**Industry** **There is a high rate of failure inherent in drug discovery and development, and failure can occur at any point in the process, including in later stages after substantial investment. New product candidates that appear promising in development or prior to being acquired may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain or maintain necessary regulatory approvals or payor reimbursement or coverage, failure to obtain placement on guidelines or recommendations published by third- party organizations that are commensurate with clinical data, the application of pricing controls, limited scope of approved uses, label changes, changes in the relevant treatment standards or the availability of newer better, or more cost- effective competitive products, difficulty or excessive costs to manufacture, insufficient infrastructure to support detection, diagnostic or other requisites for treatment, ineffectiveness in reaching healthcare professionals, including digitally given the increase in virtual engagements, or infringement of the patents or intellectual property rights of others. We may also fail to allocate research and development resources efficiently, fail to pursue or invest sufficiently in product candidates or indications that may have been successful, or fail to optimally balance trial design, conduct, and speed to accomplish desired outcomes. Regulatory agencies establish high hurdles for the efficacy and safety of new products and indications. Delay, uncertainty, unpredictability, and inconsistency in drug approval processes across markets and agencies can result in delays in product launches, lost market opportunities, impairment of inventories, and other negative impacts. In addition, it can be very difficult to predict revenue growth rates of, or variability in demand for, new products and indications, 55which in some cases leads to difficult meeting product demand or, on the other hand, excess inventory and related financial charges. We** face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do. The development and commercialization of new drug products is highly competitive. We face competition from major multi- national pharmaceutical companies, biotechnology companies, specialty pharmaceutical companies and generic drug companies with respect to our current and future product candidates. There are several large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of drug- resistant infections. Potential competitors also include academic institutions, government agencies and other public and private research organizations. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, more effectively marketed and sold or less costly than our product candidates, which could render our product candidates non- competitive and obsolete. If our competitors obtain marketing approval from the FDA, the EMA or other comparable regulatory authorities for their product candidates more rapidly than we do, it could result in our competitors establishing a strong market position before we are able to enter the market. Regulation of generic and biosimilar products varies around the world and such regulation is complex and subject to ongoing interpretation and implementation by regulatory agencies and courts. Particularly for biosimilars, health authority guidelines and legislative actions could make it less burdensome for competitor products to enter the market and further incentivize uptake of biosimilars. In the United States, the FDA has issued several “ interchangeability ” designations for biosimilar products, and is expected to continue doing so in the future. These designations could —, subject to state law requirements —, enable pharmacies to substitute biosimilars for innovator biological products. Given ~~57the~~ **the** importance of biologic products to our clinical- stage pipeline, such regulation could have a material adverse effect on our business. Many of our competitors have greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do as an organization. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain approval from the FDA, the EMA or other comparable regulatory agencies for their product candidates more rapidly than we may obtain approval for ours, which could result in product approval delays if a competitor obtains market exclusivity from the FDA or the EMA, or our competitors establish a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors seeking to encourage the use of generic drugs. Additional drugs may become available on a generic basis over the coming years. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic drugs. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot ~~successfully~~ **successfully** defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • reduced resources of our management to pursue our business strategy; • decreased demand for any product candidates or products that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • initiation of investigations by regulators; • product recalls, withdrawals

or labeling, marketing or promotional restrictions; • significant costs to defend the resulting litigation; • substantial monetary awards paid to clinical trial participants or patients; • loss of revenue; and • the inability to commercialize any drugs that we may develop. We currently hold product liability insurance coverage in an amount that may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. ~~58~~Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our product candidates upon their commercial introduction, which would negatively affect our ability to achieve profitability. Our product candidates may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved products will depend on a number of factors, including: • the effectiveness of the product; • the prevalence and severity of any side effects; • potential advantages or disadvantages over alternative treatments; • relative convenience and ease of administration; • the strength of marketing and distribution support; • the price of the product, both in absolute terms and relative to alternative treatments; and • sufficient third-party coverage or reimbursement. If our product candidates receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate product revenues sufficient to attain profitability. ~~Reduced~~ **57**Current and future healthcare reform measures may affect our results of operations. In the United States, federal and state legislatures, health agencies and third-party payors continue to focus on containing the cost of health care. Legislative and regulatory proposals, enactments to reform health care insurance programs and increasing pressure from social sources could significantly influence the manner in which our future products may be prescribed, purchased and reimbursed, which may adversely affect our results of operations. In the European Union and some other international markets, the government provides health care at low cost to consumers and regulates pharmaceutical prices and, patient eligibility or reimbursement levels rates due to control costs for the actions of governments—government-sponsored, payors, or competition or other healthcare health cost containment initiatives such as restrictions on use, may negatively impact profits. The continuing efforts of governments, pharmaceutical benefit management organizations, insurance companies, managed care organizations system. Many countries have announced or implemented measures, and may in other—the payors of future implement new or additional measures, to reduce health care costs to contain-limit the overall level of government expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possible retroactive price reductions and other recoupments and increased mandatory discounts or reduce-rebates, recoveries of past price increases and greater importation of drugs from lower-costs—cost of health care countries. These measures may adversely affect our future the price, market access, and total revenues—revenue of our products. These organizations, together with governments, have increasingly imposed utilization management tools favoring the use of generic products. As these practices expand, we may face difficulty in obtaining or maintaining timely or adequate pricing or formulary placement of our products. In addition, we have experienced and business operations expect to continue to experience increased competitive activity, which has resulted in lower overall prices for our products. Our business The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (together, “PPACA”) and other legislative or regulatory requirements or potential legislative or regulatory actions regarding healthcare and insurance matters, along with the trend toward managed healthcare in the U. S., could adversely influence the purchase of healthcare products and reduce demand and prices for our products. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures will continue and may increase increasing. More recently, presidential administrations and the U. S. Congress have taken actions in an effort to modify or replace PPACA and to implement or pass other reforms to the healthcare system, including proposed legislation related to the pricing of pharmaceuticals. There is uncertainty with respect to any potential changes that may be proposed and what the impact, if any, will be on our business, including the impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by PPACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us. We expect that additional state and federal healthcare reform measures will be considered and potentially adopted, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures and may adversely affect our operating results. ~~59~~Our product candidates may be subject to government price controls that may and other public and private restrictions on pricing, reimbursement, and access for our drugs, which could have a material adverse affect-effect on our results of operations, reputation our— or business. Public and private payors continue to take aggressive steps to control their expenditures for pharmaceuticals by placing restrictions on pricing and reimbursement for, and patient access to, medicines. Governments and private payors worldwide have intensified their scrutiny of, and actions intended to address, pricing, reimbursement, and access to pharmaceutical products and are demanding greater commercial and clinical value from pharmaceutical companies in the form of strong product differentiation and demonstrated value. The effect of reducing prices and reimbursement would significantly impact potential future revenue-revenues and business opportunities. There has been-Within the United States, state level transparency initiatives, importation rules, reporting requirements, and mandated programs, may also increase administrative costs, in some cases, compromise confidential business practices and otherwise detrimentally impact our business. heightened-Heightened governmental scrutiny over the manner in which drug manufacturers price the their United States-marketed products and the abroad-of pharmaceutical pricing-practices considering-of pharmacy benefit managers and the other supply chain entities rising cost-of prescription drugs and biologics. In the United States, such scrutiny has also resulted in several recent-U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing,

review the relationship between pricing and manufacturer patient programs, **require advance notice of list price increases, establish upper payment limits or other restrictions by drug affordability review boards, allow the importation of drugs from other countries, address pharmacy benefit manager practices**, and reform government program reimbursement methodologies for products. At the federal level, the former Trump Administration's budget proposal for fiscal year 2020 contained further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. The former Trump Administration also released a "Blueprint", or plan, to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. **In particular** HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. On November 20, 2020, CMS issued an interim final rule through the CMS Innovation Center whereby Medicare Part B reimbursement for "certain high-cost prescription drugs" would be no more than most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. While some of these and other measures may require additional authorization to become effective, members of Congress and the Biden Administration have indicated that they **the IRA will continue to seek new legislative and/or administrative measures to control drug costs**. For example, the recently enacted Inflation Reduction Act contains provisions designed to limit the prices paid by Medicare for various prescription drugs. At **While the impact of the IRA on the** state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing **industry cannot yet be fully determined, it is likely** including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to **be significant** encourage importation from other countries and bulk purchasing. Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Risks Related to Our Common Stock
Innoviva, our principal stockholder, beneficially owns greater than 50% of our outstanding shares of **common Common stock Stock**, which causes us to be deemed a "controlled company" under the rules of NYSE. In addition, Innoviva's interests in our business may be different than our other stockholders. As of December 31, **2023-2024**, Innoviva owns 69.53% of our outstanding shares and 19,364,647 warrants to purchase shares of our **common Common stock Stock**. If Innoviva were to exercise the warrants held by them, they would hold approximately **80-5880, +0**% of our issued and outstanding shares of **common Common stock Stock**. As a result, Innoviva owns more than 50% of our outstanding shares, and as such, we are a "controlled company" under the rules of the NYSE. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a "controlled company" and, as such, may elect to be exempt from certain corporate governance requirements, including requirements that: • a majority of the board of directors consist of independent directors; **60-** the board of directors maintain a nominating and corporate governance comprised solely of independent directors and with a written charter addressing the committee's purpose and responsibilities; and • the board of directors maintain a compensation committee comprised solely of independent directors and with a written charter addressing the committee's purpose and responsibilities. As a "controlled company," we may elect to rely on some or all of these exemptions, however, we do not intend to take advantage of any of these exemptions. Despite the fact we do not intend to take advantage of these exemptions, our status as a controlled company could make our **common Common stock Stock** less attractive to some investors or otherwise harm our stock price. Innoviva's large ownership stake may allow it to exert a substantial influence on actions requiring a stockholder vote, potentially in a manner that you do not support, including amendments to our articles of incorporation, adoption of measures that could delay or prevent a change in control or impede a merger, takeover, or other business combination involving us, and approval of other major corporate transactions. In addition, Innoviva's stock ownership may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of us, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price. Accordingly, our stockholders other than Innoviva may be unable to influence management and exercise control over our business. **Furthermore, any sales by Innoviva of a substantial number of shares of our Common Stock, or the expectation of such sales, could cause a significant reduction in the market price of our Common Stock.** The price of our securities has been volatile and may continue to be so, and purchasers of our securities could incur substantial losses. The price of our securities has been volatile and may continue to be so. Between January 1, **2023-2024** and December 31, **2023-2024**, the high and low sales prices of our **common Common stock Stock** as reported on **NYSE The New York Stock Exchange American** varied between \$ 1. **40-85** and \$ 4. **35-18** per share. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the companies' operating performance, in particular during the last several years. As of December 31, **2023-2024**, we had outstanding common warrants to purchase an aggregate of 19,365,847 shares of our **common Common stock Stock** at a weighted-average exercise

price of \$ 3. 59 per share. We also have outstanding options to exercise 3, 165-755, 216-965 shares of our ~~common~~ **Common stock** ~~Stock~~ at a weighted- average exercise price of \$ 5-3. 04-74 per share. To the extent any of our outstanding warrants or options are exercised, additional shares of our ~~common~~ **Common stock** ~~Stock~~ will be issued which will result in dilution to our security holders and could also have an adverse effect on the market price of our ~~common~~ **Common stock** ~~Stock~~. Raising additional capital may cause dilution to our stockholders, restrict our operations, and / or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, that we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and strategic collaboration and licensing arrangements. The terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ~~common~~ **Common stock** ~~Stock~~ to decline. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ~~ability~~ **59ability** to take specific actions, such as incurring additional debt, making capital expenditures, licensing or assigning our intellectual property rights, declaring dividends, and possibly other restrictions. To the extent that we raise additional capital through the sale of equity or convertible ~~debt~~ **loan** securities, our stockholders' interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our Common Stockholders. Attempting to secure additional financing may also divert our management from our day- to- day activities, which could impair or delay our ability to develop our product candidates. Furthermore, if, in the future, one or more banks or financial institutions enter receivership or become insolvent in response to financial conditions affecting the banking ~~61system~~ **system** or financial markets, our ability to access our existing cash, cash equivalents, and marketable securities may be threatened and could have a material impact on our business and financial condition. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts. Alternatively, we could be required to seek collaborators for our product candidates at an earlier stage than would otherwise be desirable or on terms that are less favorable than might otherwise be available. We might need to relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development and commercialization ourselves, or to license our intellectual property to others who could develop products that will compete with our products. Any of these actions could have a material adverse effect on our business, financial condition, results of operations, and prospects. General Risk Factors **Unfavorable global economic conditions, whether brought about by material global crises, health epidemics, military conflicts or war, geopolitical and trade disputes or other factors, may adversely affect our business and financial results. Our business is sensitive to global economic conditions, which can be adversely affected by epidemics and other public health crises, political and military conflict, trade and other international disputes (including tariffs, embargoes, sanctions or other trade restrictions) . significant natural disasters (including as a result of climate change) or other events that disrupt macroeconomic conditions. Pandemics, such as the COVID- 19 pandemic, have in the past impacted and may in the future impact our business, operations and financial condition and results.** Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, us and our business partners and suppliers. Further, military conflicts or wars (such as the ongoing conflicts between Russia and Ukraine and ~~Israel and Palestine~~ **in the Middle East**) can cause exacerbated volatility and disruptions to various aspects of the global economy. The uncertain nature, magnitude, and duration of hostilities stemming from such conflicts, including the potential effects of sanctions and counter- sanctions, or retaliatory cyber- attacks on the world economy and markets, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business and operations, such as worldwide supply chain issues. It is not possible to predict the short- and long- term implications of military conflicts or wars or geopolitical tensions which could include further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, cyber- attacks, supply chain challenges and adverse effects on currency exchange rates and financial markets. Additionally, the operations of our suppliers and manufacturers may be located in areas that are prone to earthquakes, wildfires and other natural disasters. Such operations and facilities are also subject to the risk of interruption by drought, power shortages, nuclear power plant accidents and other industrial accidents, terrorist attacks and other hostile acts, ransomware and other cybersecurity attacks, labor disputes, public health crises, **trade restrictions (including tariffs, embargoes and sanctions)**, and other events beyond the Company' s control. Global climate change is resulting in certain types of natural disasters occurring more frequently or with more intense effects. Such events can create delays or ~~interruptions~~ **60interruptions** to the Company' s development efforts and inefficiencies in the Company' s supply and manufacturing chain. Significant delays in our development efforts could materially impact our ability to obtain regulatory approval and to commercialize our products. ~~Any public health crises may affect our operations and those of third parties on which we rely, including our business partners and suppliers. The COVID- 19 pandemic has had an adverse impact on the global economy, including as a result of impacts associated with protective health measures that we, other businesses and governments are taking or might have to take again in the future to manage the pandemic.~~ Without limiting the foregoing, we have experienced and / or may in the future experience: ● delays in receiving authorization from regulatory authorities to initiate any planned clinical trials, inspections, reviews and approvals of products; **62** ● **delays or difficulties enrolling patients in our clinical trials; ● delays in or disruptions to the conduct of preclinical programs and clinical trials; ● constraints on the movement of products and supplies through the supply chain, which can disrupt our ability to conduct clinical trials and develop our products; ● price increases in raw materials and capital equipment, as well as increasing price competition in our markets; ● adverse impacts on our workforce and / or key employees; and ● increased risk that counterparties to our contractual arrangements will become insolvent or otherwise unable to fulfill**

their contractual obligations. Our operations could be disrupted by failure of our information systems or by successful cyber- attacks. Our operations could be disrupted if our information systems — or those of our vendors — fail, if we or our vendors are unsuccessful in implementing necessary upgrades, or if we or our vendors are subject to successful cyber- attacks. Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. We collect and maintain information, which includes confidential and proprietary information as well as personal information regarding our employees and others, in digital form. Data maintained in digital form is subject to risk of cyber- attacks, which could include the deployment of harmful malware, viruses, worms, and other means to affect service reliability and threaten data confidentiality, integrity and availability. Despite our efforts to monitor and safeguard our systems to prevent data compromise (as discussed below in Item 1C), such attacks are increasing in frequency and sophistication, and the possibility of a future data compromise, and risks associated with intrusion, tampering, and theft, cannot be eliminated entirely. We have experienced cyber- attacks in various forms, including phishing and other attempts to compromise our systems, but none of these has resulted in a material incident. A failure of our systems, or an inability to successfully expand the capacity of these systems, or an inability to successfully integrate new technologies into our existing systems could have a material adverse effect on our business, results of operations, financial condition, and cash flows. Further, our cybersecurity controls may not function as intended or our logging may be insufficient to fully investigate an incident. A system failure, accident or security breach may also result in a material disruption of our independent drug development programs. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. Our information security systems are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information or personal health information, we could incur substantial liability, our reputation would be damaged and the further development of our product candidates could be delayed. The Company's and its vendors' sophisticated information technology operations are spread across multiple, sometimes inconsistent, platforms, which pose difficulties in maintaining data integrity across systems. The ever- 61