Risk Factors Comparison 2024-03-14 to 2023-03-06 Form: 10-K

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Investing in our common stock involves a high degree of risk. The following discussion of risk factors contains forward-looking statements. You should carefully consider the risks described below, as well as the other information in this Annual Report ~~on Form 10- K~~, including our financial statements and the related notes and the section ~~titled~~ **entitled** " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The occurrence of any of the events or developments described below could materially harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business, financial condition, results of operations and growth prospects. Risk Factors Summary Risks Related to Our Financial Position and Need for Additional Capital • We are engaged in clinical drug development and have a limited operating history and no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability. • We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future. • Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives. • We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and / or eliminate one or more of our research and drug development programs or future commercialization efforts. Risks Related to the Discovery, Development and Commercialization of Our Product Candidates • Our business may be adversely affected by health epidemics, ~~including~~ **such as** the coronavirus outbreak. • We are dependent on the success of ~~one of~~ our lead ~~compounds~~ **product candidate**, ~~lirentelimab~~ **AK006**, which is currently in ~~multiple~~ **early** clinical ~~trials~~ **development**. If we are unable to obtain approval for and commercialize ~~lirentelimab~~ **AK006** for one or more indications in a timely manner, our business could be materially harmed. • If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented. Risks Related to Regulatory Approval and Other Legal Compliance Matters • The regulatory approval processes of the FDA, European Medicines Agency (" EMA ") and comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed. • Our clinical trials may reveal significant adverse events, toxicities or other side effects and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates. • We may face difficulties from changes to current regulations and future legislation. • Our business may become subject to economic, political, regulatory and other risks associated with international operations directly or indirectly. A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business. Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business • Our success is highly dependent on the services of our Chief Executive Officer, Dr. Robert Alexander, and our President, Dr. Adam Tomasi, and our ability to attract and retain **other** highly skilled executive officers and employees. • If we are unable to establish sales or marketing capabilities or enter into agreements with third- parties to sell or market our product candidates, we may not be able to ~~successfully sell or~~ **attain commercial success through the sale and** ~~market~~ **marketing of** our product candidates that obtain regulatory approval. • In order to successfully implement our **long- term** plans and strategies, we will need to ~~grow~~ **increase** the ~~size~~ **number** of **employees in** our organization, and we may experience difficulties in managing this **employee** growth. Risks Related to Intellectual Property • If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market. • We may not be able to protect our intellectual property rights throughout the world. • Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. Risks Related to Our Dependence on Third- Parties • We rely on third- parties to conduct our clinical trials and those third- parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies. • We contract with third- parties for the production of our product candidates for preclinical studies and, in the case of ~~lirentelimab~~ **AK006**, our ongoing clinical ~~trials~~ **trial**, and expect to continue to do so for additional clinical trials and ultimately for commercialization, and this reliance on third- parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. • We may not gain the efficiencies we expect from scaling- up of manufacturing of ~~lirentelimab~~ **AK006**, and our third- party manufacturers may be unable to successfully scale- up manufacturing in sufficient quality and quantity for ~~lirentelimab~~ **AK006** or our other product candidates, which could delay or prevent the conducting of our clinical trials or the development or commercialization of our other product candidates. • Changes in methods of product candidate manufacturing or formulation may result in additional costs, delays or have unintended impacts to the development of our product candidates. Risks Related to Ownership of Our Common Stock • The market price of our stock may continue to be volatile, which could result in substantial losses for investors. • Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance. • We have been and may in the future be subject to securities litigation, which is expensive and could divert management attention **from other business concerns**. General Business Risks • If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business. • Failure to comply with anti- bribery and anti- corruption laws and anti- money laundering laws, and similar laws,

could subject us to penalties and other adverse consequences. • We are subject to various governmental export control and trade sanctions laws and regulations that could impair our ability to compete in international markets or subject us to liability if we violate these controls. • We may experience disruptions and delays or incur financial damages as a result of system failures or security breaches or incidents. • The other factors discussed under " Risk Factors ". We are a clinical stage biopharmaceutical company with a limited operating history. We were incorporated and commenced operations in 2012, have no products approved for commercial sale and have not generated any revenue. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying and developing potential product candidates, conducting preclinical and clinical studies of our product candidates, including Phase 1 and Phase 2 clinical trials of lirentelimab, ~~one of~~ our ~~lead compounds~~ **former product candidate** . All of our product candidates currently under development, other than ~~lirentelimab~~ **AK006** , are in preclinical development. We have not yet demonstrated our ability to successfully complete any pivotal clinical trials, obtain marketing approvals, complete large- scale drug manufacturing or arrange for a third- party to do so on our behalf or conduct sales and marketing activities. For example, in ~~December~~ **January** ~~2021~~ **2024** , we announced that both our ~~ENIGMA study~~ **ATLAS clinical trial** and our ~~KRYPTOS study~~ **MAVERICK clinical trial** failed to meet their ~~patient- reported symptomatic co-~~ primary endpoints **. As a result of the results announced in January 2024, we implemented the 2024 Reorganization Plan to better align our resources with our development strategy focused on AK006** . As a result, it may be more difficult for you to accurately predict our future success or viability than it could be if we had a longer operating history. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer. We have incurred net losses in each reporting period since our inception, have not generated any revenue to date and have financed our operations principally through the sale and issuance of common stock and preferred stock. Our net losses were $ **185. 7 million and $** 320. 0 ~~million, $ 269. 9 million and $ 153. 5~~ million for the years ended December 31, **2023 and** 2022 ~~, 2021 and 2020~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~932~~ **1, 118** . ~~8~~ **5** million. We have devoted substantially all of our resources and efforts to research and development. **Our** ~~One of our~~ lead ~~compounds~~ **product candidate** , ~~lirentelimab~~ **AK006** , is in **early** clinical development, and our other product candidates are in preclinical development. As a result, we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential products. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter- to- quarter such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on our manufacturing and clinical activities, the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability. Our business depends entirely on the successful development and commercialization of our product candidates. Our ability to develop ~~lirentelimab~~ **AK006** and any other product candidates remains uncertain. For example, in ~~December~~ **January** ~~2021~~ **2024** ~~,~~ we announced that both our **ATLAS clinical trial and our MAVERICK clinical trial failed to meet their primary endpoints, and in December 2021 we announced that both our** ENIGMA study and our KRYPTOS study failed to meet their patient ~~-~~ reported symptomatic co- primary endpoints. We currently generate no revenues from sales of any products. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales until sometime after we have successfully completed clinical development and received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve a number of objectives, including: • successful and timely completion of preclinical and clinical development of our lead ~~compounds~~ **product candidate** , ~~lirentelimab and~~ AK006, and any other future product candidates; • timely receipt of marketing approvals for ~~lirentelimab~~ **AK006** and any future product candidates for which we successfully complete clinical development and clinical trials from applicable regulatory authorities; • the extent of any required post- marketing approval commitments to applicable regulatory authorities; • developing an efficient and scalable manufacturing process for ~~lirentelimab,~~ AK006 and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third- parties to obtain finished products that are appropriately packaged for sale; • successful launch of commercial sales following any marketing approval, including the development of a commercial infrastructure, whether in- house or with one or more collaborators; • a continued acceptable safety profile following any marketing approval; • commercial acceptance of ~~lirentelimab~~ **AK006** and any future product candidates as viable treatment options by patients, the medical community and third- party payors; • addressing any competing technological and market developments; • identifying, assessing, acquiring and developing new product candidates; • obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally; • protection of our rights in our intellectual property portfolio, including our licensed intellectual property; • negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary to develop, manufacture or commercialize our product candidates; and • attracting, hiring and retaining qualified personnel. We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional

necessary capital, grow our business and / or continue our operations. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time- consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, ~~tirentelimab~~ **AK006** and our other product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. We have also incurred and expect to continue to incur significant costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may need to reevaluate our operating plan and may be forced to delay, reduce and / or eliminate one or more of our research and drug development programs or future commercialization efforts. As of December 31, ~~2022~~ **2023**, we had $ ~~279~~ **170**. 8 million in cash, cash equivalents and ~~investments~~ **marketable securities**. We filed: (i) on August 4 ~~, 2022, a prospectus supplement to such shelf registration statement that covers the offering, issuance and sale of up to $ 75. 0 million of our common stock from time to time through an " at- the- market " program under the Securities Act and (ii) on September 19~~, 2022, a prospectus supplement to our shelf registration statement on Form S- 3 (File No. 333- 265085) that **covers the offering, issuance and sale of up to $ 75. 0 million of our common stock from time to time through an " at- the- market " program under the Securities Act of 1933, as amended, and (ii) on September 19, 2022, a prospectus supplement to such shelf registration statement that** covered the offering, issuance and sale of 29, 882, 000 shares of our common stock, at a public offering price of $ 5. 02 per share. We received aggregate net proceeds of $ 140. 6 million, after deducting the underwriting commissions and offering expenses from the September 19, 2022 follow- on offering and as of ~~March 6~~ **December 31**, 2023 received aggregate net proceeds of $ 1. 0 million under the " at- the- market " program. We believe that our existing cash, cash equivalents and ~~investments~~ **marketable securities** will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. Our estimate as to how long we expect our existing cash, cash equivalents and ~~investments~~ **marketable securities** to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. We plan to use our existing cash, cash equivalents and ~~investments~~ **marketable securities** to fund our development of ~~tirentelimab,~~ AK006 and for other research and development activities, working capital and other general corporate purposes. This may include additional research, hiring additional personnel, capital expenditures and the costs of operating as a public company. Advancing the development of ~~tirentelimab,~~ AK006 and any other product candidates will require a significant amount of capital. Our existing cash, cash equivalents and ~~investments~~ **marketable securities** will not be sufficient to fund all of the actions that are necessary to complete the development and commercial approval of ~~tirentelimab,~~ AK006 or any of our other product candidates. We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Additionally, our ability to raise additional capital may be adversely impacted by potential worsening of global economic conditions and volatility of financial markets in the United States and worldwide. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. **The** COVID- 19 **pandemic** had an adverse impact on our operations and supply chains and COVID- 19, or other health epidemics, may further disrupt our operations, supply chains or those of our contractors, and increase our expenses. We and our contractors experienced and may continue to experience disruptions in supply of items that are essential for our research and development activities, including, for example, raw materials and other consumables used in the manufacturing of our product candidates or medical and laboratory supplies used in our clinical trials or preclinical studies, in each case, for which there are or may be shortages because of ongoing efforts to address the outbreak. In particular, pursuant to the U. S. Defense Production Act, the U. S. federal government may, among other things, require domestic industries to provide essential goods and services needed for the national defense, and **it** used the Defense Production Act in the context of **the** COVID- 19 **pandemic** to divert supplies and materials to vaccine producers. For example, one of our suppliers informed us that, due to their obligation to prioritize other products or customers pursuant to the Defense Production Act, they were not able to fulfill our orders for certain materials previously ordered to be used in our manufacturing process. While this and similar delays in materials ~~have~~ **did** not ~~yet caused~~ **cause** delays in our overall timeline for clinical trials or regulatory filings, it is ~~quite~~ possible that **similar** ~~this or other such~~ delays may occur in the future, whether as a result of actions taken pursuant to the Defense Production Act or general shortages of materials attributable to the global efforts to combat ~~Covid- 19 or other~~ health epidemics, which could impact our proposed timeline for developing and commercializing ~~tirentelimab,~~ AK006 and adversely impact our business, financial condition and results of operations. In addition, the spread of COVID- 19 disrupted the United States' healthcare and healthcare regulatory systems; accordingly, COVID- 19 or health epidemics may divert healthcare resources away from, or materially delay, ~~U. S. Food and Drug Administration (" FDA ")~~ approval or any applicable foreign regulatory approval with respect to our product candidates. Furthermore, our clinical trials may be negatively affected by ~~the~~ COVID- 19 ~~outbreak~~ **outbreaks or other health epidemics**. Site initiation and patient enrollment may be delayed, for example, due to factors including prioritization of hospital resources toward ~~the~~ COVID- 19 ~~outbreak~~ **patients**, travel restrictions, the inability to access sites for initiation and monitoring, and difficulties recruiting or retaining patients in our ongoing and planned clinical trials. Furthermore, if we determine that our clinical trial participants may suffer from exposure to COVID- 19 as a result of their participation in our clinical studies, we may voluntarily terminate certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. We may therefore be unable to complete our clinical trials on the timelines we expect, if at all, which could materially and adversely impact our ability to seek regulatory approval for our product candidates. Health

epidemics may also reduce the effectiveness of our future sales efforts and / or impact our ability to launch and commercialize such product candidates; we have no experience in launching or selling a product amid pandemic conditions. Health epidemics also may have an adverse impact on the economies and financial markets of many countries, including the United States, potentially resulting in an economic downturn that could affect demand for our product candidates, if approved, impair our ability to raise capital when needed or otherwise impact our business, results of operations, cash flows and financial condition. In addition, if our operations are impacted from COVID- 19 or health epidemics, we risk a delay, default and / or nonperformance under our existing agreements arising from force majeure. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which health epidemics including COVID- 19, could adversely impact our business. Although we are continuing to monitor and assess the effects of public health conditions on our business, the ultimate impact of health epidemics is highly uncertain and subject to change. Our future success is dependent on our ability to timely complete clinical trials and obtain marketing approval for, and then successfully commercialize ~~lirentelimab~~ **AK006** , ~~one of~~ our lead **product candidate** ~~compounds, for one or more indications~~ . ~~Lirentelimab~~ **AK006** is in the **early- stage of** clinical ~~stages of~~ development and we are investing the majority of our efforts and financial resources in the research and development of **AK006** ~~lirentelimab for multiple indications~~ . Our ability to develop ~~lirentelimab~~ **AK006** remains uncertain **, especially given that we have not yet completed the Phase 1 trial for AK006** . For example, in ~~December~~ **January** ~~2021~~ **2024** , we announced that both our **ATLAS clinical trial and our MAVERICK clinical trial with lirentelimab failed to meet their primary endpoints. Similarly, in December 2021, we announced that our phase 3** ENIGMA study and ~~our~~ KRYPTOS study failed to meet their patient ~~–~~reported symptomatic co- primary endpoints. ~~Lirentelimab~~ **AK006** will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval from government regulators, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote **AK006** ~~lirentelimab,~~ or any other product candidates, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. The success of ~~lirentelimab~~ **AK006** will depend on several factors, including the following: • initiation and timely completion of our clinical trials of ~~lirentelimab~~ **AK006** ; • successful and timely enrollment of appropriate patients for the indication (s) included in our current and future clinical trials; • potential variability of patient- reported measures and outcomes; • our ability to address any potential delays resulting from factors related to health pandemics; • obtaining positive data that support demonstration of efficacy, safety and tolerability profiles and durability of effect for our product candidates that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval; • timely receipt of marketing approvals for ~~lirentelimab~~ **AK006** from applicable regulatory authorities; • the maintenance of existing or the establishment of new supply arrangements with third- party drug product suppliers and manufacturers for clinical development and, if approved, commercialization of our product candidates; • the maintenance of existing or the establishment of new scaled production arrangements with third- party manufacturers to obtain finished products that are appropriately packaged for sale; • establishing sales, marketing and distribution capabilities and the successful launch of commercial sales of our product candidates if and when approved for marketing, whether alone or in collaboration with others; • commercial acceptance by patients, the medical community and third- party payors; and • our ability to compete with other therapies. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize any product candidates from our lead programs, which would materially harm our business. If we do not receive marketing approvals for such product candidates, we may not be able to continue our operations. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. In particular, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment may also be affected by other factors, including: • travel and other restrictions due to health ~~pandemics~~ **epidemics** ; • size and nature of the patient population; • severity of the disease under investigation; • availability and efficacy of approved drugs for the disease under investigation; • patient eligibility criteria for the trial in question; • perceived risks and benefits of the product candidate under study; • efforts to facilitate timely enrollment in clinical trials; • patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; • proximity and availability of clinical trial sites for prospective patients; and • continued enrollment of prospective patients by clinical trial sites. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. The clinical trials of our product candidates may not adequately demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise produce positive results, which would prevent or delay development, regulatory approval and commercialization. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in each target indication. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early- stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies

that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. Our product candidates are in an early stage of development, and there is a high risk of failure and we may never succeed in developing marketable products. We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our ongoing and / or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to: • obtaining approval to commence a trial; • reaching agreement on acceptable terms with prospective contract research organizations (" CROs ") and clinical trial sites; • obtaining institutional review board approval at each clinical trial site; • recruiting suitable patients to participate in a trial; • patients failing to comply with trial protocol or dropping out of a trial; • clinical trial sites deviating from trial protocol or dropping out of a trial; • the need to add new clinical trial sites; or • manufacturing sufficient quantities of product candidate for use in clinical trials. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent receipt of marketing approval or our ability to commercialize our product candidates, including: • receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials; • negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs; • the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated; • third- party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • the suspension or termination of our clinical trials for various reasons, including non- compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks; • the cost of clinical trials of our product candidates being greater than anticipated; • the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and • regulators revising the requirements for approving our product candidates. If any of these events occur, we may incur unplanned costs, be delayed in obtaining marketing approval, if at all, receive more limited or restrictive marketing approval, be subject to additional post- marketing testing requirements or have the drug removed from the market after obtaining marketing approval. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities. We currently have no ~~drugs~~ **product candidates** approved for sale and we cannot guarantee that we will ever have marketable ~~drugs~~ **product candidates** . Clinical failure can occur at any stage of clinical development and has been experienced by companies pursuing approval in the indications that we are, or are contemplating, developing. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early- stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later- stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non- U. S. regulatory authorities despite having progressed through preclinical studies and early- stage clinical trials. In particular, no compound with the mechanism of action of ~~lirentelimab~~ **AK006** has been commercialized, and the outcome of preclinical studies and early- stage clinical trials may not be predictive of the success of later- stage clinical trials. From time to time, we may publish or report interim or preliminary data from our clinical trials. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and 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. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In addition, we use patient- reported outcome assessments in our clinical trials, which involve patients' subjective assessments of efficacy of the treatments they receive in the trial. Such assessments can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Our product candidates may not achieve adequate market acceptance among physicians, hospitals, patients, healthcare payors and others in the medical community necessary for commercial success. Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, hospitals, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including: • the efficacy and safety profile as demonstrated in planned clinical trials; • the timing of market introduction of the product candidate as well as competitive products; • the clinical indications for which the product candidate is approved; • restrictions on the use of our products, if approved, such as boxed warnings or contraindications in labeling, or a ~~Risk Evaluation and Mitigation Strategy (~~ REMS ~~)~~, if any, which may not be required of alternative treatments and competitor products; • the potential and perceived advantages of product candidates over alternative treatments, including standard of care treatment regimes; • the cost of treatment in relation to alternative treatments; • the availability of coverage and adequate reimbursement and pricing by third-parties and government authorities; • relative convenience and ease of administration; • the effectiveness of sales and marketing efforts; • unfavorable publicity relating to the product candidate; and • the approval of other new therapies for the same indications. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals,

healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be harmed. ~~Lirentelimab was administered intravenously in our lead Phase 3 and Phase 2 / 3 studies and we additionally plan to administer lirentelimab subcutaneously in future studies.~~ Intravenous and subcutaneous drugs are less convenient for patients than some other methods of administration, such as an orally delivered drug. The **SAD and MAD cohorts in healthy volunteers, as well as well as a cohort in patients with CSU, was administered AK006 via intravenous infusion and we plan to administer AK006 subcutaneously in future clinical trials. The** sizes of the patient populations suffering from some of the diseases we are targeting are small and based on estimates that may not be accurate. Our projections of both the number of people who have some of the diseases we are targeting, as well as the subset of people with these diseases who have the potential to benefit from treatment with ~~lirentelimab~~ **AK006** and any other future product candidates, are estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, physician interviews, patient foundations and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for ~~lirentelimab~~ **AK006** and any other future product candidates may be limited or may not be amenable to treatment with ~~lirentelimab~~ **AK006** and any other products, if and when approved. Even if we obtain significant market share for ~~lirentelimab~~ **AK006** and any other products (if and when they are approved), small potential target populations for certain indications means we may never achieve profitability without obtaining market approval for additional indications. Our business will be impacted by our ability to advance additional product candidates beyond ~~lirentelimab~~ **AK006** into clinical development and through to regulatory approval and commercialization. Our other product candidates are at even earlier stages of development than ~~lirentelimab~~ **AK006** and may fail in development or suffer delays that adversely affect their commercial viability. ~~Two of our product candidates,~~ AK006 **is** ~~and AK007, are~~ in **early** ~~our preclinical and~~ clinical **development** ~~pipeline. AK006 appears to have the potential to provide deeper mast cell inhibition than lirentelimab~~ and **our** ~~, in addition to its inhibitory activity, reduce mast cell numbers. We plan to begin human studies with AK006 in the first half of 2023. In preclinical research, AK007 polarizes tumor- associated myeloid cells and promotes anti- tumor immunity. Allakos is currently conducting preclinical studies with AK007. Our~~ other product candidates are in the early stages of development and may fail in development or suffer delays that adversely affect their commercial viability. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later- stage clinical trials of the product candidate. Our future operating results are dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize other product candidates in addition to ~~lirentelimab~~ **AK006** . The success of any product candidates we may develop will depend on many factors, including, among other things, the following: • generating sufficient data to support the initiation or continuation of clinical trials; • obtaining regulatory permission to initiate clinical trials; • contracting with the necessary parties to conduct clinical trials; • successful enrollment of patients in, and the completion of, clinical trials; • the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and • adverse events in the clinical trials. Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this " Risk Factors " section. Accordingly, we cannot assure you that we will ever be able to develop, obtain regulatory approval of, commercialize or generate significant revenue from any other product candidates. Any ~~drugs~~ **product candidates** we develop may become subject to unfavorable third- party reimbursement practices and pricing regulations. The availability and extent of coverage and adequate reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations or reimbursed by government health administration authorities, private health coverage insurers and other third- party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. In the United States, principal decisions about reimbursement for new products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private payors often follow CMS' s decisions regarding coverage and reimbursement to a substantial degree. However, one payor' s determination to provide coverage for a ~~drug~~ product does not assure that other payors will also provide coverage for the ~~drug~~ product. As a result, the coverage determination process is often time- consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical drug products. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third- party payors may limit coverage to specific drug products on an approved list, known as a formulary, which might not include all FDA- approved drugs for a particular indication. We may need to conduct expensive pharmaco- economic studies to demonstrate the medical necessity

and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain 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. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third- party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted. The biotechnology industry is highly competitive and subject to rapid and significant technological change. Products we may develop in the future are likely to face competition from other drugs and therapies, some of which we may not currently be aware. In addition, our products may need to compete with off- label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products. We are not aware of any other company or organization that is conducting clinical trials of a product candidate that targets ~~both eosinophils and mast cells, including any product candidate that specifically targets~~ Siglec- ~~8~~ **6** . The competition we may face with respect to the indications we are targeting with ~~tirentelimab~~ **AK006** includes, without limitation ~~, Regeneron, AstraZeneca, Bristol Meyers Squibb, Shire, and Dr. Falk Pharma for EGIDs, Blueprint Medicines for ISM~~ , Roche, Novartis, Regeneron, Celldex and Gossamer Bio for CU ~~and Aldeyra for SAC~~ . In addition, we are currently evaluating a host of other indications, and if we were to initiate trials in any such indication, we would likely face significant competition from a number of additional competitors. These companies, or other major multinational pharmaceutical and biotechnology companies, emerging and start- up companies, universities and other research institutions, could focus their future efforts on developing competing therapies and treatments for any of the indications we are currently targeting or may target in the future. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA or foreign regulatory authorities or discovering, developing and commercializing products in our field before we do. Smaller and other clinical stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for planned clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biotechnology industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical. We have limited resources and are currently focusing our efforts on developing ~~tirentelimab~~ **AK006** for **a limited number of** particular indications. As a result, we may fail to capitalize on other product candidates or indications that may ultimately have proven to be more profitable. We are currently focusing our efforts on **developing AK006 for** a ~~small~~ **limited** number of indications. As a result, we may forego or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial ~~drugs~~ **products** or profitable market opportunities. Our spending on current and future research and development activities for specific indications may not yield any commercially viable ~~drugs~~ **product candidates** . If we do not accurately evaluate the commercial potential or target markets for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition. Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could

result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA investigation could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management' s time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition. The regulatory approval processes of the FDA, ~~European Medicines Agency (~~EMA ~~)~~and comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed. The time required to obtain approval by the FDA, EMA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA, EMA and comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for, or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Applications for our product candidates could fail to receive regulatory approval in an initial or subsequent indication for many reasons, including but not limited to the following: • the FDA, EMA or comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials; • the FDA, EMA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use; • the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval; • the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application (" BLA ") or New Drug Application (" NDA "), or other submission or to obtain regulatory approval in the United States or elsewhere; • we may be unable to demonstrate to the FDA, EMA or comparable foreign regulatory authorities that a product candidate' s risk- benefit ratio for its proposed indication is acceptable; • the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. ~~Our development program included studies of patients with eosinophilic gastritis (EG) and / or eosinophilic duodenitis (EoD). Varied terminology had been used in the literature to describe mucosal eosinophilia in the stomach and duodenum (including eosinophilic gastritis, eosinophilic duodenitis, eosinophilic gastroenteritis and eosinophilic enteritis), and the nomenclature for grouping non- esophageal eosinophil gastrointestinal disorders (" EGIDs "), both within the medical industry and the relevant regulatory agencies, as well as the ultimate indication and label for lirentelimab, have yet to be finalized / agreed upon. For example, in a recent communication with the FDA, they commented that they believe further characterization of isolated EoD is needed to determine whether this condition is a subtype of EG or whether it should be considered a distinct indication. The FDA stated they were taking this position because the field of eosinophilic gastrointestinal diseases is advancing rapidly and that data from published literature, the academic community, and our development program would be informative. It is possible based on our communications that the FDA may determine EoD or any other subset of EGIDs are not separate disease processes. If the FDA determines that EoD is not a separate disease process, but the EoD population is included in the approval as a subset of an approved condition, then such a determination could cause confusion and adversely impact doctors' ability or willingness to prescribe our medication. In addition, if any particular subset of the EGID population falls outside the label, our marketing authorization would not extend to that population, which would impact the potential addressable market for our drug. Ultimately, whether lirentelimab will be used to treat any subset of patients with EGID or other indications will depend on the agency' s view of the efficacy and safety of lirentelimab, and our overall clinical development program.~~ The lengthy regulatory approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. We may be unable to obtain U. S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates. Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs and therapeutic biologics. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug or

therapeutic biologic can be marketed. Satisfaction of these and other regulatory requirements is costly, time- consuming, uncertain and subject to unanticipated delays. Significant regulatory hurdles remain, both near term and long term, before ~~lirentelimab~~ **AK006** can obtain regulatory approval in the United States. There can be no assurance we will be able to successfully conclude these undertakings in a timely manner, and it is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us to begin selling them. Our company has not conducted or managed clinical trials through regulatory approval, including FDA approval. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations or due to any delays in FDA regulatory review due to **public health concerns, staffing shortages, government shutdowns and furloughs, or** ~~the~~ **other** ~~COVID- 19 outbreak~~ **disruptions to FDA' s normal operations** . Examples of ~~such~~ **changes in** regulations include future legislation or administrative action, or changes in FDA policy during the period of product development, clinical ~~trials~~ - **trial requirements** and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of a BLA or NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug or biologic. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe- use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third- party payors. We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third- party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa. In order to obtain marketing approval for any of our product candidates, we must demonstrate the safety and efficacy of the product candidate for the relevant clinical indication or indications through preclinical studies and clinical trials as well as additional supporting data. If our product candidates are associated with undesirable side effects in preclinical studies or clinical trials, or have unexpected characteristics, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. ~~We have conducted Phase 1 and Phase 2 clinical trials in healthy volunteers, as well as in patients with EG, EoD, CU, ISM and SAC. However, we do not know the predictive value of these trials for our future clinical trials, and we cannot guarantee that any positive results in preclinical studies or previous clinical trials will successfully translate to patients in our future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical testing, and many product candidates fail in clinical trials despite promising preclinical results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Because Siglec- 8 is only naturally expressed in humans and certain other primates, there is no standard animal toxicology model for anti- Siglec- 8 therapies, and the acceptability of our preclinical safety data for lirentelimab depends on the continued acceptance by the FDA and EMA, and the acceptance by other regulatory authorities, of the use of our proprietary transgenic mice models for toxicology studies. Lirentelimab has generally been well tolerated in our clinical trials. The most common adverse event has been the occurrence of mild to moderate infusion- related reactions (IRRs) (consisting of flushing, feeling of warmth, headache, nausea or dizziness) which occurred mostly, but not exclusively, during the first infusion. Temporal interruption of the lirentelimab infusion and minimal intervention generally resulted in prompt resolution of symptoms and ability to resume the infusion without further complications, although there have been instances when an IRR has resulted in a subject being discontinued from a trial. Subjects in our ongoing and planned clinical trials may in the future suffer other significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials.~~ If ~~clinical trials of our product candidates fail to demonstrate efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, development and commercialization of our product candidates. If further~~ significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, the EMA, other applicable regulatory authorities or an institutional review board may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early- stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability relative to other therapies.

Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early- stage clinical testing. The FDA, EMA and applicable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction. We ~~currently~~ conduct clinical trials both in the United States and in other countries. We may in the future choose to conduct additional clinical trials in countries outside the United States, including in Europe. The acceptance of ~~study~~ **clinical trial** data by the FDA, EMA or applicable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice and (ii) the trials are performed by clinical investigators of recognized competence and pursuant to current good clinical practices **(" GCPs ")** regulations. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Even if our product candidates receive regulatory approval, they will be subject to significant post- marketing regulatory requirements. Any regulatory approvals that we may receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements, such as boxed warning on the packaging, to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with ~~current good manufacturing practices (" cGMPs ")~~ and ~~good clinical practices (GCPs)~~, for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and foreign regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including: • restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; • restrictions on the products, manufacturers or manufacturing process; • warning or untitled letters; • civil and criminal penalties; • injunctions; • suspension or withdrawal of regulatory approvals; • product seizures, detentions or import bans; • voluntary or mandatory product recalls and publicity requirements; • total or partial suspension of production; • imposition of restrictions on operations, including costly new manufacturing requirements; and • refusal to approve pending BLAs or supplements to approved BLAs. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. We may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving competing products. Regulatory authorities in some

jurisdictions, including the U. S. and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the U. S., or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. ~~We have obtained orphan drug designation for EG, EoD and EoE in the U. S. and for ISM in the U. S. and European Union and we may seek orphan drug designations for other indications or for other of our product candidates. There can be no assurances that we will be able to obtain such designations.~~ In the U. S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the U. S. provides that the FDA may not approve any other applications, including a full BLA or NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan- designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the U. S. may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. ~~Given the FDA' s stated uncertainty surrounding EGID diseases, it is possible the FDA could decide EGIDs in general, or any subset of the EGID population, is a much larger market and accordingly ineligible for orphan drug status. We have obtained orphan drug designation for EG, EoD and EoE in the U. S. but further redefinitions of the EGID diseases by the FDA could cause us to lose such status. Were this to occur, we would not only lose the financial incentives and exclusivity granted to orphan drugs, we could also be forced to undertake larger or additional clinical trials which could impact our proposed timeline for introducing lirentelimab and impact our business, financial condition and results of operations.~~ In **response to the court decision in** Catalyst Pharms., Inc. v. Becerra, 14 F. 4th 1299 (11th Cir. 2021), ~~the court disagreed with the FDA' s longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty~~ in ~~the application of the orphan drug exclusivity. On~~ January ~~24,~~ 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court' s order in Catalyst, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the Catalyst order – that is, the agency will continue tying the scope of orphan- drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity. Although we may seek a breakthrough therapy designation for ~~lirentelimab~~ **AK006** or one or more of our other product candidates, we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process. We may seek a breakthrough therapy designation for ~~lirentelimab~~ **AK006** in one or more indications or for other product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the NDA is submitted to the FDA. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U. S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have

obtained and we may not achieve or sustain profitability. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the **“** ACA **”**) substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U. S. pharmaceutical industry. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Since the enactment of the ACA, there have been judicial and Congressional challenges to certain aspects of the ACA. In ~~June 2021, the U. S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. In~~ addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, effective April 1, 2013, which will remain in effect through ~~2031~~ **2032** ~~, with the exception of a temporary suspension implemented under various COVID- 19 relief legislation from May 1, 2020 through March 31, 2022~~ , unless **Congress takes** additional ~~congressional~~ action ~~is taken. Under current legislation, starting on April 1, 2022, the actual reduction in Medicare payments varies from 1 % in 2022 to up to 4 % in the final fiscal year of the sequester~~ . There has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Under the American Rescue Plan Act of 2021 ~~, effective January 1, 2024~~ , the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs **was** ~~will be~~ eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than ~~it~~ **they** ~~receives~~ - **receive** on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act ~~of 2022~~ , which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high- priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out- of- pocket prescription drug costs for beneficiaries, among other changes. **Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional.** The impact of these **judicial challenges,** legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the **government** ~~Biden administration~~ on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures, including the prescription drug provisions under the Inflation Reduction Act, as well as or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved **. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing. For example, FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida’ s Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. Legally mandated price controls on payment amounts by third- party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product pricing** . Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U. S. Congress of the FDA’ s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. **Further, if the Supreme Court reverses or curtails the Chevron doctrine, which gives deference to regulatory agencies in litigation against FDA and other agencies, more companies may bring lawsuits against FDA to challenge longstanding decisions and policies of FDA, which could undermine FDA’ s authority, lead to uncertainties in the industry, and disrupt FDA’ s normal operations, which could delay FDA’ s review of our marketing applications.** If we fail to comply with applicable U. S. and foreign privacy and data protection laws and regulations, we may be subject to liabilities that adversely affect our business, operations and financial performance. We are subject to federal and state laws and regulations requiring that we take measures to protect the privacy and security of certain information we used and otherwise processed in our business. For example, federal and state security breach notification laws, state health information privacy laws and federal and state consumer protection laws impose requirements regarding the collection, use, disclosure and storage of personal information. In addition, in June 2018, California enacted the California Consumer Privacy Act (the “ CCPA ”), which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data

breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and protected health information governed by the federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Additionally, the California Privacy Rights and Enforcement Act (the " CPRA "), which amends and expands the CCPA, and creates a new California privacy regulatory authority, was passed via ballot initiative in November 2020 and became effective in most material respects on January 1, 2023. **Numerous** ~~Additionally,~~ other states **have proposed, and in certain cases enacted, new legislation relating to privacy and security. For example, Washington has enacted the My Health, My Data Act, which includes a private right of action. Additionally, numerous other states** , including Virginia, Colorado, Utah, ~~and~~ Connecticut **, Iowa, Indiana, Tennessee, Florida, Texas, Oregon, Delaware, and Montana** , have enacted laws addressing privacy and security that impose obligations similar to those of the CCPA and CPRA ~~, where on March 2, 2021, Virginia enacted the Virginia Consumer Data Protection Act, a comprehensive privacy statute that became effective on January 1, 2023; on June 8, 2021, Colorado enacted the Colorado Privacy Act, which takes effect on July 1, 2023; on March 24, 2022, Utah enacted the Utah Consumer Privacy Act, which takes effect on December 31, 2023; and on May 10, 2022, Connecticut enacted an Act Concerning Personal Data Privacy and Online Monitoring, which takes effect on July 1, 2023~~ . More generally, the CCPA and CPRA have prompted proposals for new federal and state privacy legislation that, if ~~passed~~ **enacted** , could increase our potential liability, increase our compliance costs, require us to modify our policies and practices, and adversely affect our business. We may also be subject to or affected by **federal, state and** foreign laws, regulations and regulatory guidance ~~,~~ governing the collection, use, disclosure, security, transfer, storage and other processing of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials and our other operations in the U. S. and abroad. We also may be or may be asserted to be subject to additional obligations relating to these matters, including industry standards. The global legislative and regulatory landscapes for privacy, data protection and information security matters continue to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, impose additional costs, and cause it to be necessary or appropriate for us to modify our policies or practices, which we may be unable to do on commercial reasonable terms or at all. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. For example, the EU has adopted the General Data Protection Regulation (EU 2016 / 679) (the " GDPR "), and the United Kingdom has adopted its General Data Protection Regulation (the " UK GDPR "), which introduced strict requirements for processing personal data. The GDPR and UK GDPR have increased our compliance burden with respect to data protection, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and otherwise process information about them. The processing of sensitive personal data, such as information about health conditions, entails heightened compliance burdens under the GDPR and the UK GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR and the UK GDPR provide for breach reporting requirements, more robust regulatory enforcement and fines of up to the greater of 20 million euros or 4 % of annual global revenue under the GDPR (or £ 17. 5 million under the UK GDPR). Numerous other jurisdictions have proposed or enacted legislation that is similar to the GDPR and the UK GDPR. Significant effort and expense are required in order to address the GDPR' s and the UK GDPR' s restrictions and obligations. Moreover, the requirements under the GDPR and UK GDPR and guidance issued by different EU member states may change periodically or may be modified, and such changes or modifications could have an adverse effect on our business operations if compliance becomes substantially costlier or otherwise more burdensome than under current requirements. For example, in July 2020, the Court of Justice of the European Union invalidated the EU- U. S. Privacy Shield Framework under which personal data could be transferred from the EEA to United States entities that had self- certified under the Privacy Shield scheme. This has increased the complexity of transferring personal data across borders and may require us to review and amend our mechanisms relating to cross- border data transfer. It is also possible that laws, regulations, and other actual or asserted obligations relating to privacy, data protection or information security may be interpreted and applied in manners that are, or are alleged to be, inconsistent with our practices. Any failure or perceived failure by us to comply with federal, state, or foreign laws, self- regulatory standards, contractual obligations or other actual or asserted obligations relating to privacy, data protection or cybersecurity could result in negative publicity, harm to our reputation, diversion of management time and effort, proceedings against us by governmental entities or others, and fines, penalties and other liabilities. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. Our relationships with customers and third- party payors will be subject to applicable anti- kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers and third- party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following: • the federal Anti- Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid; • the federal false claims and civil monetary penalties laws, including the civil False Claims Act, impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for

payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; • HIPAA imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value made to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician healthcare professionals (such as nurse practitioners and physician assistants, among others), and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information was made publicly available on a searchable website in September 2014 and will be disclosed on an annual basis; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers. Some state laws require biotechnology companies to comply with the biotechnology industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our current and future business arrangements with third- parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Our business is subject to risks associated with business operations we conduct internationally, as well as indirect impacts from our relationships with collaborators, partners, or contractors who conduct business internationally. We may seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including: • differing regulatory requirements and reimbursement regimes in foreign countries, including changes in existing regulatory requirements and implementation of new regulatory requirements or policies that impact our clinical development and business operations in foreign countries; • foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials or our interpretation of data from preclinical studies or clinical trials; • approval policies or regulations of foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; • unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; • difficulties staffing and managing foreign operations; • workforce uncertainty in countries where labor unrest is more common than in the United States; • potential liability under the FCPA or comparable foreign regulations; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • impact of the COVID- 19 pandemic or other public health concerns on our ability to produce our product candidates and conduct clinical trials in foreign countries; • production or supply shortages or other disruptions resulting from any events affecting raw material supply or manufacturing capabilities abroad, including, but not limited to, impacts due to the ongoing Ukraine- Russia war, addition of certain suppliers or companies to the Unverified List or other export restrictions or sanctions that can impact the supply chain, our business, or business operations of our suppliers, contractors or partners; and • business interruptions resulting from geo- political actions, ~~including~~ **national security concerns, trade restrictions,** ~~war~~ **wars** , such as the ongoing ~~war in~~ Ukraine **- Russia and Israel- Hamas wars** , other regional or geo- political conflicts, and terrorism. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations **. Further, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross- border operations. The U. S. government has made and continues to make significant additional changes in U. S. trade policy and may continue to take future actions that could negatively impact U. S. trade. For example, legislation has been introduced in Congress to limit certain U. S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers'**

ability to engage in business in the U. S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and / or results of operations would be materially and adversely affected . To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff, particularly our Chief Executive Officer, Dr. Robert Alexander, and our President, Dr. Adam Tomasi. If we do not succeed in attracting and retaining **other** qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers, including Dr. Alexander or Dr. Tomasi, could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. In addition to competition for personnel, the San Francisco Bay Area in particular is characterized by a high cost of living. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high- quality candidates than what we **are able to offer. Additionally, we** have **announced** ~~to~~ **two** ~~offer~~ **reorganization plans within the past 24 months, which significantly decreased our workforce. These actions may impact our ability to retain, hire, or motivate employees** . If we are unable to continue to attract and retain high- quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed **. If we are unable to establish sales or marketing capabilities or enter into agreements with third- parties to sell or market our product candidates, we may not be able to successfully attain commercial success through the sale and marketing of our product candidates that obtain regulatory approval** . We currently have a small commercial team which will need to be expanded substantially to support the marketing, sales and distribution of any of our product candidates that may be able to obtain regulatory approval. In order to commercialize any product candidates, we must build marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third- parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks **and as a result our commercialization efforts may be adversely impacted** . Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time- consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third- parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory- by- territory basis, with third- parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third- parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third- parties, our future product revenue will suffer and we may incur significant additional losses. ~~At December 31, 2022, we had 123 full- time employees, including 91 employees engaged in research and development.~~ In order to successfully implement our **long- term** development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining and motivating additional employees; • managing our internal development efforts effectively, including the clinical and FDA review process for ~~lirentelimab~~ **AK006** and any other future product candidates, while complying with any contractual obligations to contractors and other third- parties we may have; and • improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to successfully develop and, if approved, commercialize ~~lirentelimab~~ **AK006** and any other future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day- to- day **business- related** activities in order to devote a substantial amount of time to managing these growth activities. In addition, if we reduce our workforce, as we did **in the first quarter of 2024 and** in early 2022, in order to reduce operating costs or for other reasons, the rate and success at which we can discover, develop and commercialize our product candidates may be limited and the potential for successfully growing our business may be harmed. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including most aspects of clinical management and manufacturing. We cannot **be** ~~assure~~ **assured** ~~you~~ that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third- party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of ~~lirentelimab~~ **AK006** and any other future product

candidates or otherwise advance our business. We cannot **be** ~~assure~~ **assured** ~~you~~ that we will be able to manage our existing third- party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and / or engaging additional third- party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize ~~lirentelimab~~ **AK006** and any other future product candidates and, accordingly, may not achieve our research, development and commercialization goals. Our success depends in significant part on our and our current or future licensors' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have developed. We have also licensed from third- parties rights to patent portfolios. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, and other licenses may not give us such rights. The patent prosecution process is expensive and time- consuming, and we and our current or future licensors may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current and future licensors will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third- parties and are reliant on our current and future licensors. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current and future licensors 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. The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors' patent rights are highly uncertain. Our and our current or future licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our current and future licensors to narrow the scope of the claims of our or our current and future licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third- parties may initiate an opposition, interference, re- examination, post- grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our current or future licensors' patent applications cannot be enforced against third- parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our current and future licensors were the first to file any patent application related to a product candidate. Furthermore, if third- parties have filed such patent applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third- parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third- parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third- parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications. For example, one of our owned patent families that claims one of the product candidates will expire in 2035 in the United States and similar patent applications are pending in foreign jurisdictions with a projected expiration date in 2034, at which time the underlying technology covered by such patents can be used by any third- party, including competitors. Although the patent term extensions under the Hatch- Waxman Act in the United States may be available to extend the patent term, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long. Due to the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However, the applicable authorities, including the FDA and the ~~U. S. Patent and Trademark Office (" USPTO ")~~ in the United States, and any equivalent foreign regulatory authority, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Filing, prosecuting, enforcing

and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our or our current and future licensors' intellectual property rights may not exist in some countries outside the United States or may be less extensive in some countries than in 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. Consequently, we and our current and future licensors may not be able to prevent third- parties from practicing our and our current or future licensors' inventions in all countries outside the United States, or from selling or importing products made using our and our current or future licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our current or future licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our current and future licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our and our current or future licensors' 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 and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us and our current and future licensors to stop the infringement of our and our current or future licensors' patents or marketing of competing products in violation of our and our current or future licensors' proprietary rights generally. Proceedings to enforce our and our current or future licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our and our current or future licensors' efforts and attention from other aspects of our business, could put our and our current or future licensors' patents at risk of being invalidated or interpreted narrowly and our and our current or future licensors' patent applications at risk of not issuing and could provoke third- parties to assert claims against us or our current and future licensors. We or our current and future licensors may not prevail in any lawsuits that we or our current and future licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third- parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or our current and future licensors are forced to grant a license to third- parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time- consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Patent reform legislation in the United States and other countries, including the Leahy- Smith America Invents Act (" Leahy- Smith Act "), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review and derivation proceedings. After March 15, 2013, under the Leahy- Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third- party was the first to invent the claimed invention. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we or our current and future licensors fail to maintain the patents and patent applications covering our product candidates, our patent protection could be reduced or eliminated and our competitors might be better able to enter the market with competing products. If our trademark and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected. We cannot assure you that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. In addition, we do not own any registered trademarks for the mark " ALLAKOS. " We cannot assure you that any future trademark applications that we will file will be approved. During trademark registration proceedings, we

may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third- parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings, which may force us to rebrand our name. If we breach the license agreements related to our product candidates, we could lose the ability to continue the development and commercialization of our product candidates. Our commercial success depends upon our ability, and the ability of our current and future licensors, to develop, manufacture, market and sell our product candidates and use our and our current or future licensors' wholly- owned technologies without infringing the proprietary rights of third- parties. A third- party may hold intellectual property, including patent rights that are important or necessary to the development of our products. As a result, we are a party to a number of technology licenses that are important to our business. ~~For example, we have obtained an exclusive license under certain intellectual property related to Siglec- 8 from The Johns Hopkins University to develop certain products and a non- exclusive license from BioWa and Lonza to develop and commercialize products manufactured in a particular mammalian host cell line.~~ If we fail to comply with the obligations under these agreements, including payment and diligence terms, our current and future licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs. Disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights under any collaboration relationships we might enter into in the future; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our current and future licensors and us; and • the priority of invention of patented technology. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. Third- parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third- parties to challenge the validity or scope of intellectual property rights controlled by third- parties, the outcome of which would be uncertain and could have an adverse effect on the success of our business. Third- parties may initiate legal proceedings against us or our current and future licensors alleging that we or our current and future licensors infringe their intellectual property rights, or we or our current and future licensors may initiate legal proceedings against third- parties to challenge the validity or scope of intellectual property rights controlled by third- parties, including in oppositions, interferences, reexaminations, inter partes reviews or derivation proceedings in the United States or other jurisdictions. These proceedings can be expensive and time- consuming, and many of our or our current and future licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our current and future licensors. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. An unfavorable outcome could require us or our current and future licensors to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our current and future licensors a license on commercially reasonable terms or at all. Even if we or our current and future licensors obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us or our current and future licensors. 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, which could harm our business. We may be subject to claims by third- parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees, including our senior management, were previously employed at other biopharmaceutical companies, including potential competitors. Some of these employees executed proprietary rights, non- disclosure and / or non- competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third- party, and we could be required to obtain a license from such third- party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management. Our inability to protect our confidential information and trade secrets would harm our business and competitive position. In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. Trade secrets can be difficult to protect. We seek to protect

these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, contract manufacturers, consultants, advisors and other third- parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of the parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. Some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us. Failure on our part to adequately protect our trade secrets and our confidential information would harm our business and our competitive position. We do not have the ability to independently conduct our clinical trials. We currently rely on third- parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical ~~trials~~ **trial** of ~~tirentelimab~~ **AK006,** and **we** expect to continue to rely upon third- parties to conduct additional clinical trials of ~~tirentelimab~~ **AK006** and our other product candidates. Third- parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third- parties are not our employees, and except for remedies available to us under our agreements, we have limited ability to control the amount or timing of resources that any such third- party will devote to our clinical trials. Some of these third- parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our drug development activities. Our reliance on these third- parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. The third- parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. If these third- parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. We contract with third- parties for the production of our product candidates for preclinical studies and, in the case of ~~tirentelimab~~ **AK006** , our ongoing clinical ~~trials~~ **trial** , and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third- parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third- party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. ~~In the case of tirentelimab, we have previously relied on a single third- party manufacturer and we are currently in the process of developing alternative manufacturing capabilities.~~ If we were to experience an unexpected loss of supply of **AK006** ~~tirentelimab,~~ or any of our other product candidates, for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, including issues related to the COVID- 19 ~~global~~ pandemic, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. We expect to continue to rely on third- party manufacturers for the commercial supply of any of our product candidates for which we may obtain marketing approval. We may be unable to maintain required agreements with third- party manufacturers or to do so on acceptable terms. Reliance on third- party manufacturers entails additional risks, including: • the possible failure of the third- party to manufacture our product candidate according to our schedule and scale, or at all, including if our third- party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them; • the possible termination or nonrenewal of agreements by our third- party contractors at a time that is costly or inconvenient for us; • the possible breach by the third- party contractors of our agreements with them; • the failure of third- party contractors to comply with applicable regulatory requirements; • the possible failure of the third- party to manufacture our product candidates according to our specifications; • the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified; • the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being

distributed to commercial vendors in a timely manner, resulting in lost sales; and • the possible misappropriation of our proprietary information, including our trade secrets and know- how. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and / or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis. We may not gain the efficiencies we expect from scaling- up manufacturing of ~~lirentelimab~~ **AK006** , and our third- party manufacturers may be unable to successfully scale- up manufacturing in sufficient quality and quantity for ~~lirentelimab~~ **AK006** or our other product candidates, which could delay or prevent the conducting of our clinical trials or the development or commercialization of our other product candidates. Our third- party manufacturers are currently manufacturing ~~lirentelimab~~ **AK006** at a scale that is sufficient for us to complete our planned clinical trials. However, ~~we are in the process of increasing the batch scale of lirentelimab to gain cost efficiencies. If our manufacturers are unable to scale- up the manufacturing of lirentelimab, we may not gain such cost efficiencies and may not realize the benefits that would typically be expected from scaling- up manufacturing of lirentelimab. In addition,~~ in order to conduct larger clinical trials with ~~lirentelimab~~ **AK006** or with any of our other product candidates, we may need to manufacture them in large quantities. Our third- party manufacturers may be unable to successfully increase the manufacturing capacity for any of these product candidates in a timely or cost- effective manner, or at all. In addition, quality issues may arise during scale- up activities. If our third- party manufacturers are unable to successfully scale up the manufacture of our other product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and marketing approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. As product candidates progress through preclinical **studies** and clinical ~~trial~~ **trials** ~~stages~~ to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives or could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue. The manufacture of biologics is complex and our third- party manufacturers may encounter difficulties in production. If any of our third- party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented. Manufacturing biologics, especially in large quantities, is complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. If our current manufacturing locations become unavailable at their anticipated capacities or the location of the manufacturing of ~~lirentelimab,~~ AK006 or our other product candidates is changed for any reason, it could result in a delay or disruption to the manufacturing process or lead to difficulties that we did not experience at the original manufacturing locations. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. If we decide to establish collaborations, but are not able to establish those collaborations, we may have to alter our development and commercialization plans. Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third- parties. We would face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a

collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators. If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. The trading price of our common stock has been, and is likely to continue to be, highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. We priced our initial public offering at $ 18. 00 per share on July 19, 2018, and our common stock reached a high of $ 112. 87 per share during the fourth quarter of 2021. As of ~~February 28~~ **March 8** , ~~2023~~ **2024** , the closing price of our common stock was $ ~~5~~ **1** . ~~95~~ **43** . The trading price of our common stock could be subject to wide fluctuations in response to various factors, which in addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report ~~on Form 10- K~~ , include: • the timing and results of preclinical studies and clinical trials of our product candidates or those of our competitors; • the success of competitive products or announcements by potential competitors of their product development efforts; • regulatory actions with respect to our products or our competitors' products; • actual or anticipated changes in our growth rate relative to our competitors; • regulatory or legal developments in the United States and other countries; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key scientific or management personnel; • announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments; • actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • market conditions in the pharmaceutical and biotechnology sector; • changes in the structure of healthcare payment systems; • share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; • announcement or expectation of additional financing efforts; • sales of our common stock by us, our insiders or our other stockholders; • expiration of market stand- off or lock- up agreements; and • general economic, industry and market conditions. In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including in response to the COVID- 19 pandemic and ongoing economic uncertainty resulting from the war in Ukraine **and conflict in the Middle East** , inflationary pressures and rising interest rates. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a dramatic and adverse impact on the market price of our common stock. Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and / or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next **. An impairment in the carrying value of long- lived assets could negatively affect our consolidated results of operations and net worth. We have substantial amounts of long- lived assets, including right- of- use assets, property and equipment, which are subject to impairment analysis and review. Identifying and assessing whether impairment indicators exist, or if events or significant changes in market conditions have occurred, requires significant judgment.**

Any significant change in market conditions, including a sustained decline in our stock price, that indicate a reduction in carrying value, may give rise to impairment in the period that the change becomes known. We also continually evaluate whether events or circumstances have occurred that indicate the remaining estimated useful lives of our long- lived assets may warrant revision or whether the remaining balance of prepaid or other assets may not be recoverable. Any of the above actions could result in impairment charges which could substantially affect our reported earnings in the periods such charges are recorded . In addition, we measure compensation cost for stock- based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee' s requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following: • delays or increased costs related to the COVID- 19 ~~global~~ pandemic or other public health concerns; • the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time; • our ability to enroll patients in clinical trials and the timing of enrollment; • the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers; • expenditures that we will or may incur to acquire or develop additional product candidates and technologies; • the timing and outcomes of clinical trials for ~~lirentelimab~~ **AK006** and any of our future product candidates or competing product candidates; • the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated; • competition from existing and potential future products that compete with ~~lirentelimab~~ **AK006** and any of our future product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners; • any delays in regulatory review or approval of ~~lirentelimab~~ **AK006** or any of our future product candidates; • the level of demand for ~~lirentelimab~~ **AK006** and any of our future product candidates, if approved, which may fluctuate significantly and be difficult to predict; • the risk / benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with ~~lirentelimab~~ **AK006** and any of our future product candidates; • our ability to commercialize ~~lirentelimab~~ **AK006** and any of our future product candidates, if approved, inside and outside of the United States, either independently or working with third parties; • our ability to establish and maintain collaborations, licensing or other arrangements; • our ability to adequately support future growth; • potential unforeseen business disruptions that increase our costs or expenses; • future accounting pronouncements or changes in our accounting policies; and • the changing and volatile global economic environment. The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. Raising additional capital may restrict our operations or require us to relinquish rights to our technologies or product candidates, and if we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a variety of means, including equity offerings and potentially through debt financings, partnerships and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. We may also from time to time issue additional shares of common stock at a discount from the then current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our stockholders would experience additional dilution and, as a result, our stock price may decline. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. 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 or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of December 31, ~~2022~~ **2023** , our executive officers, directors, holders of 5 % or more of our capital stock and their respective affiliates beneficially owned approximately ~~47~~ **41** . ~~9~~ **7** % of our outstanding voting stock. As a result, this group of stockholders has the ability to significantly influence all matters requiring stockholder approval, including the election of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. **We have been and may in the future be subject to securities litigation, which is expensive and could divert management**

attention. The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We have been and may in the future be the target of this type of litigation. For example, on March 10, 2020, a putative securities class action complaint captioned Kim v. Allakos et al., No. 20- cv- 01720 (N. D. Cal.) was filed in the United States District Court for the Northern District of California against us, our Chief Executive Officer, Dr. Robert Alexander, and our former Chief Financial Officer, Mr. Leo Redmond. The complaint asserted claims for violations of Sections 10 (b) and 20 (a) of the Securities Exchange Act of 1934 and Rule 10b- 5 promulgated thereunder and sought damages based on alleged material misrepresentations and omissions concerning our Phase 2 clinical trials of lirentelimab. The ~~proposed class period~~ **complaint, as amended,** was ~~August 5, 2019, through December 17, 2019, inclusive. On March 31, 2022, the Court granted the defendants' motion to dismiss~~ **dismissed** ~~, with leave to amend~~ -- **and we** ~~. On April 29, 2022, the plaintiffs filed a second amended complaint which extended the proposed class period from December 17, 2019 to December 21, 2021 and added additional claims related to our Phase 3 ENIGMA clinical trial. On June 13, 2022, the defendants filed a motion to dismiss the second amended complaint. On December 6, 2022, the Court granted the defendants' motion to dismiss without leave to amend and entered judgment in the defendants' favor. The plaintiffs did not appeal the judgment, and the Company considers~~ **consider** this matter closed. That said, other securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. We have not paid and do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things: • establish a classified board of directors so that not all members of our ~~board~~ **Board** are elected at one time; • permit only the board of directors to establish the number of directors and fill vacancies on the board; • provide that directors may only be removed " for cause " ~~and only with the approval of two- thirds of our stockholders~~ ; • authorize the issuance of " blank check " preferred stock that our board could use to implement a stockholder rights plan (also known as a " poison pill "); • eliminate the ability of our stockholders to call special meetings of stockholders; • prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders; • prohibit cumulative voting; • authorize our board of directors to amend the bylaws; • establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and • require a super- majority vote of stockholders to amend some provisions described above. In addition, Section 203 of the General Corporation Law of the State of Delaware (" DGCL "), prohibits a publicly- held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15 % of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for: • any derivative action or proceeding brought on our behalf; • any action **or proceeding** asserting a claim of breach of **a** fiduciary duty **owed by any of our directors, officers, or other employees to us or our stockholders** ; • any action **or proceeding** asserting a claim ~~against us~~ arising ~~under~~ **pursuant to any provision of** the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; ~~and~~ **or** • any action **or proceeding** asserting a claim ~~against us that is~~ governed by the internal- affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act ~~(such provision, the " Federal Forum Provision "). However, on December 19, 2018, the Delaware Court of Chancery issued a decision in Matthew Sciabacucchi v. Matthew B. Salzberg et al., C. A. No. 2017- 0931- JTL (Del. Ch.), finding that such provisions such as the Federal Forum Provision are not valid under Delaware law. In light of this decision of the Delaware Court of Chancery, we do not intend to enforce the federal forum provision in our amended and restated certificate of incorporation unless and until such time there is a final determination by the Delaware Supreme Court regarding the validity of such provisions. If the decision is not appealed or if the Delaware Supreme Court affirms the Delaware Chancery Court' s decision, then we will seek approval by our stockholders to amend our certificate of incorporation at our next regularly- scheduled annual meeting of stockholders to remove the Federal Forum Provision~~ . These exclusive- forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive- forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. We are subject to

numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third- parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We have conducted and have ongoing studies in international locations, and may in the future initiate additional studies and conduct other activities in countries other than the U. S. Our business activities are subject to the FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201 the UK Bribery Act and other similar anti- bribery or anti- corruption laws and anti- money laundering laws, regulations or rules of other countries in which we operate. Anti- corruption and anti- bribery laws generally prohibit companies, their employees, agents, representatives, business partners, and third- party intermediaries from offering, promising, giving or authorizing others to give improper payments or benefits to recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls and compliance procedures designed to prevent violations of anti- corruption and anti- bribery laws. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to ~~regulation~~ **enforcement** under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. We sometimes leverage third parties to conduct our business and act on our behalf outside of the United States. We, our employees, agents, representatives, business partners and third- party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state- owned or affiliated entities and we may be held liable for the corrupt or other illegal activities of these employees, agents, representatives, business partners or third- party intermediaries even if we do not explicitly authorize such activities. While we have policies and procedures to address compliance with such laws, we cannot assure you that all of our employees, agents, representatives, business parties and third- party intermediaries will comply with our policies and procedures and applicable laws and regulations, particularly given the high level of complexity of these laws. Any allegations or violations of these laws and regulations could result in whistleblower complaints, investigations, prosecutions, settlements, enforcement actions, fines, severe criminal and civil sanctions, damages, adverse media coverage, loss of export privileges, or suspension or debarment from government contracts all of which could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition. Responding to any investigation or action will likely result in a materially significant diversion of management' s attention and resources and significant defense costs and other professional fees. In some cases, our products are subject to export control laws and regulations, including the Export Administration Regulations administered by the U. S. Department of Commerce, and our activities may be subject to trade and economic sanctions, including those administered by the United States Department of the Treasury' s Office of Foreign Assets Control, or OFAC, (collectively, " Trade Controls "). As such, a license may be required to export or re- export our products, or provide related services, to certain countries and end- users, and for certain end- uses. The process for obtaining necessary licenses may be time- consuming or unsuccessful, potentially causing delays in sales or losses of sales opportunities and these licenses may not be issued. Trade Controls are complex and dynamic regimes and monitoring and ensuring compliance can be challenging. Any failure to comply could subject us to both civil and criminal penalties, including substantial fines, possible incarceration of responsible individuals for willful violations, possible loss of our export or import privileges, and reputational harm. Although we have no knowledge that our activities have resulted in violations of Trade Controls, any failure by us or our partners to comply with applicable laws and regulations would have negative consequences for us, including reputational harm, government investigations, and penalties. We rely on both internal information technology systems and networks, and those of third parties, to transmit, store, and otherwise process information in connection with our business activities. We are increasingly dependent on our technology systems to operate our business, and our ability to effectively manage our business depends on the security, reliability and adequacy of our systems, networks, and data, and those for our CROs and other third- party service providers. Despite the implementation of security measures, the computer systems used by us or our third- party service providers are vulnerable to damage, disruption, outages, and interruptions from computer viruses, ransomware and other malicious code, denial of service and other cyberattacks, supply chain attacks, hacking and other means of obtaining unauthorized access, employee and service provider error or malfeasance, natural disasters, terrorism, war and telecommunication and electrical failure and other means to affect service reliability and threaten data confidentiality, integrity and availability. Any system failure, accident or security breach or incident that causes interruptions in our own or in third- party service providers' operations could result in a material disruption of our drug discovery and development programs. A system failure or security breach or incident that leads to the loss, unavailability or corruption of clinical trial data from completed or future clinical trials

could result in delays in our regulatory approval efforts and significantly increase our costs in order to recover or reproduce the affected data. In addition, any disruption or security breach or incident may result in the unavailability or loss of or damage to our data or applications, or inappropriate use, acquisition, disclosure or other processing of confidential or proprietary information and loss of intellectual property. Should any of these occur, we may incur liability as a result, our drug discovery programs and competitive position may be adversely affected, and further development of our product candidates may be delayed. Any such disruption, failure or security breach or incident could also cause us to incur additional costs to address the disruption, failure, breach or incident and to remedy the damages that arise from such disruption, failure or security breach or incident. We and our third- party service providers may face difficulties or delays in identifying or responding to any disruption, failure, security breach or incident, and may find it necessary or appropriate to incur substantial costs in an effort to improve the protection of our data and information technology infrastructure, whether in response to an actual or suspected security breach or incident or otherwise. Many of our employees work and access systems remotely, which increases the risk of security breaches and incidents. ~~The~~ **Geopolitical tensions and conflicts, such as the** ongoing Russia- Ukraine war may also create heightened risks of cyberattacks and other incidents. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, prevent or identify vulnerabilities or security breaches in or incidents impacting our systems or those of our third- party service providers, or prevent or identify other security breaches, incidents, or other compromises or events that lead to the loss or destruction of, or unauthorized access to, or use, disclosure or other processing of data we or our service providers process or maintain. Any actual or perceived security breach or incident may result in claims, demands and proceedings initiated by governmental actors or others, and financial, legal, business and reputational harm to us, including potential fines, penalties, and other damages and liabilities. Any such event may have a material adverse impact on our business, prospects, operating results and financial condition. Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach or incident. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: • increased operating expenses and cash requirements; • the assumption of additional indebtedness or contingent liabilities; • the issuance of our equity securities; • assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel; • the diversion of our management' s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition; • retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and • our inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline. The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts covering us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. In addition, if one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended (" Exchange Act "). We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the facts that judgments in decision- making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could harm our business. Our facility is located in a seismically active region and in a state which also experiences large scale wildfires from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. We maintain multiple copies of each of our antibody sequences and electronic data records, most of which we maintain at our

headquarters. If our facility were impacted by a seismic event, we could lose all our antibody sequences, which would have an adverse effect on our ability to discover new targets. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, ~~2022~~ **2023**, we had gross U. S. federal and state net operating loss carryforwards of $ **893. 7 million and $** 847. **2** ~~1 million and $ 682. 7~~ million, respectively. Federal net operating loss carryforwards of $ ~~785~~ **831**. ~~3~~ **8** million, which were generated after December 31, 2017, do not expire. The remaining $ 61. 8 million of federal net operating loss carryforwards expire beginning in 2032. It is possible that we will not generate taxable income in time to use our net operating loss carryforwards before their expiration (if applicable) or at all. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an " ownership change " (generally defined as a greater than 50 percentage points change (by value) in the ownership of its equity by certain stockholders over a rolling three- year period), the corporation' s ability to use its pre- change net operating loss carryforwards and certain other pre-change tax attributes to offset its post- change income and taxes may be limited. We may have had one or more ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Accordingly, our ability to utilize our net operating loss carryforwards and certain other tax attributes could be severely limited or eliminated by an " ownership change " as described above, which could result in increased tax liability to our company or reduced value of our deferred tax assets. Changes in tax laws or in their implementation or interpretation may adversely affect our financial condition, results of operations, and cash flows. We are subject to income and non- income taxes in various jurisdictions. Tax laws, regulations and administrative practices in these jurisdictions may be subject to significant change, with or without advance notice. For example, the United States enacted the Tax Cuts and Jobs Act of 2017, which, starting from January 1, 2022, eliminates the option to deduct research and development expenditures currently and instead requires taxpayers to amortize them over five or fifteen years. More recently, the United States enacted the Inflation Reduction Act ~~of 2022~~, which, among other provisions, imposes a one- percent excise tax on certain stock buybacks by U. S. publicly- traded corporations on or after January 1, 2023. In addition, the Organization for Economic Cooperation and Development proposed implementing a global minimum tax of 15 %, which is being adopted or considered by many jurisdictions. Changes in tax laws, regulations, or rulings, changes in interpretations of existing laws and regulations, or changes in accounting principles could negatively and materially affect our financial position, cash flows, and results of operations.