Risk Factors Comparison 2025-02-25 to 2024-02-28 Form: 10-K

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You should carefully consider the risks described below, as well as the other information in this Annual Report, including our audited consolidated financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The occurrence of any of the events or developments described below could adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our Class A ~~common~~ **ordinary** shares could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. Risks Related to **Commercialization** ~~Our Financial Position and Capital Needs~~ We have a history of operating losses and..... to decline. Risks Related to CommercializationWe may not be able to continue to commercialize ARCALYST or be successful in commercializing any future products, potentially impairing the commercial potential for our current and future products to generate any revenue. Since our commercial launch of ARCALYST, we have focused on establishing and expanding our internal capabilities, including but not limited to, sales, marketing, distribution, access and patient support services as well as ~~47contracting~~ -- **contracting** with third parties to perform certain services. Each aspect of commercialization on its own can be complex, expensive and time consuming, and, collectively, the required effort for coordination is intensive. While we have realized revenues from such efforts, there is no guarantee that we will be able to maintain the trajectory of growth or significant and sustained revenues in the long- term. In addition, our continued commercialization of ARCALYST or successful commercialization of any of our current or future product candidates, if approved, ~~is subject to~~ **could be materially adversely impacted by** a number of foreseen and unforeseen factors, including: ● ● our inability to recruit, train and retain adequate numbers of effective sales, marketing, access, and payor and patient support personnel; ● the inability of sales personnel to obtain access to prescribers and accounts **; ●** ~~as well as for~~ an ~~adequate~~ **inadequate** number of prescribers or accounts ~~to prescribe~~ **prescribing** ~~any of~~ our **current and** future products; ● the lack of complementary products to be supported by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; ● an absence or reduction in strong scientific- based relationships to drive disease awareness and education; ● our inability to establish the unmet medical need for a given disease **; ● our inability to provide acceptable evidence of safety and efficacy** ; ● our inability to enable our products to be viewed as the product of choice within any indications for which they are approved; ● **the prevalence and severity of side effects associated with any future product; ●** our inability to compete with current or future competitor products and / or biosimilars **; ● the convenience and ease of administration of our products relative to alternative therapies, if any** ; ● our inability or delay in gaining or maintaining reimbursement and broad patient access at a price that reflects the value of ARCALYST or any of our future products **; ● our inability to address product labeling or product insert requirements, including any changes mandated by regulatory authorities after initial approval** ; ● our inability to equip customer- facing personnel with effective materials, including medical and sales literature to help them educate physicians and other healthcare professionals regarding applicable diseases relevant to ARCALYST or any of our future products; ● any delays in ~~our ability to produce sufficient quantities of ARCALYST, or any of our future products, at an acceptable cost or quality, including such delays arising out of quality assurance concerns or changes in regulatory guidance, or those caused by our reliance on our third party manufacturers; ● any delays in~~ the ongoing technology transfer of the process for manufacturing ARCALYST drug substance; ● our inability to provide prescribers and patients adequate support and training to build comfort around the preparation and administration process to initiate and continue to use ARCALYST or any of our future products; ● our inability to develop or sustain robust patient support programs to optimize the patient and customer experience with ARCALYST or any of our future products; ● **publications of scientific literature, consensus papers and treatment guidelines unfavorable to the administration of our products and product candidates and / or the positioning of the class of drugs to which each of our products and product candidates belongs; ●** our inability to develop or obtain and sustain sufficient operational functions and infrastructure to support our commercial activities; **40** ● our inability to establish and maintain patent and trade secret protection or regulatory exclusivity for our products; ~~48~~ ● our inability to enforce and defend our intellectual property rights and claims; and ● unforeseen costs and expenses associated with creating and maintaining a sales, marketing, and access organization. If we experience any such factors that inhibit our efforts to commercialize ARCALYST or any of our product candidates, if approved, our business, results of operations, financial condition and prospects may be materially adversely affected. We rely on a select network of third party specialty pharmacies to market and sell ARCALYST **that may not meet our or our patients' needs** . We rely on a select network of third party specialty pharmacies to distribute ARCALYST and expect to use a similar strategy for our current and future product candidates, if approved. We rely on such specialty pharmacies to effectively distribute products in a timely manner, provide certain patient support services, manage prescription intake, collect accurate patient and inventory data and collect payments from payors. While we have entered into agreements with each of these specialty pharmacies, they may not perform as agreed, our strategic priorities may change or they may terminate their agreements with us. Further, an inability of our specialty pharmacies to meet our patients' needs may lead to reputational harm or patient loss. In the event that such network fails to properly meet our or our patients' needs, we may need to partner with other specialty pharmacies to replace or supplement our current network and there is no guarantee that we will be able to do so on commercially reasonable terms or at all. In addition, there is a risk that patients may discontinue or suspend their ARCALYST treatment in the process of transitioning between specialty pharmacies, and it may take time to re- integrate such patients into our network, if at all. In such an event our business, results of operations, financial condition and prospects may be materially affected. ~~Our current or future~~

~~products may not gain or sustain market acceptance by prescribers, patients, or third party payors (e. g., governments and private health insurers), in which case our ability to generate product revenues will be impaired. Even with FDA or any other regulatory authority approval of the marketing of ARCALYST or any of our other product candidates in the future (whether developed on our own or with a collaborator), prescribers, healthcare professionals, patients, the medical community or third party payors may not accept or use ARCALYST or any of our future product candidates, or may effectively block or limit their use in the case of third party payors. While ARCALYST has seen near- term success in the United States, it is not certain we will be able to sustain such success over the long- term. If ARCALYST or any of our other product candidates, if approved, do not achieve an adequate level of sustained acceptance, we may not generate a sufficient level of product revenue or profits from operations, if at all. Sustained market acceptance of ARCALYST in its approved indications, or any of our future products and continued use of such products by our patients, will depend on a variety of factors, including: ● the timing of market introduction; ● disease awareness, including understanding the severity and epidemiology of the disease; ● the number and clinical profile of competing products, whether approved or not; ● the potential and perceived advantages or disadvantages of our products relative to alternative treatments; ● our ability to provide acceptable evidence of safety and efficacy; ● the prevalence and severity of any side effects; ● product labeling or product insert requirements of regulatory authorities and our ability to maintain and expand favorable labeling when and if needed; 49 ● limitations or warnings contained in the labeling approved by regulatory authorities, including any additions mandated by authorities after initial approval; ● convenience and ease of administration, including relative to alternative therapies; ● pricing (including patient out- of- pocket costs), budget impact, affordability and cost effectiveness, particularly in relation to alternative treatments; ● market acceptance of current and future price increases of our products; ● the effectiveness of our sales, marketing and distribution activities; ● availability of adequate coverage, reimbursement and payment from health maintenance organizations and other insurers, both public and private, and the timing thereof; ● publications of scientific literature and consensus papers favorable to the administration of our products and product candidates; and ● other potential advantages over alternative treatment methods. If ARCALYST or any of our future approved products, if any, fail to gain or sustain market acceptance, our ability to generate revenue will be adversely affected. Even if ARCALYST or any future products achieve market acceptance, the relevant market may prove not to be large enough to allow us to generate significant and sustained revenue.~~ The successful commercialization of our current and future products, if any, will depend in part on the extent to which third party payors, including governmental authorities and private health insurers, provide funding, establish and maintain favorable coverage and pricing policies and set adequate reimbursement levels. Our ability to continue to commercialize ARCALYST in its approved indications or any of our future products, if any, particularly in orphan or rare disease indications, will depend in part on the availability of favorable coverage, **the adequacy of reimbursement (including affordability of** patient **cost- sharing obligations)** ~~affordability and the adequacy of reimbursement~~ for ARCALYST or the future product and alternative treatments from third party payors (e. g., governmental authorities, private health insurers and other organizations). We currently enjoy largely favorable coverage and reimbursement from third party payors for ARCALYST in the approved recurrent pericarditis indication and seek to maintain such favorable coverage and reimbursement. We cannot be certain we will continue to effectively execute our coverage and reimbursement strategy in the markets we pursue, which could limit the future commercial potential of ARCALYST in the approved recurrent pericarditis indication or any of our product candidates, if approved. Governmental authorities, private health insurers and other third party payors have attempted to control costs through a number of efforts, including by delaying the time to reimbursement, by restricting the breadth of coverage, **implementing utilization management controls such as requiring prior authorization,** limiting the amount of reimbursement for particular products and increasing the proportion of the cost for which the patient is responsible. There may be significant delays in obtaining reimbursement for newly approved products or product indications, coverage may be limited to a subset of the patient population for which the treatment is approved by the FDA or similar regulatory authorities outside the United States **including health technology assessment bodies in the EU and United Kingdom** , and reimbursement rates may vary according to the use of the product and the clinical setting in which it is used. Coverage and reimbursement barriers by payors may materially impact the demand for, or the price at which we can sell, ARCALYST and any product candidate for which we obtain marketing approval, if any. If coverage and reimbursement are not available, or available only at limited levels, or if such coverage will require patient out- of- pocket costs that are unacceptably high, our ability to successfully commercialize ARCALYST or any of the product candidates ~~for~~ **41for** which we obtain marketing approval may be adversely affected. Moreover, any coverage or reimbursement that may be obtained may be decreased or eliminated in the future. For example, in January 2023, one of the large private health insurers that currently covers ARCALYST placed ARCALYST on its exclusion list for the CAPS indication, which could create hurdles for new patients seeking coverage ~~50for~~ -- **for** their prescriptions in all indications. In addition, obtaining and maintaining favorable coverage and adequate reimbursement may require us to offer pricing concessions to third party payors. We may also be unable to adequately satisfy a third party payor' s value / benefit assessment on an ongoing basis. It is possible that third party payors will select low-cost clinical comparators that serve as benchmarks for determining relative value, including biosimilars and lower costs brands with or without the same approved indication. The result of such a change would be a more challenging value / benefit assessment and the potential for a worse relative outcome, including such payors refusing to provide coverage and reimbursement entirely, or finding the evidence not sufficiently compelling to support our desired pricing and reimbursement. Similarly, payors may implement coverage criteria that further restrict the use of ARCALYST or any of our product candidates, if approved, beyond the approved label, which could adversely affect their commercial potential, including, for example, situations where a patient must be proven to not adequately respond to the lower- cost comparator **before the payer will cover the use of ARCALYST or any of our product candidates, if approved** . We may be unable to sustain any favorable coverage and reimbursement on an ongoing basis. Third party payors may also revisit their previously established coverage policies from time to time including their assessment of the relative value / benefit provided by a drug product compared to clinical

alternatives, such as any competitive products with the same or similar indications and biosimilars. It is possible that a third party payor may consider our products and product candidates, if approved, as substitutable and only be willing to cover the cost of the alternative product. Even if we show improved efficacy, safety or improved convenience of administration with ARCALYST or any of our product candidates, if approved, pricing of competitive products may limit the amount we will be able to charge. Third party payors often introduce more challenging price negotiation methodologies when competitors exist or enter into the market. Third party payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. In some cases, when new competitor biosimilar products enter the market, there are mandatory price reductions for the innovator ~~compound~~ **product** . In other cases, payors employ " therapeutic category " price referencing and seek to lower the reimbursement levels for all treatment in the respective therapeutic category. Additionally, new competitor brand drugs can trigger therapeutic category reviews in the interest of modifying coverage and / or reimbursement levels. The potential of third party payors to introduce more challenging price negotiation methodologies could have a negative impact on our ability to continue to commercialize ARCALYST or successfully commercialize any of our product candidates, if approved. Third party payors may also employ challenging price negotiation tactics in the event of a proposed price increase of our current and future products. See " **Risk Factors —** Risks Related to Commercialization – It may be difficult for us to realize the benefit of increasing the price of certain of our commercialized products. " It may be difficult for us to realize the benefit of increasing the price of certain of our commercialized products. We have and may continue **to** periodically ~~to~~ increase the price of ARCALYST **and may implement similar pricing practices** ~~or~~ **for** ~~any of our~~ future products **, if approved,** and may be unable to realize commercial benefits from such price increases due to unfavorable actions that third party payors (including governmental authorities and private health insurers) may take in response. Even if price increases lie below contractual price protection clauses, payors may request price concessions in exchange for covering our products or may opt to change coverage or reimbursement policies with respect to such products. If we cannot successfully negotiate with such payors, we may be forced to provide significant price concessions or, if we fail to arrive at a satisfactory resolution, lose favorable coverage or reimbursement for patients served by such payor. In such an event, patients may have difficulty obtaining access to, or affording, such products and we may see materially negative impacts on our business operations. Any price concessions will reduce our overall revenue generation and may impair the benefit of any price increases we may take. Price concessions that reduce our product revenue may require us to rely on potentially dilutive capital- raising efforts to fund our operations, which may impact the price of our ~~common~~ **ordinary** shares. Even comparatively ~~small~~ **42small** discounts, if aggregated across payors, may cause materially lower revenue generation in the long- term, which may offset the increased revenue we hoped to realize through a price increase. Further, granting price concessions to one or more payors may limit our ability to negotiate prices with other payors or in other territories. Payors, including governmental payors, negotiate drug prices by reference to the prices we have set with other payors. Should payors become aware of price concessions that we have granted, they may request ~~51similar~~ -- **similar** concessions. If enough payors request and receive price concessions, our ability to generate revenue may be materially impacted, harming our business, financial condition and results of operations. Further, this may limit our ability to secure acceptable prices in potential new territories, which may materially limit our overall commercial growth. A limitation on our ability to commercialize in new and existing territories may also reduce our access to the patient populations we seek to serve, harming our ability to deliver therapeutics to patients with unmet medical need. In the event that we cannot successfully negotiate with payors requesting price concessions in connection with a price increase or otherwise, such payors may choose to not cover our current and future products at all or may ~~instate~~ **impose** onerous reimbursement policies that limit patient access. We cannot assure you that current payor coverage and reimbursement policies for ARCALYST will continue. **The** ~~As a small commercial stage company, the~~ loss of any payor, especially a large payor, or limitations on access to our drugs affecting a sizeable number of patients may materially harm our ability to generate revenue and execute on our commercial strategy. Further, as a company targeting patients with significant unmet medical need, the loss of access to our products may materially harm our targeted patient populations who cannot source adequate alternative therapies. We are also required to provide discounts or rebates under government healthcare programs or to certain government and private purchases in order to obtain coverage under federal healthcare programs. In addition, price increases that outpace inflation may also trigger additional rebate obligations, including under the Medicaid Drug Rebate Program. The incidence and prevalence for target patient populations of our products or product candidates have not been established with precision. If the market opportunities for our products and product candidates are smaller than we estimate, or if any approval that we obtain is based on a narrower definition of ~~the~~ **our targeted** patient population, our revenue and ability to achieve profitability may be materially adversely affected. The precise incidence and prevalence for all the conditions we aim to address with our programs are not known with specificity. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our products and product candidates, if approved, are based largely on our extrapolation from available population studies and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, pharmacy claims analyses, large national surveillance databases or market research, and may prove to be incorrect. Further, new trials and therapeutic options may lead to changes in the estimated incidence or prevalence of these diseases, or relevant subpopulations thereof. As a result, the number of patients who may benefit from our products or product candidates, if approved, may turn out to be lower than expected. The total addressable market for ARCALYST and any other of our current or future product candidates, if approved, will ultimately depend upon, among other things, the diagnostic criteria and applicable patient population included in the final label for the product or product candidate approved for sale for its indication; the efficacy, safety and tolerability demonstrated by the product candidate in our clinical trials; acceptance by the medical community; and patients, pricing, access and reimbursement. The number of addressable patients in the United States and other major markets outside of the United States may turn out to be

lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because the potential target populations are small for many of our approved and targeted indications, we may never achieve significant and sustained profitability. ~~Evolving~~ **43Evolving** health policy and associated legislative changes related to coverage and reimbursement aimed at lowering healthcare ~~expenditure~~ **expenditures** could impact the commercialization of our product candidates. Pharmaceutical pricing has been, and likely will continue to be, a central component of these efforts. The regulations that govern regulatory approvals, pricing and reimbursement for new pharmaceutical products vary widely from country to country. In markets of some of the countries we may pursue outside of the United States, our products and product candidates, if approved, may be subject to extensive governmental price control or other price regulations. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the ~~52pricing --~~ **pricing** review period begins after marketing approval is granted. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country ~~,~~ but then be subject to price negotiations that delay our commercial launch of the product candidate in that country, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Net prices for products may be reduced by mandatory discounts or legislated rebates that must be paid in order to participate in government healthcare programs or paid to other third party payors. Mandatory discounts can be legislated at any time in any market. Similarly, some markets currently have pricing legislation that sets the price of a pharmaceutical product in their market by referencing the price of that product in other markets, known as international reference pricing. International reference pricing has the potential to impact price cut decisions in individual countries and the countries that reference the pricing of certain other individual countries. Drug importation and cross- border trade, both sanctioned and unsanctioned, occurs when a pharmaceutical product from a market where the official price is set lower is shipped and made commercially available in a market where the official price is set higher. Any future relaxation of laws that presently restrict or limit drug importation or cross- border trade, including in the United States, could have a material negative impact on our ability to commercialize ARCALYST or any of our product candidates, if approved. As a result of the foregoing, we may not be able to achieve or sustain favorable pricing for ARCALYST or any of our product candidates, if approved, and adequate reimbursement, which may hinder our ability to recoup our investment in such drugs. For more information, see " Risk Factors – General Risk Factors – Enacted and future healthcare legislation may have a material adverse effect on our business and results of operations. " Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of ARCALYST and any product candidates that we may develop, if approved. We face an inherent risk of product liability exposure related to the commercialization of ARCALYST and the testing of our product candidates in clinical trials and other research activities. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for any products we commercialize; ● injury to our reputation and significant negative media attention; ● regulatory investigations that could require costly recalls or product modifications; ● difficulty in enrolling participants in clinical trials or withdrawal of clinical trial participants; ● significant costs to defend the related litigation; ● substantial monetary awards to trial participants; **44** ● loss of potential revenue; ● the diversion of management' s attention away from managing our business; and ● the inability to commercialize any product candidates that we may develop, if approved. ~~53Although --~~ **Although** we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur and is subject to deductibles and coverage limitations. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts. Any future growth outside of the United States would be subject to additional regulatory burdens and other risks and uncertainties. Our future **growth** ~~corporate profitability~~ may depend, in part, on our ability to commercialize our current and future products in markets outside of the United States either on our own or through collaborations with third parties. We continue to evaluate the opportunities for the development and commercialization of our product candidates in certain markets outside of the United States, including through our Managed Access Program and collaborations with third parties, including Huadong. We and our collaborators are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we, or our collaborators, must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials, manufacturing and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we obtain approval, and ultimately commercialize, our product candidates in markets outside of the United States, we would be subject to additional risks and uncertainties, including: ● our ability to obtain reimbursement for our product candidates in such markets; ● our inability to directly control commercial activities because we may rely on third parties; ● the burden of complying with complex and changing regulatory, tax, accounting and legal requirements of such countries; ● exposure to increased regulatory risk, including those arising under the FCPA (as defined below); ● different medical practices and customs in such countries affecting acceptance in the marketplace; ● import or export licensing requirements; ● longer accounts receivable collection times; ● longer lead times for shipping; ● language barriers for technical training and the need for language translations; ● reduced protection of intellectual property rights in certain countries; ● the existence of additional potentially relevant third party intellectual property rights; ~~and~~ **and45** ● foreign currency exchange rate fluctuations. **In** ~~Sales of our product candidates outside~~

~~of the United States could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. 54In~~ some countries, particularly ~~the~~ countries in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, price negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain adequate reimbursement or favorable pricing approval in some countries, we may be required to conduct a potentially costly clinical trial that compares our product candidate to other available therapies or in population groups not previously observed. Failure to demonstrate sufficiently desirable results to such parties may result in adverse pricing or reimbursement decisions. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. We may also be subject to burdensome pricing requirements. See " Risk Factors – Risks Related to Commercialization – Evolving health policy and associated legislative changes related to coverage and reimbursement aimed at lowering healthcare ~~expenditure~~ **expenditures** could impact the commercialization of our product candidates. Pharmaceutical pricing has been, and likely will continue to be, a central component of these efforts. " We are subject to ongoing obligations, regulatory requirements and continued regulatory review, which may result in significant additional expense. Additionally, our current and future products could be subject to unfavorable **regulatory** changes and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products. We are subject to ongoing regulatory requirements for a number of our activities, including manufacturing, packaging, labeling, storage, distribution, advertising, promotion, sampling, record- keeping, adverse event reporting, conduct of post- marketing trials and submission of safety, efficacy and other post- market information for our products in the United States. Such obligations, along with continued regulatory review, may result in significant additional expense. **In addition, approvals may come with potentially burdensome conditions.** Furthermore, if we seek and receive approval from regulatory authorities outside of the United States for products or any of our product candidates in the future, we will be subject to such authorities' requirements, which may be more stringent than our obligations in the United States. ~~Manufacturers~~ **See " Business – Government Regulation – BLA Review** and ~~their facilities are required to comply with extensive~~ **Approval " and " Business – Government Regulation – Post- Approval** ~~requirements~~ **Requirements "** ~~of regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we and our CDMOs will be subject to user fees and continual review and inspections to assess compliance with cGMP or similar foreign regulations and adherence to commitments made in any BLAs or MAAs. Accordingly, we and our CDMOs and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.~~ Any regulatory approvals that we receive may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor safety and efficacy. ~~For example, the holder of an approved BLA or similar foreign application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post- marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If marketing approval is obtained via the accelerated approval pathway,~~ we **fail** ~~could be required~~ to ~~conduct a successful confirmatory clinical trial to confirm clinical benefit for our products. An unsuccessful confirmatory trial or failure to complete such a trial could result in the withdrawal of marketing approval. The FDA or foreign regulatory authority also may place other conditions on approvals including the requirement for a REMS or similar risk management measures, to assure the safe use of the product. If the FDA or foreign regulatory authority concludes a REMS or similar risk management measures are needed, the sponsor of the BLA or MAA must submit a proposed REMS or the similar risk management measures before it can obtain approval. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. We also will be required to report certain adverse reactions, production problems, inadequate efficacy and other issues, if any, to applicable regulatory authorities on an ongoing basis. In addition, the identification of new safety issues could lead to new labeling or restrictions on population or use of our 55products, diminishing the addressable market or sales or both. Such conditions, requirements or events may prove to be expensive and burdensome, and the reporting of such may cause the price of our Class A common shares to decrease. Further, we must also~~ comply with ~~additional~~ **such** requirements **; if** ~~concerning advertising and promotion for our products, which are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved label. If~~ a regulatory agency discovers previously unknown problems with any of our current or future products, such as adverse events of unanticipated severity or frequency ~~, or~~ **; if** problems **arise** with the facility where a product is manufactured ~~,~~ **;** or **if a regulatory agency** disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring **suspension of sales and** withdrawal of the product from the market. If we discover previously unknown problems with a product or product candidate, including adverse events of unanticipated severity or frequency, or with our manufacturing processes; fail to comply with regulatory requirements; or a regulatory agency or enforcement authority disagrees with the promotion, marketing or labeling of our products, such regulatory agency or enforcement authority may, among other things: ● issue warning letters; ● impose civil or criminal penalties; ● suspend or withdraw regulatory approval; ● suspend any of our ongoing clinical trials; ● refuse to approve pending applications or supplements to approved applications submitted by us; **46** ● impose restrictions on our operations, including closing our CDMOs' facilities; ● require us to withdraw or correct our marketing materials; or ● seize or detain products or require a product recall. Any government investigation of alleged violations of law **and regulations** could require us to expend significant time, cost and resources in response, and could generate negative publicity or reputational harm. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our

operating results will be adversely affected. If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or the manufacture of a product, or if we or one of our distributors, licensees, co-marketers or other third parties operating on our behalf fails to comply with regulatory requirements, regulatory authorities could impose fines on us, impose restrictions on such product or its manufacture or require us to recall or remove such product from the market, in addition to withdrawing our marketing authorizations, or requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occur, our ability to sell an affected product may be impaired, and we may incur substantial additional expense to comply with such regulatory requirements. The policies of the FDA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States, Europe or in other jurisdictions. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to potentially significant enforcement actions. ~~56Our~~ -- **Our** business operations are subject to extensive healthcare regulation and enforcement by various government entities, and our failure to strictly adhere to these regulatory requirements could have a detrimental impact on our business. The **development and** marketing of pharmaceutical products and related arrangements with healthcare professionals, third party payors, patients, and other third parties in the healthcare industry are subject to a wide range of healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our current and future products. **See** ~~Restrictions under applicable federal, state and foreign healthcare laws and regulations, include the following: ● the United States federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward 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 federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ● the United States federal False Claims Act and civil monetary penalties laws, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for 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. Pharmaceutical manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to~~ " ~~cause~~ **Business – Government Regulation** " ~~the submission of false or fraudulent claims. Moreover, a claim including items and services resulting from a violation of the federal Anti- Kickback Statute is deemed a false or fraudulent claim for purposes of the False Claims Act; ● the United States Foreign Corrupt Practices Act (the " FCPA "), which prohibits United States companies and their representatives from paying, offering to pay, promising to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity abroad. In many countries, the healthcare professionals we interact with may meet the FCPA' s definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls; ● HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ● United States federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary' s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program; ● the United States federal physician payment transparency requirements, sometimes referred to as the " Sunshine Act ", which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children' s Health Insurance Program to report to the Department of Health and Human Services information related to certain financial interactions with 57physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners including physician assistants and nurse practitioners, and teaching hospitals, as well as the ownership and investment interests of physicians and their immediate family members; ● The FDCA, which, among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off- label use and regulates the distribution of samples; ● United States federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs; ● United States federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; ● analogous United States state laws and regulations, such as state anti- kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third party payors, including private insurers; and some state laws require pharmaceutical companies to adopt certain compliance standards; restrict interactions with healthcare professionals; disclose financial interactions with healthcare professionals to the government and public; report pricing information or marketing expenditures; or register sales representatives; and ● similar healthcare laws and regulations in the EU and other jurisdictions,~~

~~including reporting requirements detailing interactions with and payments to healthcare professionals, which may be applicable even if we are not commercializing a product in such jurisdictions~~. Given the broad scope and evolving government interpretation and enforcement of these laws, our business activities could be subject to challenge under one or more of such laws. We have entered into consulting and advisory board agreements with physicians and other healthcare professionals and could be adversely affected if regulatory authorities determine our financial relationships with such prescribers violate applicable laws or create a conflict of interest. For example, investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Regulatory authorities may conclude that a financial relationship between us and a principal investigator or a clinical trial site has created a conflict of interest or otherwise affected interpretation of a study. Regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized, which could result in a delay in approval, or rejection, of our marketing applications by regulatory authorities and may ultimately lead to the denial of marketing approval of our product candidates. Furthermore, investigators for our clinical trials may become debarred by regulatory authorities, which may impact the integrity of our studies and the utility of the clinical trial itself may be jeopardized. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations may involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the ~~operation~~ **47operation** of our business. If our operations, including activities conducted by our sales team, were to be 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 the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. ~~58Risks~~ -- **Risks** Related to Product Development If we are unable to advance our product candidates in clinical development and obtain regulatory approval, or experience significant delays in doing so, our business may be significantly harmed. Our product candidates are in various stages of clinical development. We base our projections about the future development and potential approval of our product candidates on indirect data from other companies and the results of our preclinical and clinical trials, but ultimate success is uncertain and involves significant risk. We cannot be certain that any of our product candidates will be successful in their clinical trials. We also cannot be certain that they will receive regulatory approval, even after completing a successful pivotal clinical trial. We may also choose **to cease development of a product candidate prior to conducting a pivotal trial for any reason, including capital conservation purposes. We may also choose** not to commercialize a product candidate that has completed a pivotal trial or received regulatory approval, for a number of reasons, including commercial viability. Such decisions may be for a particular indication or be for the product candidate entirely. In the event that a product candidate is unsuccessful in its clinical trials, fails to receive regulatory approval or is unviable for another reason, our business may be materially harmed by limiting our ability to recoup our development expenses through a successful commercial launch. Each of our product candidates requires substantial preclinical or clinical development and manufacturing support as part of our product development strategy. The clinical success of our current and future product candidates depends upon several factors, including, but not limited to, the following: ● submission to and authorization to proceed with clinical trials by the FDA under INDs ~~,~~and CTAs to applicable authorities outside of the United States for our product candidates to commence planned clinical trials or future clinical trials; ● successful completion of nonclinical studies, including toxicology studies, pharmacological, and biodistribution studies, as conducted, where applicable, under GLP; ● successful site activation for, enrollment in, and completion of clinical trials, including the ability of our CROs to successfully conduct such trials within our planned budget and timing parameters without adversely impacting our trials, and our ability to successfully oversee CRO activities; ● positive data from our clinical programs, including post- marketing trials and those intended to satisfy regulatory commitments or for label expansion, with sufficient quality to support an acceptable risk- benefit profile of our products and product candidates for the targeted indications in the intended populations to the satisfaction of the applicable regulatory authorities; ● timely receipt, if at all, of approvals from applicable regulatory authorities and maintenance of any such approvals; **48** ● as applicable, acceptance of pediatric study plans by regulatory authorities, and the follow through of any pediatric study commitments, such as development of pediatric formulations, if required; ● establishment and maintenance of arrangements with third party manufacturers, as applicable, for continued clinical supply and commercial manufacturing; ● successful development of our manufacturing processes and transfer to third party CDMO facilities to support our development and commercialization activities in a manner compliant with all regulatory requirements; ● successful manufacture of sufficient supply of our product candidates within approved specifications for purity, efficacy and cGMP requirements from our facility and from our CDMOs or other sole- source ~~59manufacturers~~ -- **manufacturers** in order to meet clinical or commercial demand, as applicable, for ourselves and for our partners; ● continued compliance with any post- marketing requirements imposed by regulatory authorities, including any required post- marketing clinical trial commitments or REMS or similar risk management measures; and ● maintenance of a continued acceptable safety profile of our product candidates before and following approval. If we do not accomplish one or more of these factors in a timely manner or at all we could experience significant delays in, or an inability to, timely or successfully commercialize our product candidates. Failure to generate sufficient revenue from the commercialization of our current and future products, whether as a result of failing to obtain regulatory approvals or unsuccessfully commercializing such products may harm our ability to continue our operations by limiting our potential commercial prospects. In such an instance, we may need to seek

capital elsewhere. See " Risk Factors – **General** ~~Risks – Risk Factors Related to Our Financial Position and Capital Needs – To further our~~ **We have a history of** ~~operational – operating losses and plans, we~~ may require substantial additional financing **in** ~~, which we may not be able to obtain when needed or on acceptable term " and " Risk Factors – Risks Related to Our Financial Position and Capital Needs – Raising additional capital may cause dilution to, or impact~~ the **future** ~~rights of, our shareholders, restrict our operations or require us to relinquish rights to our technologies, or product candidates or products~~ . " Clinical drug development is a lengthy and expensive process with uncertain timelines and outcomes. We may encounter substantial delays in our clinical trials, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities. We may therefore be unable to obtain required regulatory approvals and be unable to successfully commercialize our product candidates on a timely basis, if at all. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, time consuming and uncertain as to the outcome. Not all of our clinical trials have been conducted as initially planned or completed on our initial projected schedule, and accordingly, we cannot guarantee that any of our current or future clinical trials will be conducted as initially planned or completed on our initial projected schedule, if at all. Further, even if conducted on time, a clinical trial may result in unfavorable or statistically insignificant results ~~. For example~~ , **leading us** ~~in December 2021, we announced that the primary efficacy endpoint of the Phase 3 clinical trial of mavrilimumab in COVID- 19- related ARDS did not reach statistical significance. We subsequently decided~~ to **abandon our pursuit of a particular** ~~not progress mavrilimumab in the COVID- 19- related ARDS~~ indication **or the development of a product candidate entirely** . Clinical trials are a lengthy process that require the expenditure of significant money and human capital. Failing to achieve desired efficacy or identifying of a novel safety hazard in turn represents an inability to successfully recoup such expense via a potential commercialization of the product candidate, if approved. Sufficient inability to recoup clinical trial expenses via successful development could pose material risks to our business. See " Risk Factors – Risks Related to Product Development – If we are unable to advance our product candidates in clinical development and obtain regulatory approval, or experience significant delays in doing so, our business may be significantly harmed. " Commencing a clinical trial is subject to acceptance by the FDA of an IND or IND amendments, acceptance by competent authorities of the EU member states of a CTA under the CTR or acceptance by other applicable regulatory ~~authorities~~ **49authorities** , and finalizing the trial design based on discussions with the FDA, competent authorities of the EU member states or other applicable regulatory authorities. We have and may in the future receive feedback or guidance from regulatory authorities on our clinical trial design and protocols and, even after we incorporate such feedback or guidance from these regulatory authorities, such regulatory authorities may impose other requirements for our clinical trials; disagree that we have satisfied their requirements to commence our clinical trials; disagree with our interpretation of data from the relevant preclinical studies, clinical trials or CMC data; or disagree or change their position on the acceptability of our trial designs, including the proposed dosing level or schedule, treatment duration, our definitions of the patient populations or the clinical endpoints selected. Any of the foregoing may require us to complete additional preclinical studies, clinical trials, CMC development, other studies or impose stricter approval conditions than we currently expect. ~~60Commencing~~ – **Commencing** our planned clinical trials is also subject to approval by an institutional review board (an " IRB "), an ethics committee and / or other applicable committees for each clinical trial site before a trial may be initiated, which approval could be delayed, rejected or suspended. IRBs, regulatory authorities or other applicable safety committees may impose a suspension or termination of our clinical trials even after approval and initiation of trial sites due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by regulatory authorities, unforeseen safety issues or adverse side effects that arise in the trial, or failure to demonstrate a benefit from using a drug, any of which could result in the imposition of a clinical hold, as well as changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Successful completion of our clinical trials is a prerequisite to submitting a BLA or certain supplemental BLAs (" sBLA ") to the FDA, an MAA to the European Medicines Agency (the " EMA ") or **national** competent authorities of the EU member states, or other applicable regulatory authorities in other countries for each product candidate and, consequently, is a prerequisite to us obtaining approval and initiating commercial marketing of our current and any future product candidates. A failure of one or more of our current or future clinical trials can occur at any stage of testing, and our clinical trials may not be successful. We have experienced and may continue to experience delays in our ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, be allowed by regulatory authorities, require redesign, have timely site activation and participant enrollment or be completed on schedule, if at all. Events that have and may in the future delay or prevent commencement or successful completion of clinical development of our product candidates as planned and on schedule, if at all, include but are not limited to: ● inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical trials; ● delays or failure in reaching a consensus with regulatory agencies on trial design or implementation, including the appropriate dosage levels, frequency of dosing, or treatment period in clinical trials; ● delays or failure in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; ● difficulties in obtaining required IRB, ethics committee approval or positive opinion at each clinical trial site; ● delays or failure in obtaining regulatory approval to commence a trial, or imposition of a clinical hold by regulatory authorities; ● difficulty in identifying and enrolling suitable participants in a particular trial, **including due to competition from other companies' clinical trials for a particular indication,** which may reduce the power of a clinical trial to detect statistically significant results; ● amendments to clinical trial protocols impacting study criteria, endpoints or design, including amendments that either we initiate or are requested by regulatory authorities; **50** ● difficulty collaborating with patient groups and investigators; ● failure by our CROs, medical institutions, or other third parties we contract with in connection with our clinical trials to adhere to clinical trial requirements or to perform their obligations in a timely manner or in compliance with all applicable laws and regulations,

including the FCPA; ● failure to perform in accordance with ~~the FDA' s good clinical practices (" GCPs ")~~ or applicable comparable regulatory guidelines in other countries; ~~61~~ ● participants not completing a clinical trial or not returning for post-treatment follow- up, including as a result of trial demands on participants; ● clinical trial sites withdrawing from or being unable to conduct activities, or participants withdrawing from clinical trials, including as a result of a pandemic or other outbreak of disease and global conflict; ● participants experiencing serious adverse events or undesirable side effects or being exposed to unacceptable health risks; ● participants failing to experience confirmed pre- specified events during the clinical trial within an expected timeframe, if at all; ● safety issues, including occurrence of adverse events associated with a product candidate, that are viewed to outweigh its potential benefits; ● changes in regulatory requirements, policies and guidance that require amending or submitting new clinical protocols; ● the cost of clinical trials being greater than we anticipate; ● strategic decisions regarding clinical study priority for capital preservation purposes; ● failure by us, our CROs, or other third parties with whom we contract to properly collect, analyze, and / or assess clinical data, including the performance of assays, analyses and other activities; ● clinical trials of our product candidates producing negative, inconclusive or uncompetitive results, which may result in us deciding, or regulatory authorities requiring us, to conduct additional clinical trials or modify or cease development programs for our product candidates; ● failure to replicate safety, efficacy or other data from earlier preclinical studies and clinical trials conducted by us or third parties, including the companies from whom we have licensed or acquired or may in the future license or acquire our product candidates, in our later clinical trials; ● the occurrence of adverse or other events not observed in earlier studies; ● suspensions or terminations of our clinical trials by us or the IRBs of the institutions in which our clinical trials are being conducted, the Data Safety Monitoring Board for such trials or the FDA or comparable regulatory authorities; ● failure of manufacturers, or us, to produce sufficient quantities of or phase- appropriate supplies of our product candidates for use in our clinical trials in accordance with applicable cGMP requirements and regulations or applicable comparable regulatory guidelines in other countries; **51** ● delays in manufacturing, testing, releasing, validating or importing / exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing either as a result of quality assurance or due to our reliance on third party manufacturers; and ● disruptions to our business operations, including our manufacturing operations, and the business operations of our third party manufacturers, CROs upon whom we rely to conduct our clinical trials, or other third parties with whom we conduct business or otherwise engage, as well as disruptions in supply chain distribution in the countries in which we conduct our clinical trials, our manufacturers produce our product candidates or we otherwise conduct business or engage with other third parties, now or in the future. ~~62Delays --~~ **Delays** in the commencement or completion of our planned and ongoing clinical trials have occurred and may continue to occur. Consequences of delays have increased and may in the future increase our costs of developing our product candidates, slow down the development and approval of our product candidates, delay or jeopardize our ability to commence product sales and generate revenue, if any, from our product candidates and harm their commercial prospects. In addition, many of the factors that cause, or lead to, difficulties and delays in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates or us deciding to modify or cease development of our product candidates. Clinical trial delays could also shorten any periods during which our products have patent protection or shorten any periods during which we have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, which could impair our ability to obtain orphan exclusivity for our products that potentially qualify for this designation and to successfully commercialize our product candidates, and may harm our business and results of operations. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue and harm our business, financial condition and prospects significantly. Furthermore, clinical trials must be conducted in accordance with the laws, rules and regulations, guidelines and other requirements of the FDA, EU ~~institutions~~ **national competent authorities** , the EMA **, the UK Medicines and Healthcare products Regulatory Agency (the " MHRA ")** and other applicable regulatory authorities outside of those jurisdictions and are subject to oversight by these regulatory authorities and IRBs or ethics committees at the medical institutions where such clinical trials are conducted. Further, conducting global clinical trials, as we do for certain of our product candidates, may require that we coordinate among the legal requirements and guidelines of regulatory authorities across a number of jurisdictions, including the United States, **the** EU **, the United Kingdom** and countries outside of those jurisdictions, which could require that we amend clinical trial protocols or determine not to conduct a trial in one or more jurisdictions or to run separate trials in various jurisdictions due to the inability, cost or delay in harmonizing divergent requests from such regulatory authorities, all of which could increase costs. In addition, clinical trials that are conducted in countries outside the United States ~~and ,~~ the EU **and the United Kingdom** may subject us to risks associated with the engagement of non- United States ~~and ,~~ non- EU **and non- United Kingdom** CROs who are unknown to the FDA, the EMA or the EU **national component** ~~member states' regulatory~~ authorities **or the MHRA** and may have different standards of diagnosis, screening and medical care. Such trial sites may also incur risks associated with further delays and expenses as a result of increased shipment costs (including as a result of local quality release or in- country testing of a product candidate supply produced in a different jurisdiction for our clinical trials) and political and economic risks relevant to such countries outside the United States ~~and ,~~ the EU **and the United Kingdom** . In addition, the FDA' s and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. **Such** ~~See " Business -- Government Regulation " for a summary of rules and regulations applicable to our clinical trials, along with summaries of recent~~ changes **may require us** to ~~such rules~~ **dedicate time, resources** and ~~regulations. If~~ **capital to comply and, if** we are ~~slow or~~ unable to **do so effectively** ~~adapt to changes in existing requirements~~ or **on a timely basis** ~~the adoption of new requirements or policies governing clinical trials~~ , our development plans may be impacted **and our business** ~~. Further, conflicts around the globe~~ may ~~also~~ **suffer** ~~materially~~ -- **material harm** ~~affect our clinical activities and our product candidate development timeline~~ . **52We** ~~See " Risk Factors -- General Risk Factors -- Conflicts around the globe may have an adverse impact on our operations. " We~~ may find it difficult to enroll participants in our clinical trials in

a timely manner given the limited number of patients who have the diseases for which our product candidates are being studied, our particular enrollment criteria or competing clinical studies in the same patient population. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion, particularly given that many of the conditions for which we are evaluating our current product candidates or may evaluate in the future are in small disease populations. Accordingly, when we encounter difficulties in enrollment, we have experienced and may in the future experience delays, or we may be prevented from completing our clinical trials. Participant enrollment depends on many factors, including: ~~63~~ ● the size and nature of the patient population; ● the severity of the disease being studied; ● participant referral practices of prescribers; ● participant eligibility criteria for the clinical trial and evolving standards of care; ● the proximity of participants to clinical sites; ● the complexity of the design and nature of the clinical protocol and trial; ● the fact that our product candidates modulate the immune system and carry unique risks associated with immunosuppression, including the risk of serious infections, potential interference with vaccines and other potential serious health risks; ● the availability and nature of competing clinical trials; ● the availability of standard of care or new drugs approved for the indication the clinical trial is investigating ~~; ● competition with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates~~; ● failure to obtain, maintain and / or timely amend participant consents; ● our ability to recruit clinical trial investigators with applicable competencies and experience; ● the risk that participants enrolled in clinical trials will withdraw from the trials before completion of their treatment or follow- up period (in either case including as a result of trial demands on participants among other things); ● clinicians' and participants' perceptions as to the safety and potential advantages of the product candidate being studied in relation to other available therapies; and ● the occurrence of adverse events or undesirable side effects attributable to our product candidates. The process of finding and enrolling participants may prove costly, especially since we are looking to identify a subset of the participants eligible for our studies from a relatively small patient population for many of the diseases we are studying. If participants are unable or unwilling to participate in our clinical trials for any reason, or we experience difficulties in participant enrollment for any other reason, our costs may significantly increase and the timeline for recruiting participants, conducting trials and obtaining regulatory approval of our product candidates may be significantly delayed or prevented, the commercial prospects of our product candidates may be harmed, and our ability to commence product sales and generate product revenue from any of these product candidates, if approved, could be delayed or prevented. Any of these occurrences may harm our business, financial condition, and prospects significantly. ~~Our~~ **53Our** products and product candidates may cause undesirable side effects or have other safety risks that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences, including withdrawal of approval, following any potential marketing approval. Treatment with our products and product candidates may produce undesirable side effects or adverse reactions or events. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, ~~64delay~~ **delay** or halt clinical trials and could result in more restrictive labels or the delay or denial of regulatory approvals by regulatory authorities. Our products and product candidates modulate the immune system and carry risks associated with immunosuppression, including the risk of serious infections and other potential serious health risks. **If** ~~For mavrilimumab, there is a theoretical risk for the development of pulmonary alveolar proteinosis (" PAP ") with chronic use. PAP is a rare lung disorder in which surfactant- derived lipoproteins accumulate excessively within pulmonary alveoli due to loss of GM- CSF function. The disease can range in severity from a sub- clinical reduction in diffusion capacity to significant dyspnea during mild exertion. In preclinical studies conducted by MedImmune, certain effects were observed in the lungs of non- human primates, which led the FDA to issue a clinical hold with respect to MedImmune' s proposed clinical trial in RA. Preclinical data generated to- date suggest mavrilimumab at clinically relevant doses does not reach the lungs in sufficient quantities to induce PAP, and human trials thus far have not shown a clinical effect on pulmonary function tests attributable to mavrilimumab. However, if~~ the results of our clinical trials, including clinical trials evaluating our current products in new indications, or clinical trials conducted by collaboration partners, reveal an unacceptable severity and prevalence of certain side effects, the FDA or applicable regulatory authority outside of the United States may suspend or terminate our clinical trials, or not authorize us to initiate further trials. In addition, if other molecules in the same or related class ~~in~~ **being** ~~development~~ **developed or commercialized** by third parties show the same or similar side effects as those we observed in our trials but to a greater degree or ~~reported~~ **report** new previously **-** unreported side effects, it could have an impact on the entire class of molecules ~~in development~~, ~~as~~ **and** the applicable regulatory ~~agency~~ **authority** may **modify,** suspend **,** or terminate our clinical trials **; ,** ~~or~~ not authorize ~~us to initiate~~ further **clinical** trials ~~with~~ **; require post- marketing clinical trial commitments** ~~our~~ **or safety monitoring (e. g., REMS); or even suspend commercialization of any products or product candidates, as applicable, that contain a** molecule ~~in that~~ **within such** class. Further, third parties may have rights to independently develop and commercialize our current and future products and product candidates, which may increase the likelihood of adverse safety results. For example, Regeneron retains worldwide rights to develop and commercialize ARCALYST for local administration to the eye and ear and oncology, and Huadong holds rights to develop and commercialize ARCALYST ~~and mavrilimumab~~ in the **Huadong Territory** ~~Asia Pacific region, excluding Japan~~. The development of our product candidates and, if approved, commercialization of our products for new indications or new patient populations by these third parties may increase the possibility of uncovering adverse safety results not previously discovered during our own clinical development process or United States commercialization. Such effects, if uncovered by such third parties, may lead to regulatory authorities ordering us to cease further development of, deny or withdraw any approval of any of our products or product candidates, or require onerous label changes, for any or all targeted indications. In addition, the compassionate use of our products and product candidates, or evaluation of our products and product candidates by third parties via scientific collaborations **(e. g., our collaborative study agreement exploring ARCALYST as a treatment for cardiac sarcoidosis)** or investigator initiated studies could increase the possibility of generating adverse safety results that impact **our commercialization of such products or** our development of

such product candidates. Such adverse safety results, when reported to regulatory authorities, may negatively impact the safety profile of the drug studied as a class effect and could result in the imposition of clinical holds on all clinical trials involving such product candidate regardless of the indication studied. Further, clinical trials by their nature utilize a sample of the potential patient population. Certain rare and severe side effects associated with our products or product candidates may only be uncovered ~~with~~ **after use by** a significantly larger number of patients, including patients with different demographic characteristics than those that participated in our clinical trials ~~, exposed to the product candidates~~. If we or others later identify undesirable side effects caused by our ~~product~~ **products** ~~or any of our~~ **or** product candidates, if approved, a number of potentially significant negative consequences could result, including but not limited to: ● regulatory authorities may withdraw approvals of such product and require us to take it off the market; ● regulatory authorities may require the addition of labeling statements, specific warnings, contraindications or field alerts to prescribers and pharmacies; ~~65~~ ● we may be required to create a registry or a REMS plan or similar risk management measures, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare professionals or other elements to assure safe use; **54** ● we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; ● we may be subject to limitations on how we promote the product, or sales of the product may decrease significantly; ● we could be sued and held liable for harm caused to patients; ● the product may become less competitive; and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product or product candidate, if approved, and could significantly harm our business, results of operations and prospects. Interim, preliminary, and " top- line " data from our clinical trials that we announce or publish from time to time may change as more participant data become available following the release of the interim data; preliminary data are subject to audit and verification procedures, and deeper analysis of the data beyond the topline data may provide more color and context to the data, all of which could result in material or other changes that are reflected in the final data. From time to time, we may disclose interim data from our preclinical studies or clinical trials, which are based on an interim analysis of then-available data from ongoing studies or trials. Interim data from our preclinical studies and clinical trials are subject to the risk that one or more of the clinical observations may materially change as participant enrollment continues and more participant data become available from the particular study or trial. As a result, interim data should be viewed with caution until final data are available. Adverse differences between interim data and final data could significantly harm the development of our product ~~candidate~~ **candidates** and our business prospects with respect thereto. Further, from time to time we may announce or publish topline or preliminary data from our preclinical studies or clinical trials, which are based on a preliminary analysis of data from a completed study. Preliminary and topline data from our clinical trials are subject to change following a more comprehensive review of the data from the particular clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our preliminary analyses of the data, and we may not have received, or had the opportunity to evaluate fully and carefully, all of the data. As a result, preliminary and topline data remain subject to audit and verification procedures that may result in the final data being different from the preliminary data we previously announced or published. Third parties, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our business prospects. In addition, the information we announce or publish regarding a particular preclinical study or clinical trial may represent only a portion of extensive information generated from that study or trial, and our shareholders or other third parties may not agree with what we determine is material, important or otherwise appropriate information to include in our disclosure. If the interim, preliminary, or topline data that we report differ materially from final results, or if third parties, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business prospects, operating results or financial condition. Further, announcement of preliminary, interim or top- line data by us or differences between that data and the final data could result in volatility in the price of our Class A ~~common~~ **ordinary** shares. ~~66Risks~~ **55Risks** Related to Marketing Approval and Regulatory MattersRegulatory approval processes are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our current or future product candidates or if we fail or otherwise cease to advance their development, we will be delayed in commercializing or will not be able to commercialize, our current or future product candidates and our ability to generate additional revenue will be materially impaired. Before we can commercialize any of our current or future product candidates, we must obtain marketing approval from regulatory authorities. We may not be able to receive approval to market any of our current or future product candidates from regulatory authorities in our desired indications in any jurisdiction **,** and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We may need to rely on third party CROs and regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish a product candidate' s safety and efficacy. Securing regulatory approval also requires the submission of information about the biologic manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities, who may deny approval based on the results of such submissions and inspections. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The FDA and other regulatory authorities have substantial discretion in the approval process, including determining when or whether regulatory approval will be obtained for a product candidate. Even if we believe the data collected from clinical trials are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority or such authorities may request additional information that may be difficult to generate or provide. Further, following approval, the FDA may conduct additional inspections and, based on the results of such inspections,

deem the inspected manufacturing facilities to be deficient, suspending our ability to manufacture our product candidates until we can secure satisfactory alternative manufacturing facilities. In addition to the United States, we may seek regulatory approval to commercialize our product candidates in other jurisdictions. While the scope of regulatory approval is similar in many countries, to obtain separate regulatory approval in multiple countries will require us to comply with numerous and varying regulatory requirements of each such country or jurisdiction regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution, and we cannot predict success in any such jurisdictions. The process of obtaining regulatory approvals, both in the United States and in other countries, is time consuming, expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in **legislation, regulation or policy governing the development, approval and** marketing ~~approval policies during the development period, changes in or the enactment~~ of **biological products** ~~additional statutes or regulations, or changes in regulatory review for each submitted BLA, or equivalent application types,~~ may cause delays in ~~the approval or~~ **our** ~~rejection of an~~ **plans for submitting marketing** ~~application~~ **applications and obtaining approvals for such applications, or we may be unable to obtain marketing approvals** . For instance, **comprehensive proposals have been made for** the **complete overhaul of the existing** EU pharmaceutical legislation ~~is currently undergoing a complete review process~~ , in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission' s proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising eligibility for expedited pathways, etc.) was published in April 2023. The proposed revisions **received a positive first** ~~remain~~ **reading of** ~~to be agreed and adopted by~~ the European Parliament and European Council ~~(not expected~~ **has yet to consider the legislative proposal. It is unlikely that the new law will be adopted through the EU legislative process** before ~~early 2025~~ **2026** ~~) and~~ **. When adopted, the new law** may have a significant impact on the biopharmaceutical industry in the long- term. 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 studies or clinical or other trials for our current or future product candidates. Our current and future product candidates could be delayed in receiving, or fail to receive, regulatory approval or we may fail or cease to advance their development for many reasons, including the following: ~~67~~ **56** ● regulatory authorities may disagree with the number, design or implementation of our clinical trials to support further development or approval; ● we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for its proposed indication or that its clinical and other benefits outweigh its safety risks; ● regulatory authorities could require us to collect additional data or conduct additional clinical trials, which could include a requirement to compare our products or product candidates to other therapies for the treatment of the same indication; ● regulatory authorities, following the discovery of adverse safety signals or side effects from approved therapeutics or therapeutics in development in the same or related class as our products or product candidates, could require us to collect additional data or conduct additional clinical trials; ● the results of clinical trials may produce negative, inconclusive or uncompetitive results, which may result in us deciding, or regulatory authorities requiring us, to conduct additional clinical trials or to modify or cease development programs for our product candidates; ● the results of clinical trials may not meet the primary or secondary endpoints of the applicable trial or the level of statistical significance required by regulatory authorities; ● regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; ● the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, sBLA **, MAA** or other submission or to obtain regulatory approval in the United States **, Europe** or elsewhere; ● the number of participants required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable participants for a trial; ● our third party contractors may fail to comply with data quality and regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; ● regulatory authorities may ~~not~~ believe that we have **not** sufficiently demonstrated our ability to manufacture our candidates to the requisite level of quality standards, including that such material is sufficiently comparable to material used in previous clinical trials, or they may fail to approve our manufacturing processes or facilities, or the manufacturing processes or facilities of third party manufacturers with which we contract for clinical and commercial supplies; ● regulatory authorities may **conclude** ~~not believe~~ that ~~their~~ on- site inspections and data audits have **not** sufficiently demonstrated the quality and integrity of the clinical trial conduct and of data submitted to regulatory authorities in support of our new product approvals and marketing applications; ● the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; ● our product candidates may have undesirable side effects, toxicities or other unexpected characteristics, causing us or our investigators, regulatory authorities or IRBs to reject, suspend or terminate the clinical trials; ~~and68 --~~ **and** ● the ~~approval~~ policies ~~or~~ **,** regulations **and guidelines** of regulatory authorities **regarding the development, approval and marketing of biologic products** may significantly change **, including** in **the United States, as** a ~~manner~~ **result of the 572025 change in presidential administration, which may** ~~rendering --~~ **render** our clinical data, biologic manufacturing process and other supporting information insufficient for approval **or restrict us from marketing our product candidates in the manner in which we anticipate** . In addition, even if we were to obtain approval for one or more of our current or future product candidates, regulatory authorities may approve such product candidates for fewer indications or more limited patient populations than we request. Furthermore, regulatory authorities or payers may not approve the price we intend to charge, may grant approval contingent on the performance of costly postmarketing clinical trials, may impose certain postmarketing requirements that impose limits on our marketing and distribution activities, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our current or future product candidates. If we experience delays in obtaining approval or if we fail to obtain approval of or to advance our current or future

product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate additional revenue will be materially impaired. Our products, current product candidates and any of our future product candidates regulated as biologics in the United States may face biosimilar competition sooner than anticipated. In the United States, the BPCIA created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved under a BLA by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12 year period of exclusivity, another company may still market a competing version of the reference product for the same therapeutic indication if the FDA approves a full BLA for the competing product containing the sponsor' s own preclinical data and data from adequate and well controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. For example, although ARCALYST was approved as a biological product under a BLA for the treatment of CAPS in February 2008, and we believe it qualified for the 12 - year period of exclusivity against any biosimilars, such 12 - year period of exclusivity has lapsed. The FDA approved ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and children 12 years of age and older in March 2021. However, the 12 - year exclusivity period does not attach to the approval of an sBLA, potentially creating the opportunity for biosimilar competition, subject to any Orphan Drug exclusivity under the United States Orphan Drug Act. See " Risk Factors — Risks Related to Marketing Approval and Regulatory Matters — We may seek Orphan Drug designation for our product candidates in the United States, as well as for any of our product candidates in the EU, and we may be unsuccessful, or may be unable to maintain the benefits associated with Orphan Drug designation, including the potential for market exclusivity, for any product candidate for which we obtain Orphan Drug designation. " If we obtain FDA approval for any of our other biological product candidates, we expect any such product candidates to qualify for the 12 - year period of exclusivity under the BPCIA. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider any such approved product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Even if we obtain marketing authorization of our current or future product candidates in a major pharmaceutical market such as the United States, or the EU, we may not seek or obtain approval or commercialize our current products or product candidates in other markets, which would limit our ability to realize their full market potential. In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such country or territory regarding safety and efficacy. Regulatory requirements can vary widely from country to country, and clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be ~~69obtained~~ **58obtained** in any other country. Approval procedures vary among countries and can involve additional product testing and validation, additional administrative review periods, and additional preclinical studies or clinical trials, which would be costly and time consuming and could delay or prevent the introduction of our current or future product candidates, or ARCALYST, in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We may seek Orphan Drug designation for our product candidates in the United States, as well as for any of our product candidates in the EU, and we may be unsuccessful, or may be unable to maintain the benefits associated with Orphan Drug designation, including the potential for market exclusivity, for any product candidate for which we obtain Orphan Drug designation. We have received Orphan Drug exclusivity and designation in the United States for ARCALYST for the treatment of pericarditis ~~and mavrilimumab for the treatment of GCA, respectively~~ . In addition, we have received Orphan Drug designation in the EU for ARCALYST for the treatment of idiopathic pericarditis. In the future, we may seek Orphan Drug designation for certain of our other product candidates in the United States or the EU. We may be unsuccessful in obtaining such designation for any of our other product candidates or unable to maintain the associated benefits for any of our other current or future product candidates that are granted Orphan Drug designation, if any. **Even if we obtain Orphan Drug designation for certain product candidates for a particular orphan indication in the United States or the EU, we may not be the first to obtain marketing approval for such orphan indication due to the uncertainties associated with developing pharmaceutical products. In such case, subject to applicable laws in those jurisdictions, Orphan Drug exclusivity may no longer be available for our product candidates, if approved, unless we can show a significant benefit over the already approved orphan drug. Moreover, in the event our drug is deemed similar to the first approved orphan drug, we may be denied regulatory approval for our drug in such orphan indication for the duration of the Orphan Drug exclusivity period.** Regulatory authorities in some jurisdictions, including the United States and ~~Europe~~ **the EU** , may designate drugs or biologics intended to treat ~~relatively~~ small patient populations as Orphan Drug products **, which are subject to a number of region- specific (e. g., tax credits, user fee exemptions and potential market exclusivity) rules and regulations** . See " Business – Government Regulation – Orphan Drug Designation " and " Business – Government Regulation – Regulatory Framework in the European Union – Orphan Medicinal Products " for more information on applicable rules and regulations. In connection with the FDA' s approval of ARCALYST in the recurrent pericarditis indication, we received seven years of Orphan Drug exclusivity for ARCALYST for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older. Even if we obtain Orphan Drug exclusivity for any of our product candidates, that exclusivity may not effectively protect those product candidates from competition because different drugs can be approved for the same disease or condition. Even after an Orphan Drug is approved, the FDA can subsequently approve a later application for the same drug for the same disease or condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a

major contribution to patient care. In addition, a designated Orphan Drug may not receive Orphan Drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, Orphan Drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Foreign regulatory authorities may also make the same determination. 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. We may seek Breakthrough Therapy designation or Fast Track designation by the FDA, for one or more of our product candidates, which we may not receive. Such designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval. We may seek Breakthrough Therapy or Fast Track designation for one or more of our product candidates **, which, if granted, offers the potential for a rolling review of a BLA if a number of conditions are met, which would allow data to be submitted and reviewed as they become available rather than waiting for the full data package to 59become available to be submitted. Rolling review is often faster than the FDA' s standard review process** . See " Business – Government Regulation – Expedited Review and Approval " for more information on applicable rules and regulations. The FDA has broad discretion whether or not to grant Fast Track and Breakthrough Therapy designations, and even if we believe a particular product candidate is eligible for such designations, we cannot be certain that the FDA would decide to grant them. Even if we obtain such designations for one or more of our product candidates, we may not experience a faster development process, review or approval compared to non- expedited FDA review procedures. In addition, the FDA may withdraw Fast Track or Breakthrough Therapy designations if it believes that such designations are no longer supported. Although product candidates receiving Fast Track and Breakthrough Therapy designation are generally eligible for the FDA' s priority review procedures, receiving such designations does not guarantee that the BLA for such product candidates will receive priority review. ~~70We~~ **We** may seek ~~EMA~~ **a** PRIME designation **from the EMA** , a conditional MA or other designations, schemes or tools for one or more of our product candidates, which we may not receive. Such designations may not lead to a faster development or regulatory review or approval process and do not increase the likelihood that our product candidates will receive marketing authorization. We may seek ~~EMA~~ **a** PRIME (Priority Medicines) designation **from the EMA** , a conditional MA or other designations, schemes or tools for one or more of our product candidates **, each of which offer incentives similar to a United States Breakthrough Therapy designation** . See " Business – Government Regulation – Regulatory Framework in the European Union – PRIME Designation " and " Business – Government Regulation – Regulatory Framework in the European Union – Marketing Authorization " for more information on the applicable rules and regulations. Even if we believe one of our product candidates is eligible for PRIME, the EMA may disagree and instead determine not to make such designation. The ~~EMA~~ PRIME scheme or other schemes, designations, or tools, even if obtained or used for any of our product candidates may not lead to a faster development, regulatory review or approval process compared to therapies considered for approval under conventional procedures and do not assure ultimate approval. In addition, even if one or more of our product candidates is eligible to the PRIME scheme, the EMA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for review or approval will not be shortened. The ~~competent~~ regulatory authorities in the EU have broad discretion whether to grant such an accelerated assessment, conditional marketing authorization or marketing authorization under exceptional circumstances, and, even if such assessment or authorization is granted, we may not experience a faster development process, review or authorization compared to conventional procedures. Moreover, the removal or threat of removal of such marketing authorizations may create uncertainty or delay in the clinical development of our product candidates and threaten the commercialization prospects of our products and product candidates, if approved. Such an occurrence could materially impact our business, financial condition and results of operations. **Due to the recent change in presidential administration, we face substantial uncertainty regarding potential regulatory developments in the United States that may adversely affect our business.** We **face substantial uncertainty regarding the potential for changes in the regulatory environment in the United States following the change in presidential administration in January 2025. While many of the Trump Administration' s proposed policies appear to be focused on deregulation, the new administration and federal government could adopt legislation, regulation or policies that adversely affect our business, including by making it more difficult to continue to market ARCALYST or by creating a more challenging and costly environment to pursue the development and commercialization of our current or future product candidates. For example, the federal government, including the FDA, may implement legislative, regulatory or policy changes regarding the standards for approving biologic products that we** may be unable to ~~successfully obtain~~ **satisfy or changes regarding the** marketing **of approved biologics that may limit or prohibit the advertising and promotion of ARCALYST and, if approved, our current or future product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and** ~~approvals~~ **approval process** for ~~any of~~ our **product candidates. 60Additionally, because one objective of the** current **Trump administration appears** ~~or future product candidates. Failure~~ to ~~obtain marketing approval~~ **be to decrease spending** in **the federal government, the FDA** ~~a timely manner for any of our current or future product candidates~~ could **face staff reductions** ~~have a material adverse impact on our business and financial performance. Obtaining marketing approval for any of our current or future product candidates may require more time and expense than we anticipate. Failure to successfully complete, or delays in, any of our eventual other pivotal trials or related regulatory submissions would prevent us from, or delay us in, obtaining regulatory approval for our current or future product candidates. It is possible that regulatory authorities may refuse to accept for substantive review any regulatory submissions that we submit for our product candidates or may conclude after review of our applications for any of our current or future product candidates that the submissions are insufficient to obtain marketing approval for such product candidates. Regulatory authorities may also require that we conduct additional clinical, preclinical or manufacturing validation trials and submit that data before~~

~~they will reconsider our applications. Depending on the extent of these or any other required trials, approval or receipt of any marketing authorization may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional trials, if performed and completed, may not be considered sufficient by regulatory authorities to approve or grant marketing authorizations. Any delay in obtaining, or an inability to obtain, marketing approvals would delay or prevent us from commercializing any of our current or future product candidates, which may impair our ability to generate additional revenue. If any of these outcomes occur, we may be forced to modify or cease our development efforts for one or more of our product candidates~~ , which could ~~significantly harm our business. Disruptions at the FDA and other government agencies could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively~~ impact ~~our business. The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, potential or actual government shutdowns or debt defaults, statutory, regulatory, and policy changes,~~ the FDA' s ~~or foreign~~ **ability to engage in routine** regulatory ~~authorities'~~ **and oversight activities and result in delays or limitations on our** ability to ~~hire~~ **proceed with clinical development programs** and **obtain regulatory approvals. It is difficult to predict how executive actions** ~~retain key personnel and accept the payment of user fees, and other events~~ that may ~~otherwise~~ **be taken by the Trump administration may** affect the FDA' s ~~or 71foreign~~ **ability to exercise its** regulatory ~~authorities~~ **authority . If such executive actions impose constraints on the FDA** ' **s** ability to ~~perform~~ **engage in** routine ~~functions. Average~~ **oversight and product** review ~~times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development~~ activities **in** ~~is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other~~ -- **the** ~~agencies~~ **normal course** , ~~such as the EMA, may also slow the time necessary for new biologics or modifications to approved biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect~~ our business ~~. For example, over the last several years, the United States government has shut down several times and hit its debt limit, which has caused certain regulatory agencies, such as the FDA, to furlough critical FDA employees and stop critical activities. Further, the emergence of pandemics or other global health emergencies~~ may **be negatively** ~~cause disruptions in regulators' activities and functions. If global health concerns prevent regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact~~ **impacted** ~~the ability of such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business~~ . Risks Related to Manufacturing and Our Reliance on Third Parties We contract with third parties for manufacturing our commercial supply of ARCALYST and clinical supply for our product candidates and for certain research and other preclinical development **, which is highly regulated and complex,** and expect that we will continue to do so in the future. This reliance on third parties increases the risk that we may not have sufficient quantities of ARCALYST or our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our research and development or commercialization efforts. We do not currently own or operate any late- stage or commercial manufacturing facilities. Although we have built a development and manufacturing facility to produce drug substance to support certain research, preclinical and other clinical development for our product candidates, we rely, and expect to continue to rely, on third parties for the manufacture of our late- stage product candidates and certain early- stage product candidates for the majority of our clinical development efforts; the commercial manufacture of our current and future products; and labeling and packaging activities for our current and future products. We rely on these third parties to produce **, package and ship** our products and product candidates at sufficient quality and quantity to support our and our collaboration partners' commercialization and research and development efforts ~~business~~ .The manufacture of our current and future products and product candidates is highly regulated,complex and difficult,requiring a multi- step and controlled process,and even minor problems or deviations could result in ARCALYST or our product candidates failing to meet approved specifications,failed batches or other failures,such as defective products or manufacturing failures.Due to the highly technical requirements of manufacturing our current and future products and product candidates and the strict quality and control specifications,we and our third party providers may be unable to manufacture or supply ARCALYST or our product candidates despite our and their efforts.Failure to produce sufficient quantities of our **products and** product candidates could delay their development,result in supply shortages for our patients,result in lost revenue,if any,and diminish our potential profitability,as applicable,which may lead to lawsuits or could delay the introduction of our product candidates to the market ~~.~~. Our reliance increases the risk that we will have insufficient quantities of ARCALYST and our product candidates or that ARCALYST and our product candidates are not produced at an acceptable cost or quality, or not in a timely manner due to, for example, **deviations in operations or manufacturing facility control, or** production interruptions caused by equipment failure and an inability to source adequate replacement parts and equipment, which could delay, prevent or impair our commercialization or research and development efforts. From time to time, we have identified events in the ARCALYST manufacturing process that prevented distribution of ARCALYST material as planned, though this has yet to **materially** impact our ability to source sufficient ARCALYST material to cover our needs. **If, in the future, we are unable to source sufficient finished material, we may stock out or otherwise be unable to meet patient demand for ARCALYST, adversely affecting our business, results of operations and financial condition. In addition,** ~~Equipment~~ **equipment** used in the ARCALYST manufacturing process may no longer be supported by vendors in the event of equipment failure. Such equipment may also not be repaired, replaced or qualified in a timely manner. Further, reagents used for the analytical testing of ARCALYST have and may in the future become outdated, requiring qualification before new reagents may be used. These issues may be exacerbated by increased clinical or commercial demand by us or our collaboration partners, or if we decide to develop ARCALYST in one or more additional indications or in additional territories. ~~If we encounter events in the~~ **We may be unable to adequately address current and** future ~~that~~ **issues with the ARCALYST manufacturing process, which could** prevent additional **finished** material from being distributed in a timely manner or within specifications

~~and . If~~ we are unable to source additional commercial supply of ARCALYST, if needed, ~~or should future manufacturing or supply chain issues arise,~~ we may be unable to ~~adequately~~ **61adequately** meet patient demand for ARCALYST or may be required to effect a recall, any of which would adversely affect our business, results of operations and financial condition. Regeneron ~~and its~~ **is** ~~CDMOs are~~ the sole ~~manufacturers~~ **manufacturer** of ARCALYST **drug substance** and will remain so until we complete the technology transfer of the manufacturing process for ARCALYST drug substance to **Samsung** ~~a new CDMO~~. Regeneron is not obligated to accept our forecasts or purchase orders that are not in line with accepted forecasts and Regeneron may not have sufficient manufacturing capacity to meet our commercial or clinical demand for ARCALYST **(including increased demand arising from our need to replace material lost to manufacturing issues)**. Regeneron, in turn, relies upon CDMOs or other third parties to conduct fill / finish operations for ARCALYST. In the event that a particular batch of ARCALYST fails to meet specifications, whatever the cause, we are nonetheless obligated to pay for such ~~72material~~ **material** pursuant to the terms of the Supply Agreement. ~~As~~ **Further, we rely on** a ~~result of our~~ **third party CDMO to package and label ARCALYST. Our** reliance on Regeneron ~~and~~ **(including** its **respective** CDMOs **) and our other CDMO** as our sole manufacturers ~~,~~ **and / or service providers means that** we do not have control over ~~their~~ **ARCALYST** manufacturing operations and scheduling, which may impact our ability to meet commercial or clinical demand for ARCALYST. We may also be subject to unexpected costs arising from any manufacturing or supply chain disruptions, which may materially impact our business, results of operations and financial condition. Many of these risks may still be present after successful completion of the technology transfer of ARCALYST drug substance manufacturing and there is no guarantee that such technology transfer will materially diminish our ARCALYST manufacturing risk profile. We have qualified or engaged, as applicable, CDMOs to produce our clinical product candidates. While we have manufacturing capabilities to support early development for our product candidates, we and our CDMOs may not be able to produce sufficient quantities of our product candidates or produce them at an acceptable quality, including as a result of global supply chain issues, which could delay, prevent or impair our development or commercialization efforts and increase costs. We ~~have entered into certain~~ **are party to a** collaboration ~~agreements~~ **agreement** with Huadong for ~~each of~~ ARCALYST ~~and mavrilimumab~~. Until such time as Huadong is able to manufacture **ARCALYST** ~~these products~~, either on its own or through a third party CDMO, we are ~~the~~ **its** only source of **drug supply** ~~these products for Huadong~~. If our current ~~suppliers~~ **supplier** of drug substance and drug product for ARCALYST ~~and mavrilimumab~~ cannot produce sufficient quantities to satisfy our needs and Huadong' s needs, then this may have an adverse impact on our and Huadong' s business and operations. If we make manufacturing or formulation changes to our products or product candidates or change manufacturers or manufacturing processes, we may be unsuccessful in producing products or product candidates comparable to existing commercial supply or those used in prior clinical trials. Therefore, we may need to conduct additional process development or additional clinical trials to bridge our prior clinical results to those resulting from the new manufacturing process or new manufacturers, which could impact the timing and subsequent success of our planned commercial supply or clinical trials. In addition, as we plan to produce clinical trial and commercial material at a CDMO, the CDMO may be required to adopt different manufacturing protocols or processes. For example, in March 2023, Regeneron formally initiated a technology transfer with respect to the manufacturing process for ARCALYST drug substance. ~~Any~~ **Our replacement** CDMO **, Samsung, will** ~~that we select as part of this process may find it necessary to~~ utilize a ~~different~~ **modified** manufacturing process ~~than~~ **from** that used by Regeneron, which could require lengthy development, regulatory review and approval. For more information see " Risk Factors — Risks Related to Manufacturing and Our Reliance on Third Parties — We are conducting a technology transfer with respect to the manufacturing process of ARCALYST drug substance from Regeneron to **Samsung** ~~a new CDMO~~ and the analytical testing methods of ARCALYST drug substance and drug product to new CTLs. Such technology transfer will be subject to significant risks and uncertainties. " The facilities used by our CDMOs to manufacture **, label and package** ARCALYST and our current and future product candidates may be inspected by regulatory authorities in connection with the submission of our MAs to, and review by, regulatory authorities or based on their work for other clinical trial sponsors. While we provide oversight of ~~manufacturing~~ **such** activities, we do not and will not control the manufacturing process of, and will be completely dependent on, our CDMOs for compliance with cGMPs and other regulatory requirements in connection with the ~~manufacture~~ **manufacturing , labeling, and packaging** of current and future products and product candidates. If our CDMOs cannot successfully ~~manufacture material that~~ **perform such functions in** ~~conforms~~ **conformity** ~~to~~ **with** our specifications and the strict regulatory requirements of regulatory authorities, they will not be able to secure or maintain regulatory approval for their ~~manufacturing~~ facilities. While we review the compliance history and performance of our CDMOs and have the ability to audit their compliance and performance, we have no direct control ~~over~~ **62over** the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel other than through quality monitoring in accordance with our agreements with the CDMOs. If regulatory authorities do not approve these facilities for the ~~manufacture~~ **manufacturing , labeling and packaging** of our product candidates or if they withdraw any such approval in the future, we may need to find alternative ~~manufacturing~~ facilities **or CDMOs** , which would significantly impact our ability to develop, obtain regulatory approval for or market ARCALYST or our current or future product candidates, if approved. Further, our failure, or the failure of our third party ~~manufacturers~~ **CDMOs** , to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products or product candidates, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our products or product candidates. 73Our product candidates may also compete with..... our development or commercialization efforts. " Many additional factors could cause production interruptions at our facilities or at the facilities of our third party providers, as well as disruptions in travel, shipping or delivery capabilities into and within the countries in which we or our manufacturers produce ARCALYST or our product candidates or disruptions to production capabilities, including due to the impact of natural disasters, accidents, boycotts, labor disputes, political and economic instability, such as acts of terrorism or war

and an epidemic, pandemic or other outbreak of disease. The occurrence of any such event could adversely affect our ability to satisfy the required supply for any of ARCALYST or our product candidates or successfully complete preclinical and clinical development, which would result in additional costs to us or impair our ability to generate revenue and would harm our business, financial condition and prospects significantly. Supply chain issues related to important ancillary products may also adversely affect our business. For example, we contract with a select network of specialty pharmacies who distribute ARCALYST as well as peripheral supplies that are required to reconstitute and self- administer ARCALYST, such as sterile water for injection, syringes and needles. A delay or shortage in the supply or the distribution of the peripheral supplies required to administer ARCALYST may impact patient access to ARCALYST and could cause us to lose potential revenue, reduce our potential profitability, and damage our reputation. We also contract with third parties to source specialized placebo for use in our clinical trials which cannot be easily replaced as it must be nearly indistinguishable from our product candidates to ensure proper clinical trial blinding. If we encounter shortages of such placebo, our clinical trials may be substantially delayed unless and until we can source suitable replacements. ~~73Our~~ -- **Our products and** product candidates may also compete with other product candidates and approved products for access to and capacity within manufacturing **,packaging,and labeling** facilities.There are a limited number of ~~manufacturers~~ **CDMOs** that operate under cGMP regulations and that might be capable of ~~manufacturing~~ **performing such functions** for us.Furthermore,given the limited **capacity at such CDMOs** ~~number of available manufacturing slots~~ and the long lead times needed to reserve ~~them~~ **capacity** , ~~manufacturers~~ **CDMOs may** require monetary commitments in connection with such reservations as well as fees for changes or cancellations ~~in the reserved~~ **or additional fees to accommodate expediting of** manufacturing ~~slots~~ **,packaging,and labeling** . ~~As a result~~ **For our product candidates** ,we may wait to reserve **capacity** ~~manufacturing slots~~ until we can be informed by data from the clinical trials of our product candidates,which may ~~be~~ **take** several months ~~from the time we request manufacturing slots~~ .Any significant delay in the supply of clinical materials for our product candidates could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates.Alternatively,we may project when we may need additional clinical material for our product candidates and reserve **capacity** ~~manufacturing time- slots~~ " at- risk " prior to our product candidates having generated data from their then current clinical trials. ~~In addition,given the lead times~~ In addition, ~~our third party~~ **given the lead times we must** ~~providers~~ -- **provide** ~~may fail~~ to ~~comply~~ **Regeneron or Samsung, following the technology transfer of ARCALYST drug substance manufacturing,** with ~~cGMP and~~ **respect to** ~~other~~ -- **the** ~~stringent regulatory requirements related~~ **commercial supply of ARCALYST, we must place purchase orders based on projected demand. Such projections involve risks and uncertainties. For example, we may be unable** to **swiftly accommodate for unforeseen increases in commercial demand for ARCALYST given the lead times we must provide to Regeneron and limitations on Regeneron' s manufacturing capacity for ARCALYST. We may also be required to estimate and order safety stock as part of our planned technology transfer of** the manufacturing process **for ARCALYST drug substance, which will be subject to a number of the same risks and uncertainties** . ~~See our product candidates having generated data from their then current clinical trials.In addition,given the lead times we must provide to Regeneron or any replacement CDMO with respect to the commercial supply of ARCALYST,we must place purchase orders based on projected demand.Such projections involve risks and uncertainties.For example,we may be unable to swiftly accommodate for unforeseen increases in commercial demand for ARCALYST given the lead times we must provide to Regeneron and limitations on Regeneron' s manufacturing capacity for ARCALYST.We may also be required to estimate and order safety stock as part of our planned technology transfer of the manufacturing process for ARCALYST drug substance,which will be subject to a number of the same risks and uncertainties.~~ These risks may result in additional costs or delays in manufacturing clinical materials for our product candidates when and if we actually need them and commercial materials for ARCALYST and may result in having too little or too much of our product candidates or ARCALYST in inventory to meet actual demand. ~~Any~~ **63Any** performance failure on the part of our existing or future ~~manufacturers~~ **CDMOs** could delay,as applicable,clinical development or marketing approval or commercialization efforts for our current and future products.If our current CDMOs cannot perform as agreed,we may be required to replace **them** ~~such manufacturers~~ .Although we believe that there are several potential alternative ~~manufacturers~~ **CDMOs** who could ~~manufacture our product candidates~~ **provide the services we currently contract for** ,we may incur added costs and delays in identifying and qualifying any such replacement.In addition,we may not be able to establish new agreements on acceptable terms,if at all,with such alternative manufacturers.Further,establishing ~~a~~ replacement ~~manufacturer~~ **CDMOs** for ARCALYST or our product candidates,if required,is unlikely to be accomplished in a timely or cost- effective manner,if at all.Furthermore,despite our efforts,we may be unable to procure a replacement ~~supplier~~ **contractor** or do so on commercially reasonable terms,which could have a material adverse impact upon our business,results of operations and financial condition.If we or our CDMOs are able to find a replacement ~~supplier~~ **contractor** ,such replacement ~~supplier~~ **contractor** would need to be qualified and may require additional regulatory approval,which could result in further delay.We are conducting a technology transfer with respect to the manufacturing process of ARCALYST drug substance from Regeneron to **Samsung** ~~a new CDMO~~ and the analytical testing methods of ARCALYST drug substance and drug product to new CTLs.Such technology transfer will be subject to significant risks and uncertainties.In March 2023,Regeneron,our sole supplier of ARCALYST drug substance,initiated a technology transfer related to the manufacturing process of ARCALYST drug substance and the analytical testing methods of ARCALYST drug substance and drug product. ~~We plan to collaborate with Regeneron~~ **Since then,we have worked** to qualify **Samsung** ~~and contract with a new CDMO~~ who will serve as the new manufacturer of ARCALYST drug substance and new CTLs who will serve as the new testing labs of ARCALYST drug substance and drug product. **We have also contracted with Samsung to document the technology transfer and enable the commercial manufacturing of ARCALYST drug substance should the technology transfer succeed.** Pharmaceutical development,manufacture and analytical testing requires significant expertise and capital investment,and the manufacture and testing of biologics,in particular,can be complex and difficult.While we have selected ~~a~~ **Samsung as our** replacement CDMO and **have selected** replacement CTLs,we are still in the early stages of the

technology transfer process and still must determine whether **Samsung and** such ~~CDMO and~~ CTLs can meet our requirements regarding production costs and yields,process controls,quality control,quality assurance,data integrity and cGMP compliance,among other factors.We would also need to source sufficient raw materials to facilitate new manufacturing and analytical testing,which may be affected by supply chain disruptions,materials shortages or an inability to negotiate satisfactory terms with suppliers.The technology transfer process is a time- consuming and difficult task that may require significant time and focus from ~~74our --~~ **our** management and technical teams.Further,because of the complexities of this process,the technology transfer may be subject to substantial delay,which could materially harm our business and operations.Because **Samsung will** ~~such CDMO would~~ be manufacturing ARCALYST drug substance at a new manufacturing site and with a potentially different manufacturing process,and such CTLs ~~would~~ **will** be testing ARCALYST drug substance and drug product at new testing sites and potentially with different testing methods,we expect that the FDA will need to approve such changes before we are able to complete the technology transfer.The FDA generally requires that any ~~new~~ **replacement** CDMO be able to manufacture drug substance at sufficient levels of comparability with the materials produced by the original manufacturer **.We are still in the process of confirming comparability between the drug substance produced by Samsung and the drug substance produced by Regeneron** .Failure to provide sufficient evidence of comparability may result in the FDA requesting a bioequivalence or pharmacokinetic study,which would delay our expected technology transfer timeline.Even if such study were to be performed,there is no guarantee that the FDA would accept our findings and approve any new facilities for the manufacture of ARCALYST drug substance. **In addition,because the Samsung manufacturing facility is located in South Korea,unlike** Regeneron **' s United States- based manufacturing facility,we may face new risks arising from tariffs,import / export restrictions,customs proceedings,product being lost or damaged during international shipping,differing regulations,supply chain interruptions and other risks inherent to international operations.These risks,should they occur,could increase our costs and affect our ability to meet clinical and commercial demand for ARCALYST,which could materially impact our business,financial condition and results of operations.64Regeneron** is contractually obligated to continue manufacturing ARCALYST drug substance for at least a portion of the time that it will take **us** to qualify **Samsung as** a replacement CDMO.During such time,Regeneron will remain subject to many of the risks described elsewhere in this ~~" Risk Factors " section,including the risk that it is unable to manufacture sufficient quantities of ARCALYST~~ " Risk Factors **" section, including** ~~— We contract with third parties for manufacturing 76our commercial supply of ARCALYST and clinical supply for our product candidates and for certain research and other preclinical development and expect that we will continue to do so in the future. This reliance on third parties increases~~ the risk that ~~we may not have~~ **it is unable to manufacture** sufficient quantities of ARCALYST ~~or~~ **and at sufficient quality to meet** ~~our~~ **ours and** ~~product candidates or~~ **our patients' and collaborators' needs. Further, because we expect the timeline for any successful technology transfer to extend beyond Regeneron' s contractual obligations, our ability to meet patient demand will depend significantly on whether we can secure sufficient safety stock from Regeneron, negotiate continued ARCALYST drug substance manufacture by Regeneron beyond its contractual obligations or some combination thereof. Purchasing significant amounts of safety stock would require substantial upfront capital investment and, if the technology transfer process is delayed beyond our expectation,** such ~~quantities ,such~~ safety stock may expire or be depleted before **Samsung** ~~a new CDMO~~ can begin manufacturing ARCALYST drug substance.Regeneron may also disagree with our forecasted safety stock requirements and manufacture less ARCALYST drug substance than we request,exposing us to risks if the **technology transfer** process is significantly delayed.Any arrangement that we negotiate with Regeneron to manufacture ARCALYST beyond their contractual obligations may not be on as favorable terms as our current relationship,which could materially increase our costs and as a result negatively impact our financial condition and results of operations.A failure to secure sufficient safety stock or negotiate satisfactory manufacturing terms with Regeneron could result in supply shortages for our patients and collaborators while we work to complete the technology transfer.A failure to either complete our planned technology transfer on our expected **timeline or** at an acceptable cost **and /** ~~, which could delay, prevent or impair our~~ **or secure** ~~development or commercialization efforts. " If we or any of our third party providers are not able to establish and maintain procedures and processes~~ sufficient **supply** ~~to satisfy cGMP or similar foreign standards, we could experience a delay, interruption or other issues in our manufacture, fill- finish, packaging, storage or delivery~~ of ARCALYST **through the technology transfer process would have a material impact on** ~~or~~ **our business** ~~our product candidates~~ , **financial condition** and **results** ~~any related failure~~ of ~~the facilities or~~ operations ~~of third parties to pass any regulatory agency inspection could significantly impair our ability to supply our products and product candidates. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation. Any adverse developments affecting the operations of our third party providers could result in a shortage of commercial products or product candidates, the imposition of additional commercial product requirements by regulatory authorities, the withdrawal of our product candidates or approved products, shipment delays, lot failures or recalls. We may also have to write off inventory and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Such manufacturing issues could increase our cost of goods, cause us to lose potential revenue, reduce our potential profitability or damage our reputation .~~ The third parties upon whom we rely for the supply of ~~the drug substance and drug product used in~~ our products and product candidates are our sole source of supply, and the loss of any of these suppliers could significantly harm our business or the business of our partners. The drug substance and drug product used in ARCALYST ~~, mavrilimumab~~ and ~~vixarelimab~~ **KPL- 387** are supplied to us from single- source suppliers and we obtain the drug substance and drug product used in abiprubart from a limited number of sources. **For KPL- 1161, we plan to manufacture drug substance in our in- house manufacturing facility and use a single supplier to manufacture drug product. While our in- house manufacturing capabilities have the limited capabilities to produce pre- clinical and early- stage clinical drug supply, we lack internal large- scale manufacturing capabilities necessary to support commercial requirements.** Regeneron is currently our sole source manufacturer ~~, but with~~

~~its initiation~~ of ~~a technology transfer of the manufacturing process for~~ ARCALYST drug substance **and** ~~in March 2023,~~ will ~~cooperate with us to~~ **remain so until we** qualify **Samsung as** a ~~suitable~~ replacement CDMO **. We expect that Samsung will be our sole source manufacturer of ARCALYST drug substance following such qualification** . For more information see " Risk Factors — Risks Related to Manufacturing and Our Reliance on Third Parties — We are conducting a technology transfer with respect to the manufacturing process of ARCALYST drug substance from Regeneron to **Samsung** ~~a new CDMO~~ and the analytical testing methods of ARCALYST drug substance and drug product to new CTLs. Such technology transfer will be subject to significant risks and uncertainties. " **Further, we have historically outsourced all ARCALYST packaging and labeling activities to a single CDMO and expect to do so for any future approved products.** Our ability to continue to commercialize ARCALYST, to develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet market demand, depends in part on our ability to obtain the drug substance and drug product for ARCALYST and these product candidates **and package and label such drugs, as applicable, in each case** in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. Successful completion of a technology transfer of the manufacturing process for ARCALYST drug substance will be integral to our ability to meet such requirements. With respect to ARCALYST ~~and mavrilimumab~~ , we do not currently have arrangements in place for a redundant or second-source ~~supply~~ **manufacturer** of ~~any such~~ drug substance ~~and~~ **or** drug product **, or a redundant or second- source packager and labeler,** in the event any of our current **vendors** ~~suppliers of such drug substance and drug product~~ cease **or have a substantial delay in** their operations or stop offering us sufficient quantities of these materials for any reason **, as applicable** . With respect to abiprubart **, KPL- 387 and KPL- 1161** , while we anticipate having more than one source for drug substance ~~and drug product~~ **now or in the future, as applicable** , such sources are nonetheless limited and subject to similar risks as our other products and product candidates. We are not certain that our ~~single- source~~ suppliers will be able to meet our demand for our products and product candidates, ~~either~~ because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers **given their manufacturing capacity constraints** . It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have ~~generally~~ **65generally** met our demand on a timely basis in the past, they may subordinate our needs in the future to their other customers. In addition to manufacturing our products and product candidates in the quantities that we believe would be required to meet anticipated market demand, our third party manufacturers may need to increase manufacturing capacity and, in some cases, alternative sources of commercial supply may need to be secured, which could involve significant challenges and may require additional regulatory approvals. In addition, the development of commercial- scale manufacturing capabilities may require us and our third party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third party ~~77manufacturers~~ -- **manufacturers** may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. Moreover, our ability to progress our preclinical and clinical programs or successfully commercialize our products could be materially and adversely impacted if any of the third party suppliers upon which we rely for raw materials and preclinical and clinical stage product candidate and commercial stage product supply were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our manufacturing facilities or equipment or those of our third party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our products and product candidates on a timely basis. In addition to the above, we have entered into, and may, in the future, enter into collaboration and other agreements requiring us to provide commercial or clinical drug supply to third party partners. A failure by our CDMOs to supply sufficient quantities of drug supply may cause us to breach our contractual obligations, triggering potential penalties under our agreements, including termination of such agreements, if we fail to adequately cure such breach. Establishing additional or replacement suppliers for the drug substance and drug product used in ARCALYST or our product candidates, if required, is unlikely to be accomplished quickly and can take several years, if at all. Furthermore, despite our efforts, we may be unable to procure a replacement supplier or do so on commercially reasonable terms, which could have a material adverse impact upon our business. If we or our CDMOs are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we and our CDMOs may seek to maintain adequate inventory of the drug substance and drug product used in ARCALYST or our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such drug substance and drug product from alternate sources of comparable quality at acceptable prices in a timely manner could impede, delay, limit or prevent our development or commercialization efforts, which could harm our business, results of operations, financial condition and prospects. Certain of the materials required in the manufacture and the formulation of our products and product candidates are derived from biological sources. Such materials are difficult to procure and may be subject to contamination or recall. Access to and supply of sufficient quantities of raw materials which meet the technical specifications for the production process is challenging, and often limited to single- source suppliers. Finding an alternative supplier could take a significant amount of time and involve significant expense due to the nature of the products and the need to obtain regulatory approvals. If we or our manufacturers are unable to purchase the materials necessary for the manufacture of ARCALYST or our product candidates on acceptable terms, in a timely manner, at sufficient quality levels, or in adequate quantities, if at all, our ability to produce sufficient quantities of such drugs for clinical or commercial requirements would be negatively impacted. A material shortage, contamination, recall or restriction on the use of certain biologically derived substances or any other material used in the manufacture of our products and product candidates could adversely impact or disrupt manufacturing, which would increase costs and impair our ability to generate revenue from the sale of ARCALYST or our product candidates, if approved . ~~Our~~ **66Our** business involves the use of hazardous materials,and we and our third party manufacturers and suppliers must comply with environmental laws and

regulations,which can be expensive and restrict how we do business.Our research and development activities and our third party manufacturers' and suppliers' activities involve the controlled storage,use and disposal of hazardous materials owned by us,including the components of ARCALYST or our product candidates and other hazardous compounds.We and our manufacturers and suppliers are subject to laws and regulations governing the use,manufacture,storage,handling and disposal of these hazardous materials.In some cases,these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' and suppliers' facilities pending their use and disposal.We cannot eliminate the risk of contamination,which could cause an interruption of our commercialization efforts,research and development efforts and business operations,environmental damage resulting in costly cleanup and liabilities under applicable laws and regulations governing the use,storage,handling and disposal of these materials and specified waste products.Although we believe that our safety procedures and the safety procedures utilized by our third party manufacturers and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations,we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials.In such an event,we may be held liable for any resulting damages and such liability could exceed our resources,and state or federal or other applicable authorities may curtail our use of certain materials or interrupt our business operations.Furthermore,environmental laws and regulations are complex,change frequently and have tended to become more stringent.We ~~75cannot~~ -- **cannot** predict the impact of such changes and cannot be certain of our future compliance.We do not currently carry biological or hazardous waste insurance coverage . We rely, and expect to continue to rely, on third parties, including independent investigators and CROs, to activate sites, conduct and otherwise support our research activities, preclinical studies, clinical trials and other trials for our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates, and our business could be substantially harmed. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to activate sites, conduct or otherwise support our preclinical studies and clinical trials for our product candidates properly and on time. We also rely on third parties to conduct other research related to our product candidates. We expect to rely heavily on these parties for such site activation, execution of and otherwise supporting clinical trials for our product candidates. While we have agreements governing their activities and we review the compliance history and performance of our CROs as well as have the ability to audit such activities, we have no direct control over their activities and have limited influence over their actual performance other than through quality monitoring in accordance ~~78with~~ -- **with** our agreements with the CROs. The third parties with whom we contract for execution of our preclinical studies and our clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. Except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our preclinical studies and clinical trials in accordance with applicable GLP or GCP requirements, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not and will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies or clinical trials, we could be subject to warning letters or enforcement actions that may include civil penalties and criminal prosecution. We and our CROs are required to comply with regulations, including GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial participants are adequately informed of the potential risks of participating in clinical trials and their rights are protected. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product candidates produced under cGMPs or similar foreign regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register certain clinical trials and post the results of completed ~~clinical~~ **67clinical** trials on a government- sponsored database within certain timeframes. Failure to do so when required can result in fines, adverse publicity and civil and criminal sanctions. Although we have and intend to continue to design the clinical trials for our product candidates, CROs will activate sites and conduct and oversee all of the clinical trials together with the various clinical trial sites that we engage to conduct the studies. As a result, many important aspects of our development programs for our product candidates, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to activate sites and conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may: ● have staffing difficulties; ● have disruptions to their business and operations, including as a result of the impact from a pandemic or other outbreak of disease or as the result of war, conflict or terrorism; ● fail to comply with contractual obligations; ● have difficulty controlling the performance of their subcontractors; ● experience regulatory compliance issues; ● undergo changes in priorities or become financially distressed; or ● form relationships with other entities, some of which may be our competitors. These factors may materially adversely affect the willingness or ability of third parties to activate sites and conduct and oversee our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs, their subcontractors or the clinical trial sites do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed or unsuccessful. In addition, if we are unable to rely on clinical data collected by our CROs, their subcontractors or the clinical trial sites, we could be required to repeat, extend ~~79the~~ -- **the** duration of or increase the size of any clinical trials we conduct, and this could significantly delay commercialization and require significantly greater expenditures. Further, if our CROs, their

subcontractors or the clinical trial sites fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates. In addition, the use of third party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information is misappropriated. If the third parties conducting our preclinical studies or our clinical trials do not perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed. ~~Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we rely on third parties to develop and manufacture our products and product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, invention assignment agreements, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, independent contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business. To the extent that we share trade secrets of third parties that are licensed to us, unauthorized use or disclosure could expose us to liability. See also, " Risk Factors – Risks~~ **68Risks** ~~Related to Intellectual Property – If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed. " Risks~~ Related to Competition, Executing our Strategy and Managing GrowthWe face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do. The development and commercialization of new drugs and biologics is highly competitive. **ARCALYST currently faces competition in its CAPS and DIRA indications and is facing potential future competition in its recurrent pericarditis indication. KPL- 387 is being developed for recurrent pericarditis and we believe, if commercialized, would likely face additional competition from drugs that may offer either more convenient dosing methods or frequencies than what is currently available.** We ~~face competition~~ **have not yet announced an indication for KPL- 1161, but expect that it will compete** with **a number of drugs** ~~respect to our current product candidates and will face competition with respect to any product candidates~~ that **inhibit IL- 1** ~~we may seek to develop~~ or ~~commercialize in the~~ **other** ~~future,~~ **mechanisms. Competition may come** from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide **, each** ~~. There are a number~~ of **whom may** ~~large pharmaceutical and biotechnology companies that currently~~ market and sell drugs or biologics or **pursue** ~~are pursuing~~ the development of therapies in the fields in which we are interested. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, ~~80development~~ -- **development** , manufacturing and commercialization. See " Business – Competition " for a list of our principal competition. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and participant registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Further, a competitor conducting a clinical trial in a rare disease indication for which we market a product may reduce the number of patients on our commercial therapy by recruiting such patients to be trial participants. Our competitors also may obtain FDA or other regulatory approval and / or marketing exclusivity for their products more rapidly than we may obtain for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. ~~The~~ **Further, our clinical trials may need to compete for participants and trial sites against other drugs in clinical development for the same indication. We believe the** key competitive factors affecting the success of ~~all of our~~ **ARCALYST and any** product candidates ~~, if approved~~ **that we successfully develop and commercialize** , are ~~likely to be~~ their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related products, market acceptance by prescribers and patients, the level of biosimilar competition and the availability of reimbursement from government and other third party payors. We may not be successful in executing our growth strategy to identify, discover, develop, in- license or acquire additional product candidates or technologies, and our growth strategy may not deliver the anticipated results or we may

refine or otherwise alter our growth strategy. We may seek to acquire businesses or undertake business combinations, collaborations or other strategic transactions which may not be successful or on favorable terms, if at all, and we may not realize the intended benefits of such transactions. We have acquired or in- licensed certain of our existing product candidates, and as part of our strategy we plan to identify new product candidates or technologies that we believe are complementary to our existing portfolio. We may do this through our internal discovery program, or by acquiring the rights to product candidates and technologies through a variety of transaction types, including in- licensing, strategic transactions, mergers or acquisitions. If we are unable to identify, discover, develop, in- license or otherwise acquire and integrate product candidates, or their related companies, in accordance with this strategy, our ability to pursue this component of our growth strategy would be limited and we ~~may~~ **69may** need to refine or otherwise alter this strategy. We cannot be certain that we will be successful in such efforts, and even if we are successful in such efforts, we cannot be certain that such discovery or transaction will be on favorable terms, or that, following any such discovery or transaction, we will be able to realize the intended benefits of it. Research programs and business development efforts to identify new product candidates and technologies require substantial technical, financial and human resources. We may focus our efforts and resources on potential product candidates, technologies or businesses that ultimately prove to be unsuccessful. In- licensing and acquisitions of product candidates, technology or businesses often require significant payments and expenses and consume additional resources. We will need to continue to devote a substantial amount of time and personnel to research, develop and commercialize any such in- licensed or acquired product candidate or technology, or integrate any new business, and we may decide to reprioritize our efforts even after having expended resources on a particular prospect. Our research programs and business development efforts, including businesses or technology acquisitions, collaborations or licensing attempts, may fail to yield additional complementary or successful product candidates for clinical development and commercialization or successful business combinations for a number of reasons, including, but not limited to, the following: ● we may be unsuccessful in identifying potential product candidates or businesses with a high probability of success for development progression; ~~81~~ ● we may not be able or willing to assemble sufficient resources or expertise to in-license, acquire or discover additional product candidates or acquire businesses or undertake business combinations, collaborations, or other strategic transactions; ● we may not be able to agree to acceptable terms with potential licensors, partners or acquisition targets; ● we may incur substantial liabilities as part of an acquisition or merger that may not be offset by the benefits of the acquired assets or the synergies we hope to realize; and ● any product candidates or technologies to which we acquire the rights or that we discover may not allow us to leverage our expertise and our development and commercial infrastructure as currently expected. If any of these events occurs, we may not be successful in executing our growth strategy to identify, discover, develop, in- license or acquire additional product candidates or technologies or to acquire businesses or undertake business combinations, collaborations, or other strategic transactions, or our growth strategy or strategic transactions may not deliver the anticipated results or we may refine or otherwise alter this strategy. The consummation or performance of any acquisition, business combination, collaboration or other strategic transaction we may undertake in furtherance of our growth strategy or any refined or otherwise altered strategy, may involve additional risks, such as difficulties in assimilating different workplace cultures; retaining personnel and integrating operations, which may be geographically dispersed; increased costs; exposure to liabilities; incurrence of indebtedness; use of a substantial portion of our available cash for all or a portion of the consideration; or causing dilution to our existing shareholders if we issue equity securities for all or a portion of the consideration. If any of these events occurs or we are unable to meet our strategic objectives for any such transaction, we may not be able to achieve the expected benefits from the transaction and our business may be materially harmed. We have entered into and may seek to enter into collaboration, licensing or other strategic transactions or arrangements to further develop, commercialize or otherwise attempt to realize value from our products and product candidates, and any such transactions or arrangements that we enter into may not be successful or be on favorable terms, which could adversely affect our ability to develop, commercialize or attempt to realize value from our products and product candidates. We have entered into and may seek to enter into collaboration, licensing or other strategic transactions or arrangements to further develop, commercialize or otherwise attempt to realize value from one or more of our products and product candidates instead of developing or commercializing our products and product candidates ourselves. For ~~example~~ **70example**, in February 2022, we granted Huadong exclusive rights to develop and commercialize **ARCALYST** ~~rilonacept and mavrilimumab~~ in the Asia Pacific region, excluding Japan. In August 2022, we entered into a license agreement with Genentech where we granted exclusive worldwide rights to develop and commercialize vixarelimab ~~. We are currently seeking collaboration partners for mavrilimumab, and we may seek to jointly develop, commercialize or otherwise exploit one or more of our other product candidates with a third party in the future~~. To the extent that we decide to enter into such transactions or arrangements, we may face significant competition in seeking appropriate collaborators, licensees or other strategic partners. Moreover, these transactions and arrangements are complex and time consuming to negotiate, document, implement and to close or maintain. We may not be successful in our efforts to establish collaborations, licenses or other strategic transactions or arrangements should we choose to do so. The terms of any such transactions or arrangements that we may establish may have unfavorable tax consequences for our shareholders in the United States. Further, granting territory- specific rights for our products and product candidates may reduce their attractiveness for subsequent business development activity. In addition, our right to grant a sublicense of intellectual property licensed to us under certain of our current agreements requires the consent of the applicable licensor. Any current or future collaborations, licenses or other strategic transactions or arrangements that we enter into may not be successful. The success of these potential collaborations, license arrangements and other strategic transactions or arrangements may depend heavily on the efforts and activities of our collaborators, sublicensees or other strategic partners. We have experienced collaboration failure in the past and may experience similar failures in the ~~82future~~ -- **future**. Collaborations, licenses or other strategic transactions or arrangements are subject to numerous risks, which may include risks that the collaborator, licensee or other strategic partner, as applicable: ● may not pursue development and commercialization of the applicable licensed drugs or may elect not to continue

or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or product candidates or their internal development of competitive products and product candidates, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities; ● raise disputes with respect to the ownership or inventorship of any intellectual property developed pursuant to our collaborations or licenses; ● may not properly prosecute, maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; ● may own or co-own intellectual property covering products that results from our arrangement with them, that is not properly prepared, prosecuted, maintained or defended in a way that could impact that patentability of the intellectual property or validity for any granted patent, which could shorten the term during which we are owed royalties on such intellectual property; ● may own or co- own intellectual property covering products that results from our arrangement with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property, and even if we are able to license such exclusive rights, we may have to enter into a license agreement that ~~include~~ **includes** obligations to make milestone, royalty or other payments under such agreement; ● may not achieve applicable development, regulatory, or commercial milestones, which may materially impact the collaboration revenue that we expect to realize from such relationship; ● raise disputes that cause the delay or termination of the research, development or commercialization of our current or future products and product candidates or that results in costly litigation or arbitration that diverts management attention and resources; ● cause us to be named defendants in lawsuits due to their improper use of the licensed intellectual property and not indemnify us against losses in such lawsuits; **71** ● enforce licensed intellectual property rights against third parties that lead such third parties to challenge the validity or enforceability of the licensed intellectual property and potentially cause the licensed intellectual property to become invalid or rendered unenforceable; ● fail to maintain issued licensed patents that are under their control, or prosecute licensed patent applications in ways that diminish their value, all of which actions may adversely affect our business if our agreements with them terminate and the rights to the licensed intellectual property return to us or an upstream licensor; may delay, dispute or refuse to pay milestone and royalty payments, which may impact our ability to satisfy upstream payment obligations, if applicable; and ● may conduct sales and marketing activities or other operations that may not comply with applicable laws, resulting in civil or criminal proceedings. In addition, disputes may arise with respect to the ownership of any intellectual property developed pursuant to these arrangements. These arrangements may also be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. ~~83We~~ **We** need to continue to develop our company and expand our scope of operations, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations. We expect to continue to develop our company and expand the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems and infrastructure, expand our facilities over time and continue to recruit and train qualified personnel. Also, our executive and senior management teams have and may continue to divert a disproportionate amount of their attention away from their day- to- day activities and devote a substantial amount of time to managing these development and expansion activities. ~~We additionally expect to devote significant resources to compliance as we conform to heightened audit requirements applicable to non- smaller reporting companies. For more information see " Risk Factors — Risks Related to Ownership of Our Common Shares — We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to related compliance initiatives. "~~ We may not be able to develop these skills internally or in sufficient time and capacity, which could require us to expend additional resources to acquire them. Due to our limited resources, certain employees have and may continue to perform activities that are beyond their regular scope of work, and we may not be able to effectively manage the development of our company, expansion of our operations or recruitment and training of qualified personnel. This may result in weaknesses of our systems and infrastructure; managerial, operational and financial mistakes; loss of business opportunities; loss of employees; and reduced productivity among remaining employees. The development of our company and expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of one or more of our product candidates. If our executive and senior management teams are unable to effectively manage our anticipated development and expansion, our expenses may increase more than expected, our ability to generate revenue could be reduced and we may not be able to implement our business strategy as planned ~~, including with respect to our commercialization of ARCALYST in recurrent pericarditis~~ . Our future financial performance and our ability to commercialize our product candidates, if approved, ~~and to compete effectively~~ will depend, in part, on our ability to effectively manage the future development of our company and expansion of our operations. Risks Related to Intellectual Property If we are unable to adequately protect our proprietary technology or obtain and maintain patent protection for our technology and products, if the scope of the patent protection obtained is not sufficiently broad, or if the terms of our patents are insufficient to protect our product candidates for an adequate amount of time, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be materially impaired. Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our products and product candidates ~~, including ARCALYST, abiprubart and mavrilimumab~~ . We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the United States and abroad related to our proprietary technology, inventions and improvements that are important to ~~the development and implementation of~~ our business. We ~~also~~ **72also** rely on trade secrets, **proprietary** know- how and continuing technological innovation to develop and maintain our proprietary ~~and~~ **or** intellectual property position. We acquire, in- license and file patent applications directed to our products and product candidates in an effort to establish intellectual property positions directed to their compositions of matter and manufacture as well as uses of these products and product candidates in the treatment of diseases. Our intellectual property

rights ~~includes~~ -- **include** patents and patent applications that we own as well as patents and patent applications that we in-license. For example, we have a field- specific exclusive license under a license agreement with Regeneron to patent applications and patents relating to ARCALYST ~~,~~ **and** an exclusive license under ~~the MedImmune Agreement to patent applications and patents relating to mavrilimumab, and an exclusive license under~~ our license agreement with BIDMC to patent applications and patents related to abiprubart. ~~84Certain~~ -- **Certain** provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. We or our licensors have not pursued or maintained, and we or our licensees may not pursue or maintain in the future, patent protection for our products or product candidates in every country or territory in which our products or product candidates may be sold, if approved. In addition, we cannot be sure that any of our pending patent applications or pending trademark applications will issue or that, if issued, they will be in a form that is advantageous to us. The United States Patent and Trademark Office (the " USPTO ") international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications and our issued patents may be successfully challenged, may be designed around or may otherwise be of insufficient scope to provide protection for our commercial products. Further, the USPTO, international trademark offices or judicial bodies may deny our trademark applications and, even if published or registered, these trademarks may not effectively protect our brand and goodwill. ~~Like~~ **As with** patents, trademarks also may be successfully opposed or challenged. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully commercialize our products and product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our owned or in **-** licensed patents have, or that any of our owned or in- licensed pending patent applications that mature into issued patents will have, claims with a scope sufficient to protect ~~ARCALYST, abiprubart, mavrilimumab, or~~ **our** ~~any~~ **current and** future products and product candidates. A United States patent covering ARCALYST as a composition of matter expired in 2020, and relevant composition of matter patents issued outside of the United States expired in October 2023. A United States patent covering methods of using ARCALYST in the treatment of recurrent pericarditis was issued in June 2021 and has a statutory term that expires in 2038, not including any patent term adjustment. ~~The~~ **We are unable to obtain** composition of matter patents **covering amino acid sequences,** ~~for~~ -- **or** ~~mavrilimumab generally~~ **corresponding nucleic acid sequences, of KPL- 387. We own a pending patent application covering methods of using KPL- 387 in the treatment of recurrent pericarditis. If issued, patents covering methods of using KPL- 387 in treating recurrent pericarditis will** have statutory expiration dates in ~~2027~~ **2046** , not including any **patent term** extensions or adjustments. The issued composition of matter patents for abiprubart owned by us have statutory expiration dates in 2036, not including any extensions. The issued composition of matter patents licensed from BIDMC related to abiprubart have statutory expiration dates in 2032, not including any patent term extensions or adjustments. **.** In the United States, the natural **(i. e., statutory)** expiration of a patent is generally 20 years after it is filed. Various extensions and adjustments may be available; however, the life of a patent, and the protection it affords, is limited. The actual protection afforded by a patent varies on a product- by- product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory- related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. For example, the applicable regulatory exclusivity period is often triggered by the date a product candidate obtains regulatory approval, and we cannot predict with any certainty whether and if so, when, the applicable product would receive regulatory approval in any given jurisdiction. Furthermore, the type, scope and duration of such exclusivities will ~~vary~~ **73vary** on a country- by- country basis depending on the jurisdiction in which a product candidate is approved and the particular regulatory exclusivity for which the product is eligible as of the time of approval in such jurisdiction. Patents may be eligible for limited patent term extension in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Act. Similar patent extensions exist in the EU (supplementary protection certificate) and Japan, subject to the applicable laws in those jurisdictions. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non- provisional patent application. In the United States, a patent' s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent. In certain countries, the term of a patent that covers a drug product may also be eligible for patent term extension when regulatory approval is granted, provided **that** the legal requirements are met. We may not receive an extension if we or our licensees fail to apply within applicable deadlines or fail or are unable to apply prior to expiration of relevant patents. For example, no patent term extension was obtained in the United States following the FDA' s approval of ARCALYST for the treatment of CAPS in 2008, and the deadline for applying for such extension has passed. Accordingly, patent term extension in the United States based on the FDA' s approval of ~~85ARCALYST~~ -- **ARCALYST** for CAPS, or any other indication for which the FDA may grant approval in the future, is unavailable. Further, while patent term extension was awarded for relevant patents in certain European countries following the EMA' s approval of ARCALYST for the treatment of CAPS, in 2012 the marketing authorization for CAPs was withdrawn. Patent term extensions may no longer be in effect or available, subject to the applicable laws in those countries as well as other factors, such as whether a marketing approval for ARCALYST is reissued and whether such reissuance is prior to the expiration of the patent' s natural 20- year patent term. Moreover, the length of the extension could be less than we request. In addition, the laws of other countries may not protect our rights to the same extent as the laws of the United States. If we or our licensees are unable to obtain patent term extension or the term of any such extension is less than requested, the period during which our patent rights can be enforced for that product will be shortened and competitors may obtain approval to market competing

products sooner, impacting our revenue. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized, thereby limiting protection such patent would afford the respective product and any competitive advantage such patent may provide. In some cases, an in- licensed patent portfolio may have undergone a considerable loss of patent term prior to our initiation of development and commercialization of the product or product candidate. For example, the patents in the United States and Europe covering ARCALYST as a composition of matter have expired ~~, and the~~ **. We are unable to obtain composition of matter** patents covering ~~mavrilimumab as a composition of matter have a term that expires in 2027 in~~ the ~~United States~~ **amino acid sequences** , ~~not including any patent term adjustments or patent term extensions, and in 2027 in Europe, not including any patent term extensions. We or our~~ **or corresponding nucleic acid sequences,** ~~licensees may not receive any patent term extension for patents covering mavrilimumab as a composition~~ of **KPL- 387** ~~matter if such patent in an applicable jurisdiction expires before mavrilimumab would be eligible to receive regulatory approval in such jurisdiction~~ . As a result, our owned and in- licensed patent portfolio may not provide adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to our product candidates. In such cases, regulatory exclusivity **, such as data exclusivity or orphan exclusivity as applicable,** is expected to be relied upon for our or our licensees' product candidates. The expiration date of regulatory exclusivity is determined on a country- by country- basis if the applicable product is approved in such country and if any applicable regulatory exclusivity applies and is granted. The actual expiration date of any such regulatory exclusivity, however, is subject to significant uncertainty. For instance, the applicable regulatory exclusivity period is often triggered by the date a product candidate obtains regulatory approval, and we cannot predict with any certainty whether and if so, when, the applicable product would receive regulatory approval in any given jurisdiction. Furthermore, the type, scope and duration of such exclusivities will vary on a country- by- country basis depending on the jurisdictions in which a product candidate is approved and the particular regulatory exclusivity for which the product is eligible as of the time of approval. Other parties may have developed or may develop technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our patent applications or issued patents, with respect to either the same methods or formulations or the same subject matter, in either case, that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we ~~or~~ **74or** our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty. In addition, the patent prosecution process is expensive and time consuming, and we or our licensees may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO is often significantly narrowed by the time they issue, if at all. The claims of our issued patents or patent applications when issued may not cover our product candidates, proposed commercial technologies or the future products that we develop, or even if such patents provide coverage, the coverage obtained may not provide any competitive advantage. Further, it is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we in- license from, or out- license to, third parties. Therefore, these patents and applications may not be ~~86prepared~~ **prepared** , prosecuted, enforced or maintained in a manner consistent with the best interests of our business. In the case of our field- limited license from Regeneron, another licensee may have the right to enforce patents covering the product in their field. As a result, we may need to coordinate prosecution, enforcement or maintenance with another party, and even then, the other party could prosecute, enforce or maintain the patents in a manner adverse to our interests or otherwise put the patents at risk of invalidation. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other countries. Even if we acquire patent protection that we expect should enable us to maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity, enforceability or term, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party submission of prior art to the USPTO challenging the priority of an invention claimed within one of our patents, which submissions may also be made prior to a patent' s issuance, precluding the granting of any of our pending patent applications. We or our licensees may become involved in contested proceedings challenging our patent rights or the patent rights of others from whom we have obtained licenses to such rights. For example, patents granted by the USPTO may be subject to third party challenges such as (without limitation) derivation, re- examination, interference, post- grant review or inter partes review proceedings, and patents granted by the European Patent Office may be challenged by any person in an opposition proceeding within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in some jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. Competitors may claim that they invented the inventions claimed in our issued patents or patent applications prior to the date our inventions were invented, or may file patent applications before we or our licensees do. In such case, we or our licensees may have to participate in interference or derivation proceedings in the USPTO, to determine which party is entitled to a patent on the disputed invention. We or our licensees may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our

products, product candidates and technology. Such proceedings can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn harm our business, whether or not we receive a determination favorable to us or our licensees. We may not be able to correctly estimate or control our future operating expenses in relation to such proceedings, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of such proceedings. Since patent applications are confidential for a period of time after filing, we cannot be certain that we, our licensees or our licensors were the first to file any patent application related to our product and product candidates. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid or enforceable for a number of reasons. If a court agrees, rights to those challenged patents may be diminished or lost. ~~In~~ **75In** addition, we may in the future be subject to claims by our, our licensees' or our licensors' former employees or consultants asserting an ownership right in our patents or patent applications as a result of the work they performed on our or their behalf, respectively. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know- how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we, our licensees' or our licensors have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our or our licensees' ability to stop others from using or commercializing similar or identical technology and products, without payment to us, could limit the duration of the patent protection covering our technology, product and product candidates, or could reduce the period of time during which our licensees are obligated to make royalty payments to us ~~87for~~ -- **for** the sale of licensed products. Such challenges may also result in our inability to manufacture or commercialize our product and product candidates without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us or our licensees with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non- infringing manner. For example, a third party may develop a competitive drug that provides benefits similar to our product **,** or one or more of our product candidates **,** but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product or product candidates is not sufficiently broad to impede such competition, or if the breadth, strength or term (including any extensions or adjustments) of protection provided by the patents and patent applications we hold or pursue with respect to our product candidates or any future product candidates is successfully challenged, our or our licensees' ability to successfully commercialize our product or product candidates could be negatively affected, which would harm our business. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates or any future product candidates under patent protection would be reduced. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If we breach any of the agreements related to our product or product candidates, we could lose the ability to continue the development and commercialization of the related product or product candidate. Additionally, our current licensing and acquisition agreements contain limitations and restrictions that could limit or adversely affect our ability to develop and commercialize other products in the future. We are party to agreements granting us the rights to develop and commercialize ARCALYST, abiprubart ~~, mavrilimumab~~ and vixarelimab. Each of these agreements requires us to use commercially reasonable efforts to develop and commercialize such drugs, make timely milestone and other payments, provide certain information regarding our activities with respect to such drugs and indemnify the other party with respect to our development and commercialization activities under the terms of the agreements. These agreements and any future such agreements that we enter into impose a variety of obligations and related consequences. Further, disputes may arise between us and any of these counterparties regarding such obligations under, or the intellectual property subject to, such agreements, including: ● our diligence obligations to develop and commercialize the licensed technology, and what activities satisfy those diligence obligations; ● the scope of rights granted under the agreement and other interpretation- related issues; ● **whether our use of the licensed technology is within the scope of the rights granted to us or otherwise consistent with the agreement; 76 ●** our obligations to make milestone, royalty or other payments under those agreements; ● **other parties' performance being maintained under these agreements; ●** whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement; ● our right to sublicense patents and other rights to third parties; ● the ownership of inventions, know- how and other intellectual property, including intellectual property rights resulting from the joint creation or use of intellectual property by us and our licensors, licensees, partners or collaborators; ● our right to transfer or assign the license; and ● the effects of termination. ~~88These~~ -- **These** or other disputes over our obligations or intellectual property that we have in- licensed, out- licensed or acquired may prevent or impair our ability to maintain our current arrangements on acceptable terms, or may impair the value of the arrangement to us. Any such dispute could have an adverse effect on our business. If we fail, or our sublicensees cause us to fail, to meet our obligations under our agreements in a material respect, the respective licensor / seller would have the right to terminate the respective agreement. We then not only would have to return the licensed technology, but we may also be required to grant the licensor rights to any intellectual property controlled by us and developed during the period the agreement was in force that relate to the applicable licensed technology. This means that the licensor / seller for each of these agreements could effectively take control of the development and commercialization of our product and product candidates after an uncured, material breach of the agreement

by us. This would also be the case if we voluntarily elected to terminate the relevant agreement, which we have the right to do under each of these agreements. While we would expect to exercise our rights and remedies available to us in the event we fail, or our sublicensees cause us to fail, to meet our obligations under these agreements in any material respect, including seeking to cure any breach by us or our sublicensees, and otherwise seek to preserve our rights under the technology licensed to or acquired by us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the in-licenses could result in our loss of exclusive rights and may lead to a complete termination of our product development and any commercialization efforts for our product and each of our product candidates. Termination of one of these agreements for any reason, and the related discontinuation of the development or commercialization of a product or product candidate could impair our ability to raise additional capital, generate revenue and may significantly harm our business, financial condition and prospects. Additionally, under the Regeneron Agreement, Regeneron retains worldwide rights to develop and commercialize ARCALYST for local administration to the eye and ear and oncology and the right to develop and commercialize ARCALYST for all applications in the Middle East and North Africa. The development of ARCALYST in other fields could increase the possibility of identifying adverse safety results that may impact the commercialization of ARCALYST for the treatment of recurrent pericarditis in our territory. We have also entered into agreements to grant to others licenses under our owned intellectual property and sublicenses under intellectual property that we license from others for those third parties to develop and commercialize ARCALYST ~~, mavrilimumab~~ and vixarelimab, including the **ARCALYST Huadong** Collaboration ~~Agreements~~ - **Agreement** ~~with Huadong~~ and the Genentech License Agreement. Under each of these agreements, our licensees have certain responsibilities to develop and commercialize the applicable licensed drugs, make timely milestone and royalty payments, provide to us certain information regarding their activities and indemnify us with respect to their development and commercialization activities under the terms of the agreements. Additionally, under the Genentech License Agreement, we granted Genentech the first right to file, prosecute, maintain, defend, enforce and extend the life of the patents that we own and licensed to Genentech. These collaborations may be subject to a number of risks, including those listed under " — Risks ~~Related~~ **77Related** to Competition, Executing our Strategy and Managing Growth – We have entered into and may seek to enter into collaboration, licensing or other strategic transactions or arrangements to further develop, commercialize or otherwise attempt to realize value from one or more of our products and product candidates, and any such transactions or arrangements that we enter into may not be successful or be on favorable terms, which could adversely affect our ability to develop, commercialize or attempt to realize value from our products and product candidates " above. Finally, certain of our agreements may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, under the Regeneron Agreement, Regeneron has a right of first negotiation over the assignment or sale of our rights to any product we develop under the Regeneron Agreement to third parties and we must obtain Regeneron' s prior consent to assign or sublicense our rights under such agreement to a third party. ~~Under the MedImmune Agreement, we cannot sublicense the rights licensed or sublicensed to us without the consent of MedImmune and certain applicable third party licensors, if required by agreements between MedImmune and such third party licensors. 89Third~~ -- **Third** parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability and the ability of our sublicensees to develop, manufacture, market and sell our products and product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We cannot assure you that our products, product candidates or any future product candidates, including methods of making or using these product candidates, will not infringe existing or future third party patents. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products and product candidates and technology, including contested proceedings before the USPTO. Our competitors or other third parties may assert infringement claims against us, alleging that our products are covered by their patents. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. Many companies have filed, and continue to file, patent applications related to immunomodulation **and antibody- related technologies** . Some of these patent applications have already been allowed or issued, and others may issue in the future. For example, we are aware of third party patents that contain claims potentially relevant to abiprubart ~~and mavrilimumab~~ . If the claims of any of these patents are asserted against us, we do not believe our proposed activities related to abiprubart ~~and mavrilimumab~~ would be found to infringe any valid claim of these patents. While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. If we were to challenge the validity of any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent' s claims. In order to avoid infringing these or any other third party patents, we may find it necessary or prudent to obtain licenses to such patents from such third party intellectual property holders. However, we may be unable to secure such licenses or otherwise acquire or in- license any compositions, methods of use processes or other intellectual property rights from third parties that we identify as necessary for our current or future product candidates. The licensing or acquisition of third party intellectual property rights is a competitive area, and several more established companies may also pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to

successfully obtain rights to required third party intellectual property or maintain the existing intellectual property rights we have, we may have to cease development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Since our **products and** product candidates **treat or** are being developed **to treat indications** ~~for use in fields~~ that are competitive and of strong interest to pharmaceutical and biotechnology companies, we will likely seek to file additional patent applications and may have additional patents granted in the future, based on our future research and development efforts. ~~Furthermore~~ **78Furthermore** , because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications of third parties now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our **products or** product candidates. Regardless of when filed, we may fail to identify relevant third party patents or patent applications, or we may incorrectly conclude that a third party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes our **products or** product candidate infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. Moreover, we may face patent infringement claims from non- practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product candidate that is the subject of the actual or threatened suit. ~~90If~~ **If** we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product candidates and technology. Under any such license, we would most likely be required to pay various types of fees, milestones, royalties or other amounts. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non- exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or product candidate, or forced to redesign it, or to cease some aspect of our business operations. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third party patent rights. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Even if we are successful in defending against such claims, litigation can be expensive and time consuming and would divert management' s attention from our core business. Any of these events could harm our business significantly. We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights. Competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights, whether owned or in- licensed. To counter infringement or unauthorized use, we or our current or future licensees may be required to file infringement claims against these infringers. A court may disagree with our allegations, however, and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third party technology in question. Further, such third parties could counterclaim that we infringe their intellectual property or that a patent we or our licensees have asserted against them is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims challenging the infringement, validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us or our licensees to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non- enablement, or foreign equivalents thereof. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. It is possible that prior art of which we or our licensors and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid or unenforceable. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us if we or our licensees assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation. An adverse result in any litigation proceeding could put one or more of our patents, whether owned or in- licensed, at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering our product or one of our product candidates, we or our licensees ~~would~~ **79would** lose at least part, and perhaps all, of the patent protection covering such product candidate. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. If we or our licensees lose a patent lawsuit outside of the United States, alleging our infringement of a competitor' s patents, we or our licensees could be prevented from marketing our current or future products and product candidates in one or more such countries. Any of these outcomes would have a materially adverse effect on our business. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, ~~91because~~ -- **because** of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our Class A ~~common~~ **ordinary** shares. Such litigation or proceedings could substantially increase our operating losses and reduce the

resources available for development activities or any future sales, marketing or distribution activities. We or our licensees may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we or our licensees may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Obtaining and maintaining 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. The USPTO and various governmental patent agencies outside of the United States require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and patent agencies outside of the United States over the lifetime of the patent. While an unintentional 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, but are not limited to, 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 licensees fail to appropriately file and prosecute patent applications covering the licensed products, product candidate or technologies, and maintain any patent issuing from such patent applications, we or our licensees may not be able to stop a competitor from marketing products that are the same as or similar to the licensed products, product candidates or technologies, which would have a material adverse effect on our business. In addition, if we or our licensees fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patents, or receive royalties from a licensee. In addition, if we are responsible for patent prosecution and maintenance of patent rights in- licensed to us, any of the foregoing could expose us to liability to the applicable patent owner. We may not be able to effectively enforce our intellectual property rights throughout the world. Filing, prosecuting and defending patents on our product and product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely ~~affected~~ **80affected** by unforeseen changes in intellectual property laws outside of the United States. In addition, the patent laws of some such countries do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions outside of the United States. Varying filing dates in international countries may also permit intervening third parties to allege priority to patent applications claiming certain technology. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many countries outside of the United States have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against certain parties, including government agencies or government contractors. Consequently, we or our licensees may not be able to prevent third parties from practicing inventions covered by our patents, whether owned or in- licensed, in all countries outside the United States. Competitors may use our or their technologies in jurisdictions ~~92where~~ **where** we or they have not obtained patent protection, or where we or they have obtained patent protection, but such jurisdictions do not favor the enforcement of patents, and other intellectual property rights, to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our or our licensees' ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products and product candidates or the products and product candidates that we have out- licensed, and our or our licensees' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights, whether owned or in- licensed, in jurisdictions outside of the United States, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to pursue protection for our intellectual property rights in the major markets for our product and product candidates, we cannot ensure that we or our licensees will be able to initiate or maintain similar efforts in all jurisdictions in which we or they may wish to market our or our out- licensed products and product candidates. Accordingly, our or our licensees' efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and other countries may affect the ability to obtain and enforce adequate intellectual property protection for our technology. In addition, geo- political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product or our current or future product candidates. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time

consuming and inherently uncertain. **Current and proposed** ~~Patent~~ **patent** reform ~~legislation~~ in the United States and other countries **may** contribute to those uncertainties and costs ~~. The Leahy- Smith Act includes a number of significant changes to United States patent law. These include provisions that have affected the way patent applications are prosecuted and have redefined prior art and provided more efficient and cost- effective avenues for competitors to challenge the validity of patents. In addition, the Leahy- Smith Act has transformed the United States patent system into a first- to- file system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that has filed a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us or our licensees to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our product or product candidates or (2) invent any of the inventions claimed in our patents or patent applications. Even where we have a valid and enforceable patent, we or our licensees may not be able to exclude others from practicing the claimed 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. Among some of the other changes introduced by the Leahy- Smith Act are changes that (i) affect the way patent applications are prosecuted, (ii) redefine prior art, and (iii) provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. These include changes that limit where a patentee may file a patent infringement suit and provide new opportunities for third parties to challenge issued patents in the USPTO. We or our licensees may be subject to the risk of third party prior art submissions on pending applications or become a party to 93opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patents. There is a lower standard of evidence necessary to invalidate a patent claim in a USPTO proceeding relative to the standard in United States district or federal court. This could lead third parties to challenge and successfully invalidate our or our licensees' patents that would not otherwise be invalidated if challenged through the court system. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our or our licensees' patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy- Smith Act and its implementation increase the uncertainties and costs surrounding the prosecution of our or our future licensees' 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 Supreme Court of the United States 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. In addition, **future actions by** ~~there have been recent proposals for additional changes to the patent laws of~~ the United States **Congress, the United States Courts, the USPTO** and **relevant law- making bodies in** other countries ~~that, if adopted,~~ could impact our or our licensees' ability to obtain or maintain patent protection for our or our out- licensed proprietary technology or our or their ability to enforce our or our out- licensed proprietary technology, respectively ~~. Depending on future actions by the United States Congress, the United States 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; enforce or shorten the term of our or our licensees' existing patents and patents that we might obtain in the future; shorten the term that has been lengthened by patent term adjustment of our or our licensees' existing patents or patents that we might obtain in the future; or challenge the validity or enforceability of our patents that may be asserted against us by our competitors or other third parties. Any of these outcomes could have a material adverse effect on our business~~ . For example, with respect to patent term adjustment, the Federal Circuit' s recent holding in In re Cellect, LLC, 81 F. 4th 1216 (Fed. Cir. 2023), that obviousness- type double patent analysis for a patent that has received patent term adjustment must be based on the expiration date of the patent after the patent term adjustment has been added, may negatively impact the term of certain United States patents. ~~Finally~~ **81Finally** , Europe' s ~~new~~ Unitary Patent system and Unified Patent Court (the " UPC ") may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. In 2012, the European Patent Package (the " EU Patent Package "), regulations were passed with the goal of providing a single pan- European Unitary Patent system and a new UPC, for litigation involving European patents. Implementation of the EU Patent Package occurred in June 2023. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, ~~will~~ by default automatically fall under the jurisdiction of the UPC. The UPC ~~will provide~~ **provides** our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain pan- European injunctions. ~~It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC.~~ Under the EU Patent Package we will have the right to opt our patents out of the UPC over the first seven years of the court' s existence, but doing so may preclude us from realizing the benefits of the new unified court **. Depending on future actions by governmental authorities, including legislative bodies, administrative authorities and court systems, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents, or may weaken the patent rights of existing patents in certain situations or to enforce our existing patents and patents that we might obtain in the future. If such an event were to occur, our business, financial condition, results of operations and future prospects may be adversely affected** . If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed. In addition to the protection afforded by patents, we may rely upon unpatented trade secret protection, unpatented know- how and continuing technological innovation to develop and maintain our competitive position. Although we seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, contractors, employees,

independent contractors and consultants, and invention assignment agreements with our independent contractors, consultants, scientific advisors and employees, we may ~~not~~ be ~~able~~ **unable** to prevent the unauthorized disclosure or use of our technical know- how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation (e. g., in countries that do not favor the enforcement of ~~94intellectual~~ **intellectual** property rights), and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. Monitoring unauthorized use of our intellectual property is difficult and costly. We may ~~not~~ be ~~able~~ **unable** to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. The steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached. Detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time consuming, and the outcome is unpredictable. Further, we may ~~not~~ be ~~able~~ **unable** to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. We may in the future rely on trade secret protection, which would be subject to the risks identified above with respect to confidential information. ~~Our~~ **82Our** trade secrets could otherwise become known or be independently discovered by our competitors. Competitors could purchase our product or product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, our competitive position could be adversely affected, as could our business. ~~See also " Risk Factors – Risks Related to Manufacturing and Our Reliance on Third Parties – Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. "~~ If our trademarks and trade names are not adequately protected, then we may ~~not~~ be ~~able~~ **unable** to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may ~~not~~ be ~~able~~ **unable** to protect our rights to these trademarks and trade names in the United States or jurisdictions outside of the United States, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects. ~~95We~~ **We** have not yet registered trademarks for a commercial trade name for our product candidates in the United States or jurisdictions outside of the United States and failure to secure such registrations could adversely affect our business. ~~We~~ **Although the trademark ARCALYST has been registered by Regeneron (and we have permission to use it pursuant to the Regeneron License Agreement), we** have not yet registered trademarks for a commercial trade name for some of our product candidates in the United States or any jurisdiction outside of the United States. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many jurisdictions outside of the United States, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. General Risk **FactorsWe** ~~FactorsConflicts around the globe may~~ have **a history of operating losses** ~~an~~ **and** ~~adverse impact~~ **may require substantial**

additional financing in the future. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Our ability to generate product revenue sufficient to sustain our organization will depend heavily on **a number of factors, including the** ~~our operations. We operate globally and may be impacted by global and regional conflict. Conflict has adversely affected and may continue~~ **continued** ~~to adversely affect~~ **commercialization of ARCALYST, the development and eventual commercialization of one** ~~our~~ **or more of our current or future product candidates, if approved, and the management of our costs consistent with our current operating plan. Our future capital expenditures are expected to be substantial, and we may incur operating losses in the future if we encounter greater than expected expenses as we: 83 ● support our sales, marketing and distribution capabilities, infrastructure and organization to commercialize ARCALYST and any product candidates for which we may obtain marketing approval; ● conduct new and ongoing research and pre- clinical and** clinical development ~~efforts by~~ **of our product candidates that may or may not ever be approved or successful in the future** , **including our planned Phase 2 / 3 clinical trial of KPL- 387 in recurrent pericarditis, our ongoing Phase 1 clinical trial of KPL- 387 in normal healthy volunteers and our pre- clinical investigations of KPL- 1161; ● manufacture our products and product candidates** for ~~example~~ **clinical or commercial use** , ~~limiting the regions~~ **increase our manufacturing capabilities, add additional manufacturers or suppliers** and ~~countries in which we may recruit~~ **perform activities related to our technology transfer of the process for manufacturing ARCALYST drug substance; ● seek regulatory** and ~~conduct~~ **marketing approvals for our product candidates that successfully complete** clinical trials **, if any; ● identify, assess and study new or expanded indications** for our **products and** product candidates ~~. In~~ **and / or new or alternative dosing levels, dosing frequencies or administrations of our products and product candidates; ● make milestone or** ~~the other event Phase 2 clinical trial for abiprubart in RA ● seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials,if any;● make milestone or other~~ payments under any current or future license,acquisition,collaboration or other strategic transaction agreement;● seek to identify,assess and study new or expanded indications for our products or product candidates,new or alternative dosing levels and frequency for our products or product candidates,or new or alternative administration of our products or product candidates,including method,mode or delivery device;● seek to identify,assess,acquire or develop additional product candidates;● **address litigation arising out of,but not limited to,product liability claims,intellectual property disputes,disputes arising from our collaboration and license agreements and employment- related disputes;●** enter into licensing,acquisition,collaboration or other strategic transaction agreements;● seek to maintain,protect and expand our intellectual property portfolio;● seek to attract and retain skilled personnel;● create additional infrastructure to support our product development and commercialization efforts;and ● experience delays or encounter issues with any of the above,including but not limited to failed trials,complex results,safety issues,regulatory challenges ~~that require~~ that ~~conflict occurs after we have begun~~ **require longer follow- up of existing** trials ~~in a region~~ , ~~we~~ **additional major trials, additional supportive trials in order to pursue marketing approval, a pandemic or other outbreak of disease or disruptions to the national or global economy. Further, our financial results** may **fluctuate significantly from quarter- to- quarter and year- to- year, such that a period- to- period comparison of our results of operations may not** be **a good indication of our future performance. Corporate profitability may not be sustained in subsequent periods. If we are** unable to ~~secure alternative clinical sites~~ **fund our operations through commercial ARCALYST revenue, we may need to obtain substantial additional funding to progress our operating plans via accessing capital markets. If we are unable to raise capital** when needed ~~or~~ on acceptable terms, if at all **, we** ~~. This in turn~~ may ~~cause significant~~ **be forced to** ~~delays~~ **delay** ~~or disruptions to~~ **, limit, reduce** ~~our~~ **or** ~~clinical~~ **cease one or more of our product** development ~~efforts~~ **plans** , **research** ~~which could have a material impact on our business, operations~~ and financial position. Furthermore, it is..... s business or operations, impede our development programs for our product candidates **, or commercialization efforts. We also may be unable to expand** ~~or~~ **our operations or otherwise capitalize on our business opportunities or may be 84required to relinquish rights to our product candidates or products. Any of these occurrences could** materially ~~impact~~ **affect our business, financial condition and results of operations. Financing our activities also carries risk. The sale of additional equity** ~~our~~ **or** ~~ability to commercialize~~ **convertible securities would dilute all of** our ~~products~~ **shareholders** . ~~" A global pandemic~~ **Further, new investors could gain rights superior to our existing shareholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants** , such as **limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and** ~~the~~ **other operating restrictions that** ~~COVID- 19 pandemic, and measures taken in response to such pandemic,~~ could ~~have an adverse~~ **adversely** impact ~~that is significant on~~ **our ability to conduct** our business ~~and operations as well as~~ **. Obtaining funds through licensing, collaboration or** ~~the~~ **other** ~~business~~ **strategic transactions** or **arrangements with** ~~operations of the~~ third parties ~~with whom we conduct business~~ **may require us to relinquish rights to some of our technologies, product candidates or future revenue streams,** or otherwise ~~engage~~ **agree to terms unfavorable to us** , **any of** which may have a material adverse effect on our business, ~~operations~~ **operating results** and **prospects** ~~financial position~~ . **If** ~~Global pandemics, such as the COVID- 19 pandemic, and measures taken in response to such pandemics, could cause significant disruption in our business and operations and could cause significant disruption in the business and operations of our manufacturers, CROs upon whom~~ we **raise funds through research grants** ~~rely to conduct our clinical trials~~ , ~~clinical trial sites, and other third parties with whom~~ we **may be subject** ~~conduct business or otherwise engage, including the FDA and other regulatory authorities. In the past, governmental authorities around the globe implemented measures in response~~ to **certain requirements** ~~the COVID- 19 pandemic~~ , ~~including significant restrictions on businesses as well as travel into and within the countries in~~ which **may** ~~our manufacturers produce our product candidates, where we conduct our clinical trials or where we otherwise conduct business or engage with other third parties. In addition, the COVID- 19 had a direct impact on our business and operations by, among other things: 96 ● disrupting global supply chains for our products and product candidates, the raw materials required for~~

~~manufacturing our products and product candidates and important ancillary products needed to administer our products and product candidates; ● causing disruptions, staffing shortages, production slowdowns, stoppages or reprioritizations at the third party CDMOs that we rely on to produce our products and product candidates; ● impeding clinical trial activities, including activities related to enrolling and monitoring our clinical participants; ● limiting~~ --- **limit** our ability to **use the funds** ~~access third party payors, prescribers and patient advocacy groups to build disease awareness; ● limiting our~~ ~~workforce' s ability~~ to **share information from** ~~collaborate in- person at our facilities; and ● causing disruption and volatility in United States and global capital markets. Such impacts were also felt by a number of the third parties with whom we interact, which further affected our business and operations. In the event that a new global pandemic emerges, or~~ **our research** ~~a new variant of the COVID- 19 pandemic emerges, we may be subject to the same or similar restrictions~~ and **development** ~~adverse events. We cannot ultimately predict the scope and severity of any such future event; however, such events may be severe and have a material impact on our business, results of operations and financial condition~~ . If we fail to comply with reporting and payment obligations under the MDRP or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We participate in governmental programs that impose extensive drug price reporting and payment obligations on pharmaceutical manufacturers **,** including the **Medicaid Drug Rebate Program (the "** MDRP **")** , the **Federal Supply Schedule (the "** FSS **")** and **the** PHS 340B Drug Pricing Program ~~. See " Business – Government Regulation – Government Programs and Price Reporting " for more information on applicable rules and regulations~~ . If we are found to have violated the requirements of such programs, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts, which can change and evolve over time. Such pricing calculations and reporting, along with any necessary restatements and recalculations, could increase our costs for complying with the laws and regulations governing the MDRP and other governmental programs, and under the MDRP could result in an overage or undercharge in Medicaid rebate liability for past quarters. Price recalculations under the MDRP also may affect the ceiling price at which we are required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B, if applicable, for our covered outpatient drugs. Pursuant to the IRA, the AMP figures we report will also be used to compute rebates under Medicare Part D triggered by price increases that outpace inflation. We cannot assure you that our submissions will not be found to be incomplete or incorrect. Enacted and future healthcare legislation may have a material adverse effect on our business and results of operations. In the United States, the **United Kingdom, the** EU and other jurisdictions, there have been and we expect there will continue to be a number of legislative and regulatory initiatives and proposed changes to the healthcare system that could affect our ~~97operations~~ -- **operations** . See " Business – Government Regulation – Healthcare Reform and Potential Changes to Healthcare Laws " for more information on such initiatives and changes in the United States and the EU. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, the **United Kingdom, the** EU or elsewhere. For example, such actions may result in changes to governmental policies and regulations that affect our operations and business, including our clinical trials, regulatory approval, pharmaceutical pricing and reimbursement. If we or any third party we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third party are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained which may have a material impact on our business and **.Our information technology** systems,or those of our third party CDMOs,CROs,specialty pharmacies,third party logistics providers and other contractors,consultants and service providers,may fail or suffer cyberattacks or security breaches,which could result in a material disruption of our or such third party' s business or operations,impede our development programs for our product candidates or materially impact our ability to commercialize our products.Despite the implementation of security measures,our information technology systems and those of our third party CDMOs,CROs,specialty pharmacies,third party logistics providers and other contractors,consultants and service providers are vulnerable to attack,damage or interruption from viruses and malware (e.g.,ransomware),malicious code,theft,natural disasters,terrorism,war,telecommunication and electrical failures,hacking,cyberattacks,phishing attacks and other social engineering schemes,employee misuse,human error,fraud,denial or degradation of service attacks,sophisticated nation- state and nation- state- supported actors or unauthorized access or use by persons inside our organization,or persons with access to systems inside our organization.Attacks upon information technology systems are increasing in their frequency,levels of persistence,sophistication and intensity,and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise.Technologies such as artificial intelligence and machine learning are additionally being used to create more sophisticated attacks on targets,including targeted social engineering attempts.We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees,such as our commercial field force,who are working remotely,which may create additional opportunities for cybercriminals to exploit vulnerabilities.Employees may also fail to comply with our cybersecurity protocols,exposing us to vulnerabilities despite our safeguards.Furthermore,because the techniques used to obtain unauthorized access to,or to sabotage,systems change frequently and often are not recognized until launched against a target,we may be unable to anticipate these techniques or implement adequate preventative measures.In addition,because we have outsourced elements of our information technology infrastructure to vendors,such vendors may or could have access to our confidential information.A breach at a CDMO,CRO,contractor,consultant,service provider or other third party with which we engage may increase our exposure by

allowing criminals to exploit our relationship with such persons.Such security breaches may remain undetected for an extended period.Even if identified,we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls,to avoid detection,and to remove or obfuscate forensic evidence.We and certain of our service providers are from time to time subject to cyberattacks and security incidents.While we do not believe that we have experienced any ~~current or past~~ significant system failure,accident or security breach ~~that has materially affected or would be reasonably likely to materially affect us,including our business strategy,results of operations or financial condition~~ to date,if such an event were to occur and cause interruptions in our business and operations or those of our third party CDMOs,CROs,specialty pharmacies,third party logistics providers and other contractors,consultants and service providers,the costs associated with the investigation,remediation and potential notification of a breach to counter- parties and data subjects could be material.A breach could result in a material disruption of our or such third party' s business or operations.For example,the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.To the extent that any disruption or security breach results in a loss of or damage to our data or applications or **other data or applications relating to our technology or product candidates,or** inappropriate disclosure or theft of confidential or proprietary information,the further development of our product candidates could be delayed.Further disruptions to our or our third party providers' infrastructure may inhibit our ability to commercialize ARCALYST through,among other things,interruptions in our logistics fulfillment,loss of patient and prescriber information,interruptions in our ability to communicate with the third party providers upon which we rely and impairments in our ability to service our patients and address their concerns.Any of these events could adversely impact our business and ability to generate product revenue.Although we maintain cybersecurity insurance coverage,it may not be adequate to cover all liabilities that we may incur from cyberattacks or security breaches and is subject to deductibles and coverage limitations. ~~Actual~~ **99Actual** or perceived failures to comply with applicable data protection,privacy and security laws,regulations,standards and other requirements could adversely affect our business,results of operations,and financial condition.We are or in the future may be subject to data privacy and protection laws,regulations,policies and contractual obligations that govern the collection,transmission,storage,processing and use of personal information or personal data.The regulatory framework for data privacy and security worldwide is continuously evolving and developing and,as a ~~86result~~ -- **result** ,interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.This evolution may affect our ability to operate in certain jurisdictions;impede our ability to collect,store,transfer,use and share personal information;necessitate the acceptance of more onerous obligations in our contracts;result in liability;or impose additional costs on us.The cost of compliance with these laws,regulations and standards is high and is likely to increase in the future.Any failure or perceived failure by us to comply with federal,state or foreign laws or regulations,our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity,government investigations and enforcement actions,claims by third parties and damage to our reputation,any of which could have a material adverse effect on our business,results of operation,and financial condition.For example,most healthcare professionals,including research institutions from which we obtain patient health information,are subject to privacy and security regulations promulgated under HIPAA **,as amended** .We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties.However,any person may be prosecuted under HIPAA' s criminal provisions either directly or under aiding- and- abetting or conspiracy principles.Consequently,depending on the facts and circumstances,we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA- covered healthcare professional or research institution that has not satisfied HIPAA' s requirements for disclosure of individually identifiable health information.In addition,we may maintain sensitive personally identifiable information,including health information,that we receive throughout the clinical trial process,in the course of our research collaborations,directly from individuals (or their healthcare professionals) who enroll in our patient support program and directly from individuals who consent to be included in our marketing database.As such,we may be subject to state laws requiring notification of affected individuals and state regulatory authorities in the event of a breach of personal information,which is a broader class of information than the health information protected by HIPAA.In addition,certain state laws govern the privacy and security of health information in certain circumstances,some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect,thus complicating compliance efforts.Failure to comply with these laws,where applicable,can result in the imposition of significant civil and / or criminal penalties and private litigation.Certain states have also adopted comparable privacy and security laws and regulations governing the privacy,processing and protection of personal information.For example,the California Consumer Privacy Act,as amended by the California Privacy Rights Act (together,the " CCPA ") gives California residents expanded rights to access,correct,and delete their personal information,opt out of certain personal information sharing,receive detailed information about how their personal information is used and also imposes ~~limitations~~ **limitation** ~~on~~ **son** data uses,new audit requirements for higher risk data and opt outs for certain uses of sensitive data.The CCPA provides for civil penalties for violations,as well as a private right of action for data breaches that has increased the likelihood of,and the risks associated with data breach litigation.Further,the California Privacy Rights Act created a California data protection agency authorized to enforce the CCPA and issue substantive regulations,which could result in increased privacy and information security enforcement.Similar laws have been passed in other states and are continuing to be proposed at the state and federal level,reflecting a trend toward more stringent privacy legislation in the United States.The Washington My Health My Data Act,which ~~is~~ **will be** applicable to companies doing business in Washington or targeting products or services to consumers in Washington **beginning in 2024** ,imposes disclosure and consent requirements,among other things,with respect to broadly defined consumer health data,and is enforceable through consumer class actions.Additional compliance investment and potential business process changes may also be required.Furthermore,the Federal Trade Commission (" FTC ") and many state Attorneys General continue to enforce federal

and state consumer protection laws against companies for online collection,use,dissemination and security practices that appear to be unfair or deceptive.For example,according to the FTC,failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation ~~of~~ **100of** Section 5 (a) of the Federal Trade Commission Act.The FTC expects a company' s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds,the size and complexity of its business,and the cost of available tools to improve security and reduce vulnerabilities.Our clinical trial programs outside the United States may implicate international data protection laws,including the GDPR,and legislation of EU member states and EEA countries implementing it.The GDPR imposes strict ~~87requirements~~ -- **requirements** for processing the personal data of individuals within the EEA.In addition,some of the personal data we process in respect of clinical trial participants is special category or sensitive personal data under the GDPR,and subject to additional compliance obligations and to local law derogations.Companies that must comply with the GDPR face increased compliance obligations and risk,including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million or 4 % of the annual global revenues of the noncompliant company,whichever is greater.In addition to fines,a breach of the GDPR may result in regulatory investigations,reputational damage,orders to cease or change our data processing activities,enforcement notices,assessment notices (for a compulsory audit) and / or civil claims (including class actions).Among other requirements,the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data,including the United States,and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain.Case law from the Court of Justice of the European Union (" CJEU ") states that reliance on the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism) alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by- case basis.We currently rely on the EU standard contractual clauses and the **UK** ~~United Kingdom~~ Addendum to the EU standard contractual clauses,as applicable,to transfer personal data outside the EEA and the **UK** ~~United Kingdom~~ ,including to the United States,with respect to both intragroup and third party transfers.Following a period of legal complexity and uncertainty regarding international personal data transfers,particularly to the United States,we expect the regulatory guidance and enforcement landscape to continue to develop,in relation to transfers to the United States and elsewhere.As a result,we may have to make certain operational changes and we will have to implement revised standard contractual clauses and other relevant documentation for existing data transfers within required time frames.Further,following the withdrawal of the **UK** ~~United Kingdom~~ from the EU on January 31,2020,and the expiration of the transition period,from January 1,2021,companies have had to comply with the GDPR and also the **UK** ~~United Kingdom~~ GDPR,which,together with the amended UK Data Protection Act 2018,retains the GDPR in UK national law.The **UK** ~~United Kingdom~~ GDPR mirrors the fines under the GDPR,e.g.,fines up to the greater of € 20 million (£ 17.5 million) or 4 % of global turnover.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. ~~The Swiss Federal Act on Data Protection (the " DPA ") also applies to the collection and processing of personal data by companies located in Switzerland,or in certain circumstances,by companies located outside of Switzerland.The DPA may lead to an increase in our costs of compliance,risk of noncompliance and penalties for noncompliance as we potentially expand our footprint in Switzerland.~~ Failure or perceived failure to comply with the GDPR,the **UK** ~~United Kingdom~~ GDPR ~~,the DPA~~ and other countries' privacy or data security- related laws,rules or regulations could result in significant regulatory penalties and fines,affect our compliance with contracts entered into with our partners and collaborators,and could have an adverse effect on our reputation,business and financial condition.Furthermore,certain health privacy laws,data breach notification laws,consumer protection laws and genetic testing laws may apply directly to our operations or those of our collaborators and may impose restrictions on our collection,use and dissemination of individuals' health information.Moreover,patients about whom we or our collaborators obtain health information,as well as the providers who share this information with us,may have statutory or contractual rights that limit our ability to use and disclose the information.We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws.Claims that we have violated individuals' privacy rights or breached our contractual obligations,even if we are not found liable,could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.Although we work to comply with applicable laws,regulations and standards,our contractual obligations and other legal obligations,these requirements are evolving and may be modified,interpreted and applied in an inconsistent manner from one jurisdiction to another,and may conflict with one another or other legal obligations with which we must comply.In addition,we make public statements about our use,collection,disclosure and other processing of ~~personal~~ **101personal** data through our privacy policies and information provided on our website.Although we endeavor to comply ~~88with~~ -- **with** our public statements and documentation,we may at times fail to do so or be alleged to have failed to do so.If we or our third party CDMOs,CROs or other contractors,consultants or service providers fail to comply,or are perceived to have failed to comply,with applicable regulatory requirements,applicable policies or notices relating to privacy or data protection,contractual or other obligations to third parties,or any other legal obligations,laws,rules,regulations and standards relating to privacy or data protection,we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize,or could substantially increase the costs and expenses of developing,commercializing and marketing our products.Any threatened or actual government investigation or enforcement action,litigation,claims or other proceedings could also generate adverse publicity,harm our reputation,result in significant liability and require that we devote substantial resources that could otherwise be used in other aspects of our business.Our future success depends on our ability to retain key executives and senior management;attract,retain and motivate qualified personnel;and implement succession planning efforts to ensure our long- term success.We are highly dependent on the research and development,clinical,medical,regulatory,manufacturing,commercial and business development expertise of

members of our executive and senior management teams,as well as the other members of our management,scientific and clinical teams.Although we have entered into employment agreements with our executive officers and certain members of senior management,each of them or we may terminate their employment with us at any time.An executive terminating their employment or taking an extended leave of absence without sufficient notice may leave a gap in the organization that we may be unable to fill on a timely basis,if at all.We do not maintain " key person " insurance for any of our executives,senior management or other employees.In addition,we rely on consultants and advisors,including scientific and clinical advisors,to assist us in formulating our research and development and commercialization strategy.Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.If we are unable to continue to attract and retain high quality personnel,our ability to pursue our growth strategy will be limited.Recruiting and retaining qualified ~~corporate,~~ scientific,clinical,regulatory,manufacturing and sales and marketing personnel is also critical to our success.The failure to recruit,or the loss of the services of our executive officers,senior management or other key employees could impede the achievement of our research,development and commercialization objectives,including with respect to our sales,marketing and distribution capabilities,infrastructure and organization to commercialize products for which we have obtained marketing approval and maintain proper regulatory oversight functions,any of which would seriously harm our ability to successfully implement our business strategy.Furthermore,replacing executive officers,senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop,gain regulatory approval of and commercialize products.Changes in our senior management may be disruptive to our business,and,if we are unable to manage an orderly transition of responsibilities,our business may be adversely affected.Competition to hire from this limited pool is intense,and we may be unable to hire,train,retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.We also experience competition for the hiring of ~~corporate,~~ scientific,sales,marketing and clinical personnel from other pharmaceutical companies,universities and research institutions,as applicable.Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific and clinical personnel. ~~In addition,laws and regulations may restrict our ability to attract,motivate and retain the required level of qualified personnel.For example,our business operations may rely on foreign personnel who require work permits.Any changes in immigration policies,work permit regulations,or visa requirements could adversely affect our ability to retain skilled employees.If work permits are denied,revoked,or not renewed,we may face disruptions in its operations,increased costs for hiring and training replacements,and potential delays in project execution.~~ If we are not able to continue to attract and retain,on acceptable terms,the qualified personnel necessary for the continued development of our business,we may not be able to sustain our operations or growth. ~~89Effective~~ -- **Effective** succession planning is also important to our long- term success and ability to operate as a generational company.As we encounter employee turnover,including turnover of key personnel,we may be unable to timely train or locate replacement personnel in a way that delays our strategic planning and clinical and commercial execution. ~~Our~~ **102Our** employees,principal investigators,CROs,consultants and other third party service providers may engage in misconduct or other improper activities,including noncompliance with regulatory standards and requirements and insider trading.We are exposed to the risk that our employees,principal investigators,CROs,consultants and other third party service providers may engage in fraudulent conduct or other illegal activity.Misconduct by these parties could include intentional,reckless or negligent conduct **or disclosure of unauthorized activities to us** that violate the regulations of the FDA and other regulatory authorities,including those laws requiring the reporting of true,complete and accurate information to such authorities;healthcare fraud and abuse laws and regulations in the United States and abroad;or laws that require the reporting of financial information or data accurately.In particular,sales,marketing and business arrangements in the healthcare 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,including off- label promotion,sales commission,customer incentive programs and other business arrangements.Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials,which could result in regulatory sanctions and cause serious harm to our reputation.It is not always possible to identify **and deter misconduct by employees and other third parties.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.Additionally,we are subject to the risk that a person could allege such fraud or other misconduct,even if none occurred.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 civil,criminal and administrative penalties,damages,monetary fines,possible exclusion from participation in Medicare,Medicaid and other federal healthcare programs,contractual damages,reputational harm,diminished profits and future earnings and curtailment of our operations,any of which could adversely affect our ability to operate our business and our results of operations** operations. Unfavorable global economic or operational conditions could adversely affect our business, financial condition or results of operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. In addition, global credit and financial markets have recently experienced volatility and disruptions, including severely diminished liquidity and credit availability, rising interest rates, declines in consumer confidence, declines in economic growth, increase in unemployment rates and uncertainty about economic stability. These disruptions could adversely affect our ability to manufacture, market and sell our commercialized products, including ARCALYST, and satisfy the required supply for any of our product candidates or successfully complete preclinical and clinical development of our product candidates, which could require us to incur additional costs, and impair our ability to obtain

regulatory approval of our product candidates and generate revenue. Doing business internationally involves a number of other risks, including but not limited to: ● multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, employment laws, regulatory requirements, permits and export and import restrictions; ● failure by us to obtain and maintain regulatory approvals for the use of our products in various countries; ● additional potentially relevant third party patent rights; **90** ● complexities and difficulties in obtaining protection and enforcing our intellectual property; ● difficulties in staffing and managing operations outside of the United States; ● complexities associated with managing multiple payor reimbursement regimes, government payors or patient self- pay systems; ● limits in our ability to penetrate international markets; ● financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations; ● natural disasters, political and economic instability such as war, terrorism, political unrest, outbreak of disease, labor disputes and boycotts; ● curtailment of trade, and other business restrictions; ● certain expenses including, among others, expenses for travel, translation and insurance; ~~and98 --~~ **and** ● regulatory and compliance risks that relate to maintaining accurate information and control over clinical activities, sales and other functions that may fall within the purview of the United States Foreign Corrupt Practices Act, its books and records provisions or its antibribery provisions. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business . Our information technology systems, or..... our business and our results of operations . The increasing and evolving focus on environmental, social and governance (“ ESG ”) matters could increase our costs, harm our reputation, adversely impact our access to capital and financial results or otherwise adversely impact our business. There has been increasing and evolving public focus by investors, patients, environmental activists, the media and governmental and nongovernmental organizations on a variety of ESG matters, such as climate change and diversity, equity and inclusion matters. We may experience pressure from stakeholders, including our suppliers, employees, patients and shareholders, to set goals or make commitments relating to ESG matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to ESG topics. ~~If we are not effective in addressing~~ **We may also receive pushback from other stakeholders regarding our initiatives related to** ESG matters **.** ~~affecting our business, or~~ **For example** ~~setting and meeting relevant ESG goals~~ , **in January 2025, President Trump signed a number of executive orders focused on DEI matters, which indicate continued scrutiny of such initiatives and may implicate the initiatives of non- governmental entities, including publicly traded companies. If we do not successfully manage expectations across varied stakeholder interests, it could erode stakeholder trust or impact** our reputation **,** and **our** financial results may suffer. In addition, even if we are effective at addressing such concerns, we may experience increased costs as a result of **balancing competing interests related to ESG matters and** executing upon our ESG goals ~~that~~ **, which costs** may not be offset by any benefit to our reputation, **and** which could have an adverse impact on our business and financial condition. ~~In addition~~ **Outside of the United States** , ~~this emphasis~~ **continued global focus** on ESG matters has resulted in the adoption of new laws and regulations, including ~~new~~ reporting requirements **imposed by the United Kingdom** , ~~and may~~ **which will impact the annual reports we are required to file in the United Kingdom as a** result ~~in the adoption~~ of ~~additional laws and regulations in~~ the ~~future~~ **Redomiciliation** . New reporting requirements may be particularly difficult or expensive to comply with and, if we fail to comply, we may be required to issue financial restatements, suffer harm to our reputation or otherwise have our business be adversely impacted. Such ESG matters may also impact our suppliers or patients, which may adversely impact our business, financial condition and results of operations. ~~In~~ **91In** addition, organizations that provide information to investors on corporate governance and related matters have developed ratings processes for evaluating companies on ESG matters. Such ratings are used by some investors to inform their investment or voting decisions. Unfavorable ESG ratings could lead to negative investor sentiment toward ~~103us~~ **us** and / or our industry, which could have a negative impact on our access to and costs of capital. To the extent ESG matters negatively impact our reputation, we may be affected in a number of ways, including an inability to recruit and retain personnel and a decrease in the trading price of our Class A ~~common~~ **ordinary** shares. Climate change, and related regulation, may result in increased costs or otherwise negatively impact our operations and harm our business. The impacts of climate change on the global economy and our industry are rapidly evolving. Physical impacts of climate change (including but not limited to floods, droughts, more frequent and / or intense storms and wildfires), could negatively impact our business and operations, as well as the business and operations of our third party CDMOs and CROs upon whom we rely. Such events may result in damage or loss of our products and product candidates during their manufacture and shipment, cause delays in clinical development due to trial site disasters or result in losses of critical data, any of which may adversely impact our operations. An evolving climate may also result in uncertain and potentially onerous regulatory requirements as agencies and governmental authorities adjust, such as new or changed emissions reporting and auditing requirements. Failure to comply with such requirements in a timely manner may adversely affect our reputation, business, or financial performance. Risks Related to Ownership of Our ~~Common~~ **Ordinary** SharesThe concentration of ownership of our Class B ~~common~~ **ordinary** shares, which are held primarily by our executive officers and certain other members of our senior management, and the conversion rights of the holders of our Class A1 ~~common~~ **ordinary** shares, which shares are held primarily by entities affiliated with certain of our directors, and Class B1 ~~common~~ **ordinary** shares, all of which shares are held by entities affiliated with certain of our directors, means that such persons are, and such entities may in the future be, able to influence certain matters submitted to our shareholders for approval, which may have an adverse effect on the price of our Class A ~~common~~ **ordinary** shares and may result in our Class A ~~common~~ **ordinary** shares being undervalued. Each Class A ~~common~~ **ordinary** share is entitled to one vote per Class A ~~common~~ **ordinary** share and each Class B ~~common~~ **ordinary** share is entitled to ten votes per Class B ~~common~~ **ordinary** share. Our Class A1 ~~common~~ **ordinary** shares and Class B1 ~~common~~ **ordinary** shares have no voting rights. As a result, all matters submitted to our shareholders are decided by the vote of holders of our Class A ~~common~~ **ordinary** shares and Class B ~~common~~ **ordinary** shares. As a result of the multi- class voting structure of our ~~common~~ **ordinary** shares, our executive officers and certain other members of our senior

management collectively control a substantial amount of the voting power of our ~~common~~ **ordinary** shares and therefore are able to control the outcome of certain matters submitted to our shareholders for approval. As of December 31, ~~2023~~ **2024** , the holders of Class A ~~common~~ **ordinary** shares accounted for approximately ~~67~~ **70** % of our aggregate voting power and the holders of Class B ~~common~~ **ordinary** shares accounted for approximately ~~33~~ **30** % of our aggregate voting power. Our executive officers and certain other members of our senior management hold Class A ~~common~~ **ordinary** shares and Class B ~~common~~ **ordinary** shares representing approximately ~~30~~ **26** % of our aggregate voting power as of December 31, ~~2023~~ **2024** and may have the ability to influence the outcome of certain matters submitted to our shareholders for approval. However, this percentage may change depending on any conversion of our Class B ~~common~~ **ordinary** shares, Class A1 ~~common~~ **ordinary** shares or Class B1 ~~common~~ **ordinary** shares as set forth in our **articles of association** ~~amended and restated bye- laws~~ . For example, as of December 31, ~~2023~~ **2024** , entities affiliated with certain members of our directors could convert their Class A1 ~~common~~ **ordinary** shares and Class B1 ~~common~~ **ordinary** shares upon 61- days' prior written notice into Class A ~~common~~ **ordinary** shares and Class B ~~common~~ **ordinary** shares, respectively, which in the aggregate would result in such entities holding approximately ~~78~~ **76** % of our aggregate voting power and having the ability to control the outcome of certain matters submitted to our shareholders for approval. Due to these conversion rights, holders of our Class A1 ~~common~~ **ordinary** shares and our Class B1 ~~common~~ **ordinary** shares could, at any time with appropriate advance notice to us, significantly increase their voting control of us, which could result in their ability to significantly influence or control matters submitted to our shareholders for approval and significantly decrease the voting power of our currently outstanding Class A ~~common~~ **ordinary** shares. ~~These~~ **92These** conversion rights as well as concentrated control that limit certain shareholders' ability to influence corporate matters may have an adverse effect on the price of our Class A ~~common~~ **ordinary** shares. Holders of our Class B ~~common~~ **ordinary** shares, which have ten votes per share on most matters, may have significant control over the outcome of ~~104certain~~ --- **certain** matters submitted to our shareholders for approval, including the election of directors. Due to the conversion rights of the holders of our Class A1 and B1 ~~common~~ **ordinary** shares, entities affiliated with certain of our directors could significantly increase their voting control of us. This concentration of control might adversely affect certain corporate actions that some of our shareholders may view as beneficial, for example, by: ● delaying, deferring or preventing a change of control of us; ● impeding a merger, consolidation, takeover or other business combination involving us; or ● discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. The price of our Class A ~~common~~ **ordinary** shares may be volatile and fluctuate substantially, which could result in substantial losses for holders of our Class A ~~common~~ **ordinary** shares. Our share price may be subject to change as a result of volatility in the stock market driven by events often unrelated to our operating performance. As a result of this volatility, our shareholders may not be able to sell their Class A ~~common~~ **ordinary** shares at or above the price they paid for their shares. The market price for our Class A ~~common~~ **ordinary** shares may be influenced by many factors, including: ● our ability to generate revenue through the successful commercialization of our products and product candidates, if approved; ● the size of the market for our products and product candidates, if approved; ● the results of clinical trials for our product candidates or any delays in the commencement, enrollment and the ultimate completion of clinical trials; ● failures in obtaining approval of our product candidates; ● the results and potential impact of competitive products or technologies; ● our ability to manufacture and successfully produce our products and product candidates; ● actual or anticipated changes in estimates as to financial results, capitalization, development timelines or recommendations by securities analysts; ● the level of expenses related to any of our products and product candidates or clinical development programs; ● variations in our financial results or those of companies that are perceived to be similar to us; ● financing or other corporate transactions, or our inability to obtain additional funding; ● failure to meet or exceed the expectations of the investment community; ● regulatory or legal developments in the United States and other countries; ● the recruitment or departure of key personnel; **93** ● developments or disputes concerning patent applications, issued patents or other proprietary rights; ~~105~~ ● the results of our efforts to discover, develop, acquire or in- license additional product candidates or from our entering into collaborations or other strategic transaction agreements; ● changes in the structure of healthcare payment systems; ● market conditions in the pharmaceutical and biotechnology sectors; ● general economic, industry and market conditions, including pandemics or other outbreaks of disease and rising inflation rates; ● changes in voting control of, or sales of our shares by, our executive officers and certain other members of our senior management or entities affiliated with certain of our directors that hold our shares; and ● the other factors described in this " Risk Factors " section. Market conditions are often difficult to predict and there can be no assurance as to the performance of our Class A ~~common~~ **ordinary** shares or that we will not experience any adverse effects that may be material to our consolidated cash flows, results of operations, financial position or our ability to access capital. In the past, following periods of volatility in the market, securities class action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management' s attention and resources, which could materially and adversely affect our business and financial condition. If securities or industry analysts cease publishing about us or publish unfavorable research or reports about us, our business or our market, our share price and trading volume could decline. The trading market for our Class A ~~common~~ **ordinary** shares is influenced by the research and reports that equity research analysts publish about us and our business. We do not have any control over the analysts or the content and opinions included in their reports. The price of our Class A ~~common~~ **ordinary** shares could decline if one or more equity research analysts downgrades our shares or issues other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our Class A ~~common~~ **ordinary** shares could decrease, which in turn could cause the price of our Class A ~~common~~ **ordinary** shares or its trading volume to decline. Sales of a number of our Class A ~~common~~ **ordinary** shares in the public market, including Class A ~~common~~ **ordinary** shares issuable upon conversion of our Class B, Class A1 and Class B1 ~~common~~ **ordinary** shares, could cause the share price of our Class A ~~common~~ **ordinary** shares to fall. A significant number of our Class A ~~common~~ **ordinary** shares are issuable upon conversion of our Class B, Class A1, and Class B1 ~~common~~ **ordinary** shares,

subject to certain limitations on conversion. As of December 31, ~~2023~~ **2024** , approximately 2. 0 million Class A ~~common~~ **ordinary** shares directly held by our executive officers and directors, inclusive of Class A ~~common~~ **ordinary** shares issuable upon conversion of our Class B, Class A1, and Class B1 ~~common~~ **ordinary** shares, were eligible for resale in the public market to the extent permitted by the provisions of Rule 144 promulgated under the Securities Act of 1933, as amended (the " Securities Act "), and such rule, Rule 144. In addition, as of December 31, ~~2023~~ **2024** , there were approximately ~~14~~ **13** . ~~0~~ **5** million Class A ~~common~~ **ordinary** shares subject to outstanding share options and RSUs under our equity incentive plans that may become eligible for sale in the public market to the extent permitted by the provisions of applicable vesting schedules and Rule 144 and Rule 701 under the Securities Act. A majority of our ~~common~~ **ordinary** shares are held by our executive officers and other members of our senior management team, together with entities affiliated with certain of our directors. As of December 31, ~~2023~~ **2024** , on an as- converted to Class A ~~common~~ **ordinary** shares basis, these shareholders collectively held approximately 33. 8 million of our Class A ~~common~~ **ordinary** shares. If any of these shareholders sell, convert or transfer, or indicate an intention to sell, convert or ~~transfer~~ **94transfer** , a substantial amount of their ~~common~~ **ordinary** shares (after certain restrictions on conversion or resale lapse), the market price of our Class A ~~common~~ **ordinary** shares could decline. ~~106Pursuant~~ --- **Pursuant** to our amended and restated investor rights agreement (our " Investors Rights Agreement "), certain shareholders are entitled to certain registration rights with respect our Class A ~~common~~ **ordinary** shares, including Class A ~~common~~ **ordinary** shares issuable upon conversions of our Class B, Class A1, and Class B1 ~~common~~ **ordinary** shares and upon the exercise of certain rights to acquire Class A ~~common~~ **ordinary** shares, or collectively registerable securities, under the Securities Act. As of December 31, ~~2023~~ **2024** , on an as- converted to Class A ~~common~~ **ordinary** shares basis, we have registered approximately 31. 8 million Class A ~~common~~ **ordinary** shares held by certain holders affiliated with certain of our directors as well as certain other shareholders pursuant to our investor rights agreement, which are freely tradable without restriction under the Securities Act, to the extent permitted by Rule 144. Further, pursuant to the Investors Rights Agreement (a) the holders affiliated with certain of our directors are entitled to certain registration rights under the Securities Act with respect to registrable securities they may own now or in the future and (b) our executive officers are also entitled to certain registration rights under the Securities Act with respect to registrable securities they may own now or in the future, including, on an as- converted to Class A ~~common~~ **ordinary** shares basis, approximately 1. ~~8~~ **7** million Class A ~~common~~ **ordinary** shares held by certain of our executive officers as of December 31, ~~2023~~ **2024** . If any of these Class A ~~common~~ **ordinary** shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our Class A ~~common~~ **ordinary** shares could decline. We have anti- takeover provisions in our **articles of association** ~~amended and restated bye- laws~~ that may discourage a change of control. Our **articles of association** ~~amended and restated bye- laws~~ contain provisions that could make it more difficult for a third party to acquire us. These provisions provide for: ● a classified board of directors with staggered three- year terms; ● directors only to be removed for ~~cause~~ **a limited number of reasons** ; ● ~~an affirmative vote~~ **limitations on the acquisition** of **more than 30** ~~66 2 / 3~~ % **or more** of ~~the~~ **our** voting **rights, except through** ~~power of our voting shares for~~ certain **defined permitted acquisitions** ~~" business combination " transactions that have not been approved by our board of directors~~ ; ● our multiclass ~~common~~ **ordinary** share structure, which provides our holders of Class B ~~common~~ **ordinary** shares with the ability to significantly influence the outcome of matters requiring shareholder approval, even if they own less than a majority of our outstanding Class A ~~common~~ **ordinary** shares; **and** ● restrictions on the time period in which directors may be nominated ~~; and ● our board of directors to determine the powers, preferences and rights of our preferred shares and to issue the preferred shares without shareholder approval~~ . These anti- takeover defenses could discourage, delay or prevent a transaction involving a change in control of our company and may prevent our shareholders from receiving the benefit from any premium to the market price of our Class A ~~common~~ **ordinary** shares offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our Class A ~~common~~ **ordinary** shares if the provisions are viewed as discouraging takeover attempts in the future. These provisions could also discourage proxy contests, make it more difficult for our shareholders to elect directors of their choosing and cause us to take corporate actions other than those our shareholders desire. Because we do not anticipate paying any cash dividends on our shares in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our shareholders. We have never declared or paid cash dividends on our shares. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Additionally, the proposal to pay future dividends to shareholders will effectively be at the sole discretion of our board of directors after considering various factors our board of directors deems relevant, including our business prospects, capital requirements, financial performance and new product development. As a result, capital appreciation, if any, of our Class A **ordinary shares will be the sole source of gain for our shareholders for the foreseeable future. 95Risks Related to Our Jurisdiction of Incorporation and Certain Tax RisksAs a result of increased shareholder voting requirements in the United Kingdom relative to Bermuda, we will have less flexibility with respect to our ability to issue new shares. Prior to the Redomiciliation, our principal holding company was incorporated in Bermuda. Under Bermuda law, a company' s directors may issue, without shareholder approval, any authorized but unissued** common shares **. English law allows our shareholders to authorize the allotment of share capital which can be issued by our board of directors without further shareholder approval, but this authorization must be renewed by the shareholders at least every five years and we cannot guarantee that this authorization** will **always** be ~~the sole source~~ **approved. Our articles** of ~~gain~~ **association currently authorize, subject to the requirements of the Nasdaq Global Select Market, our board of directors to issue new ordinary or preferred shares (up to a maximum of ten percent (10 %) of the issued share capital of the Company) without shareholder approval** for **a period of 15 months from the date of adoption of the articles of association. Subsequent authority to issue new ordinary** ~~our~~ **or preference shares can be given by the** shareholders **of the Company by an ordinary resolution from time to time (i. e., approval from shareholders holding more than 50 % of the voting rights), with such authority capable of applying in respect of any period specified in such resolution up to a maximum of**

five years. Additionally, subject to specified exceptions, including an opt- out included in our articles of association, English law grants statutory preemptive rights to existing shareholders to subscribe for new issuances of shares for cash. English law requires that this opt- out must be renewed by the ~~foreseeable~~ shareholders at least every five years, and we cannot guarantee that the opt- out of preemptive rights will always be approved. A waiver of pre- emption rights under English law requires approval of the shareholders holding at least 75 % of the voting rights in an English company. In the future , our plans may be impeded due to a lack of flexibility that we previously enjoyed in Bermuda, potentially materially affecting our business, financial condition and results of operations . Our articles of association waive the statutory pre- emption rights in relation to new ordinary or preferred shares issued by the board of directors (up to a maximum of ten percent (10 %) of the issued share capital of the Company) for a period of 15 months from the date of adoption of the articles of association. While both the general authority to allot and waiver of pre- emption rights could be approved on an annual (or multi- year) basis by shareholders at the annual general meeting, it cannot be guaranteed. The rights afforded to our shareholders are governed by English law. Not all rights available to shareholders under United States law will be available to holders of our ordinary shares. Our parent company is organized under the laws of England and Wales. The rights of holders of our ordinary shares are governed by English law and our articles of association, and these may not provide the same rights as shares offered by American or Bermudan companies. In addition, English law may be subject change in the future in ways that are disadvantageous to United States- based shareholders, which could adversely affect the rights of our investors. Rights afforded to shareholders under English law differ in certain respects from the rights of shareholders in companies incorporated in the United States or Bermuda. In particular, English law currently significantly limits the circumstances in which the shareholders of English companies may bring derivative actions (i. e., legal actions brought by a shareholder on behalf of a company against a third- party). Under English law, in most cases, only Kiniksa Pharmaceuticals International, plc may be the proper plaintiff for the purposes of maintaining proceedings in respect of wrongful acts committed against it and, generally, neither an individual shareholder, nor any group of shareholders, has any right of action in such circumstances. In addition, English law does not afford appraisal rights to dissenting shareholders in the form typically available to shareholders in an American company. It also may be difficult to enforce foreign civil liabilities against us because of our country of incorporation. See " Risk Factors — ~~107Risks~~ --- Risks Related to our Jurisdiction of Incorporation ~~Owning Shares in a Bermuda Exempted Company~~ and Certain Tax ~~RisksWe~~ -- Risks ~~are a Bermuda company and —~~ United States investors may find it difficult to enforce their civil liabilities against us. " 96Investors in the United States may find it difficult to enforce their civil liabilities against us. It may be difficult for U. S. investors to bring and / ~~our~~ - or effectively ~~shareholders to~~ enforce ~~judgments~~ suits against us outside of the United States ~~or our directors and executive officers~~ . We are a ~~Bermuda exempted~~ public limited company incorporated in England and Wales . ~~As~~ If a ~~result,~~ judgment is obtained in the ~~rights~~ U. S. courts based on civil liability provisions of the U. S. federal securities ~~holders of our Class A common shares will be governed by Bermuda law~~ laws ~~and~~ against us ~~our~~ - or ~~memorandum of association and amended and restated~~ our directors or officers, it may, depending on the jurisdiction, ~~bye~~ - be difficult to enforce the judgment in the non - ~~laws~~ U . S ~~The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in other jurisdictions~~ . ~~It may be difficult for investors to enforce in the United States judgments obtained in United States~~ courts against us . Accordingly, U. S. shareholders may be forced to bring legal proceedings against us under English law and in the English courts in order to enforce any claims that they may have against us or our directors and officers. The enforceability of a U. S. judgment in the United Kingdom will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and the United Kingdom do not currently have a treaty providing for reciprocal recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Nevertheless, it may be difficult for U. S. shareholders to bring an original action in the English courts to enforce liabilities based on the U. S. federal ~~civil liability provisions of the United States~~ securities laws ~~. It is doubtful whether courts in Bermuda will enforce judgments obtained in other jurisdictions, including the United States,~~ against us ~~or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions. Our amended and restated bye- laws designate the Supreme Court of Bermuda as the choice of jurisdiction for disputes that arise concerning the Bermuda Companies Act 1981, as amended (the " Companies Act "), or out of or in connection with our amended and restated bye- laws, which could limit our shareholders' ability to choose the judicial forum for disputes with us or our directors or officers. Our amended and restated bye- laws provide that, unless we consent in writing to the selection of an alternative jurisdiction, any dispute that arises concerning the Companies Act, or out of or in connection with our amended and restated bye- laws, including any question regarding the existence and scope of any bye- law or whether there has been a breach of the Companies Act or the amended and restated bye- laws by any of our officers or directors (whether or not such a claim is brought in the name of a shareholder or in the name of our company) shall be subject to the jurisdiction of the Supreme Court of Bermuda. Any person or entity purchasing or otherwise acquiring any interest in any of our shares shall be deemed to have notice of and consented to this provision. This choice of jurisdiction provision may limit a shareholder' s ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors or officers, which may discourage lawsuits against us and our directors and officers. If a court were to find either choice of jurisdiction provision in our amended and restated bye- laws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations. Bermuda law differs from the laws in effect in the United States and may afford less protection to our shareholders. We are organized under the laws of Bermuda. As a result, our corporate affairs are governed by the Companies Act, which differs in some material respects from laws typically applicable to United States corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder

~~lawsuits and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to act against directors or officers of the company and may only do so in limited circumstances. Shareholder class actions are not available under Bermuda law. The circumstances in which shareholder derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of United States corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company' s memorandum of association or bye- laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company' s shareholders than those who actually approved it. When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company' s affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our amended 108and restated bye- laws and as permitted by Bermuda law, each shareholder has waived any claim or right of action against our directors or officers for any action taken by directors or officers in the performance of their duties, except for actions involving fraud or dishonesty. In addition, the rights of our shareholders and the fiduciary responsibilities of our directors under Bermuda law are not as clearly established as under statutes or judicial precedent in existence in jurisdictions in the United States, particularly the State of Delaware. Therefore, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the United States. There are regulatory limitations on the ownership and transfer of our common shares. Common shares may be offered or sold in Bermuda only in compliance with the provisions of the Companies Act and the Bermuda Investment Business Act 2003, as amended, which regulates the sale of securities in Bermuda. In addition, the Bermuda Monetary Authority must approve all issues and transfers of shares of a Bermuda exempted company. However, the Bermuda Monetary Authority has, pursuant to its statement of June 1, 2005, given its general permission under the Exchange Control Act 1972 and related regulations for the issue and free transfer of our common shares to and among persons who are non- residents of Bermuda for exchange control purposes as long as the shares are listed on an appointed shares exchange, which includes Nasdaq. This general permission would cease to apply if we were to cease to be listed on Nasdaq~~ . We may become subject to unanticipated tax liabilities **, including liabilities arising from the reallocation of our taxable income among our subsidiaries** . Although we are incorporated under the laws of ~~Bermuda~~ **England and Wales** , we may become subject to income, withholding or other taxes in certain other jurisdictions by reason of our activities and operations, including the movement of assets to and between one or more foreign subsidiaries. It is also possible that taxing authorities in any such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Any such ~~non- Bermudian~~ tax liability **, if greater than our overall effective tax rate,** could materially adversely affect our results of operations. **For example** ~~Taxing authorities could reallocate our taxable income among our subsidiaries~~ , **we** ~~which could increase our overall tax liability. We~~ are **currently** incorporated under the laws of ~~Bermuda~~ **England** and ~~currently~~ **Wales and** have subsidiaries in the United States, the United Kingdom **, Bermuda** , Germany, Switzerland and France. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various tax jurisdictions subject to transfer pricing arrangements between us and such subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation is maintained to support the transfer prices. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows. Changes **and uncertainties** in **the** ~~laws related to~~ tax **system** ~~practices and substance requirements~~ in ~~Bermuda and other~~ -- **the** ~~jurisdictions could adversely affect our~~ **countries in which we have** operations ~~. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Europe (including the United Kingdom and Switzerland), the United States, Bermuda, and other jurisdictions, as well as being affected by certain changes currently proposed by the Organization for Economic Cooperation and Development and their action plan on Base Erosion and 109Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation were to arise in the future, it could adversely impact our tax position and our effective tax rate. There remains significant uncertainty as to any other tax policies and strategies which this or any future administration may adopt. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties, and reputational damage, which could adversely affect our business, results of operations and our financial condition. Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: ● the jurisdictions in which profits are determined to be earned and taxed; ● the resolution of issues arising from any future tax audits with various tax authorities; ● changes in the valuation of our deferred tax assets and liabilities; ● changes to and increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; ● changes in the taxation of share- based compensation; ●~~

~~changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles; and ● challenges to the transfer pricing policies related to our structure. Pursuant to the Bermuda Economic Substance Act 2018 (as amended) and related Economic Substance Regulations (collectively, " ES Laws "), certain entities in Bermuda engaged in " relevant activities " are required to maintain appropriate physical presence in Bermuda and to satisfy economic substance requirements. The list of " relevant activities " includes carrying on as a business in any one or more of the following categories: banking, insurance, fund management, financing and leasing, headquarters, shipping, distribution and service center, intellectual property and holding entities. Under the ES Laws, any relevant entity carrying on a relevant activity must satisfy economic substance requirements locally or face financial penalties, restriction or regulation of its business activities or may be struck off as a registered entity from the Bermuda Register of Companies. Because we are not engaged in any " relevant activities ", as defined by the ES Laws, we believe that we are not obliged to meet the economic substance requirements. We will continue to monitor our status with respect to the ES Laws and whether further action may be required in the future by the Company to comply with the ES Laws. In December 2023, the Bermuda Government passed final legislation to introduce a corporate income tax that would be considered when calculating the effective tax rate of Bermuda- incorporated businesses under the OECD' s global anti- base erosion (" GloBE ") rules. Under this legislation, Bermuda corporate income tax will apply only to multinational enterprises, as defined in the GloBE rules, with EUR 750 million or more in total global revenue in at least two of the previous four accounting periods. The Bermuda corporate income tax legislation will be effective for tax years beginning on or after January 1, 2025. Prior to this legislation, Bermuda did not have corporate income tax. The imposition of Bermuda corporate income tax, if applicable to our business~~ , could materially adversely affect ~~the~~ **our** financial condition and results of operations ~~. Governmental agencies may enact significant changes to the taxation of business entities including~~ , ~~among others,~~ ~~an~~ **and reduce net returns to** ~~increase in the corporate income tax rate, the imposition of minimum taxes or~~ **our shareholders** ~~surtaxes on certain types of income, significant changes to the taxation of income derived from international operations, and an addition of further limitations on the deductibility of business interest. While certain draft legislation has been publicly released, the likelihood of these changes being enacted or implemented is unclear~~ . We are unable to predict ~~whether~~ **what tax reform may be proposed or enacted in the future by the United States, United Kingdom, Switzerland or the OECD or what effect** such changes **would have** ~~will 110occur. If such changes are enacted or implemented, we are unable to predict the ultimate impact~~ on our business and ~~therefore~~ **results of operations. Changes in tax rates, laws, practices, treaties, policies or regulations, or the change in interpretation** ~~there~~ **thereof** ~~can be no assurance~~ **, could increase our effective tax rate** ~~our~~ **or otherwise** ~~business will not be adversely affected~~ -- **affect our financial position, results of operations and financial condition and / or increase the complexity, burden and cost of tax compliance** . ~~We~~ **97We** may be treated as a passive foreign investment company (" PFIC ") for United States federal income tax purposes. If we were to be classified a PFIC, this could result in adverse United States federal income tax consequences to United States Holders. We completed an analysis of the Company' s and its subsidiaries sources of income and character of their assets for United States federal income tax purposes and determined that neither the Company nor any of its subsidiaries would be classified as a PFIC for the taxable year ending December 31, ~~2022~~ **2023** . We plan to perform an analysis to determine whether the Company or its subsidiaries are expected to be treated as PFICs for the taxable year ending December 31, ~~2023~~ **2024** , and do not believe that the Company or its subsidiaries will be treated as a PFIC for the taxable year ending December 31, ~~2023~~ **2024** . However, there can be no guarantee that **we** ~~the Company~~ , **or** ~~or~~ **our** ~~its~~ subsidiaries, will not be treated as a PFIC for any taxable period. A non- United States company will generally be considered as a PFIC for any taxable year if (i) at least 75 % of its gross income is passive (including interest income), or (ii) at least 50 % of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. If we, or our subsidiaries, are classified as a PFIC in any year with respect to which a **beneficial owner of our Class A ordinary shares who is (a) an individual who is a citizen of the United States, (b) a corporation organized under the laws of the United States or any state, district or territory thereof, (c) an estate taxable with income subject to United States federal income tax or (d) certain trusts (each, a "** United States Holder **"** ~~(as defined below~~) owns our Class A ~~common~~ **ordinary** shares, we will continue to be treated as a PFIC with respect to such United States Holder in all succeeding years during which the United States Holder owns the Class A ~~common~~ **ordinary** shares, regardless of whether we continue to meet the PFIC test described above, unless we cease to be a PFIC and the United States Holder made a " qualified electing fund " election or " mark- to- market " election for (a) the first taxable year the United States Holder was treated as owning our shares while we were a PFIC or (b) for the taxable year in which we were a PFIC and the United States Holder made a " deemed sale " election or was qualified to and made a " deemed dividend " election. ~~A " United States Holder " is a beneficial owner of our Class A common shares that, for United States federal income tax purposes, is or is treated as any of the following: ● an individual who is a citizen or resident of the United States; ● a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia; ● an estate, the income of which is subject to United States federal income tax regardless of its source; or ● a trust that (i) is subject to the supervision of a United States court and all substantial decisions of which are subject to the control of one or more " United States persons " (within the meaning of Section 7701 (a) (30) of the United States Internal Revenue Code of 1986, as amended (the " Code ")), or (ii) has a valid election in effect to be treated as a United States person for United States federal income tax purposes.~~ If we, or our subsidiaries, are classified as a PFIC for any taxable year during which a United States Holder holds our Class A ~~common~~ **ordinary** shares, certain adverse United States federal income tax consequences could apply to such United States Holder, including (i) the treatment as ordinary income of any gain realized on a disposition of our shares and distributions on our shares not being qualified dividend income, (ii) the application of a deferred interest charge on the tax on such gain and distributions, and (iii) the obligation to comply with certain reporting requirements. If a United States Holder is treated as owning at least 10 % of our shares, by vote or by value, such holder may be subject to adverse United States federal income tax consequences. We believe we will likely be classified as a " controlled foreign corporation " (as such term is

defined in the Code) for the taxable year ended December 31, ~~2023~~ **2024** . Even if we were not classified as a controlled foreign corporation, certain of our non- United States subsidiaries could be treated as controlled foreign corporations because our group includes one or more United States subsidiaries. If a United States Holder is treated as owning (directly, indirectly or constructively) at least 10 % of the value or voting power of our shares, such United States Holder may be treated as a " United States shareholder " (as such term is defined in the Code) with respect to us (if we are classified as a controlled ~~111~~ **foreign corporation) and each controlled foreign corporation in our group (if any). A United States shareholder of a controlled foreign corporation may be required to annually report and include in its United States taxable income its pro rata share of " Subpart F income, " " global intangible low- taxed income, " and investments in United States property by such controlled foreign corporation, regardless of whether such corporation makes any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a United States corporation. Failure to comply with these reporting obligations or income inclusions may subject such shareholder to significant monetary penalties and may prevent the statute of limitations with respect to such shareholder' s United States federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist investors in determining whether such investor is treated as a United States shareholder with respect to us or any of our non- United States subsidiaries. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the reporting and tax paying obligations discussed above. United States Holders should consult their tax advisors regarding the potential application of these rules to any investment in our Class A ordinary shares. 98**