Risk Factors Comparison 2025-02-27 to 2024-03-08 Form: 10-K

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Our business is subject to numerous risks and uncertainties, including those described in Part I. Item 1A. " Risk Factors " in this Annual Report. You should carefully consider these risks and uncertainties when investing in our American Depositary Shares (" ADSs "). The principal risks and uncertainties affecting our business include the following: We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We will require substantial additional capital to finance our operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development programs, commercialization efforts or other operations. Our approach to the discovery of product candidates based on our technology platform is unproven, and we do not know whether we will be able to develop any products of commercial value. We are early in our development efforts and only have ~~two~~ **four** product candidates, ~~GSBR~~ **aleniglipron, ACCG** - ~~1290 and~~ **2671,** ANPA- 0073 **and LTSE- 2578** , in early clinical development. All of our other development programs are in the preclinical or discovery stage. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed. Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes. The results of prior clinical ~~trials~~ **studies** and preclinical studies are not necessarily predictive of future results, and may not be favorable, or receive regulatory approval on a timely basis, if at all.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our planned clinical ~~trials~~ **studies** could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Serious adverse events ~~(" SAEs ")~~ , undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates, any of which would limit the commercial potential of such product candidate. As an organization, we have never conducted later- stage clinical ~~trials~~ **studies** or submitted a New Drug Application (" NDA "), and may be unable to do so for any of our product candidates. The marketing approval processes of the U. S. Food and Drug Administration (" FDA ") and applicable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed. We have **may** conducted, or plan to conduct, our initial clinical studies for ~~GSBR~~ **aleniglipron, ACCG** - ~~1290~~ **2671** , ANPA- 0073, LTSE- 2578 and our other product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such ~~trials~~ **studies** , in which case our development plans will be delayed, which could materially harm our business. We rely on third parties for the manufacture of our product candidates for preclinical and clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis. We rely on third parties to conduct, supervise and monitor our discovery research, preclinical studies and clinical ~~trials~~ **studies** . We have experienced delays due to actions of third parties in the past and if in the future third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We have entered into, and may in the future enter into, collaboration agreements and strategic alliances to maximize the potential of our structure- based drug discovery platform and product candidates, and we may not realize the anticipated benefits of such collaborations or alliances. We expect to continue to form collaborations in the future with respect to our product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans. Our existing discovery collaborations with Schrödinger, LLC (together with its affiliates, " Schrödinger ") are important to our business. If we are unable to maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected. **5** We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us. ~~5~~ We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue. We conduct certain research and development operations through our Australian wholly- owned subsidiaries. If we lose our ability to operate in Australia, or if any of our subsidiaries are unable to receive the research and development tax credit allowed by Australian regulations, or are required to refund any research and development tax credit previously received or reserve for such credit in our financial statements, our business and results of operations could suffer. Changes in the political and economic policies or in relations between China and the United States may affect our business, financial condition, results of operations and the market price of our ADSs. If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to

successfully commercialize our products may be adversely affected. We may rely on one or more in- licenses from third parties. If we lose these rights, our business may be materially adversely affected, and if disputes arise with one or more licensors, we may be subjected to future litigation as well as the potential loss of or limitations on our ability to develop and commercialize products and technologies covered by these license agreements. PART IItem 1. Business. OverviewWe are a clinical stage global biopharmaceutical company ~~aiming to develop~~ **developing** ~~and deliver~~ novel oral **small molecule** therapeutics to treat a wide range of chronic diseases with unmet medical need. Our differentiated technology platform leverages **both** structure- based drug discovery and **our expertise in** computational chemistry ~~expertise and enables us~~ to **discover and** develop ~~oral~~ small molecule therapeutics **against** ~~for the treatment of various diseases including those impacting the metabolic, cardiovascular, and pulmonary systems. In February 2023, we completed our Initial Public Offering (" IPO ") for net proceeds of approximately $ 166. 7 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. In September 2023, we entered into a share purchase agreement with certain institutional investors (the " Purchase Agreement "), pursuant to which we issued and sold an aggregate of 21, 617, 295 ordinary shares and 2, 401, 920 non-voting ordinary shares for net proceeds of approximately $ 281. 5 million (the " Private Placement "). Our initial focus is on~~ G-protein coupled receptors (" GPCRs ") ~~as a therapeutic target class~~. ~~GPCRs~~ **These important receptors** regulate numerous **and** diverse physiological and pathological processes **. In fact** , ~~and~~ approximately one in every three marketed medicines targets GPCR- associated pathways **for the treatment of various metabolic, cardiovascular and pulmonary disorders** . By leveraging our world- class GPCR know- how, we **are** ~~aim to design~~ **designing** differentiated small molecule therapies to overcome the limitations of biologics and peptide therapies **that** ~~targeting~~ --- **target** this family of receptors. ~~We are developing~~ **Our most advanced product candidate to date is aleniglipron, also known as** GSBR- 1290, ~~our~~ **an** oral small molecule **selective** ~~product candidate targeting the validated~~ glucagon- like- peptide- 1 receptor (" GLP- 1R ") **agonist currently in two Phase 2 clinical trials** for the treatment of **obesity, overweight and related conditions. Our obesity pipeline also includes ACCG- 2671, an oral small molecule amylin receptor agonist development candidate in investigational new drug (" IND ")- enabling studies, multiple preclinical discovery stage small molecules targeting glucose- dependent insulinotropic polypeptide (" GIP ") and glucagon (" GCG ") receptors, as well as ANPA- 0073, an oral small molecule agonist targeting the apelin (" APJ ") receptor in GLP- toxicology studies and Phase 2 ready. Importantly, these programs have the potential to be developed as monotherapy as well as in fixed dose combination with our backbone therapeutics aleniglipron or ACCG- 2671, as demonstrated below. These 6combination products enable us to potentially address diseases beyond obesity including** type 2 diabetes mellitus (" T2DM ") **, heart failure, sleep apnea, chronic kidney disease** ~~and obesity. We completed our Phase 1 single ascending dose~~ (" ~~SAD~~ **CKD** ") ~~study of GSBR~~ **, osteoarthritis, metabolic dysfunction** - **associated steatotic liver disease** ~~1290 in September 2022. GSBR- 1290 was generally well tolerated and demonstrated dose- dependent pharmacokinetic~~ (" ~~PK~~ **MASH** ") and ~~pharmacodynamic~~ **potentially even addiction and Parkinson' s disease and Alzheimer' s disease, areas where we are starting to see encouraging data with GLP- 1Rs. Our product candidates, as oral small molecules, have the potential to be more accessible medicines than biologics and peptide therapies with potential potentially differentiated effectiveness and safety and, from a manufacturing standpoint, more scalable towards meeting global demand. Metabolic Franchise Strategy: Fixed- Dose Combinations and Potential Indication ExpansionObesity MarketObesity is a complex, heterogeneous, chronic, and progressive disease, which substantially affects health, quality of life and mortality. "' Obesity " and " severe obesity " are defined by a body mass index** (" ~~PD~~ **BMI** ") ~~activity. We submitted~~ **of greater than 30** ~~an~~ **and** ~~investigational new drug~~ **40 kg / m2, respectively, with abnormal or excessive fat accumulation. " Overweight " is defined by a BMI of greater than 25 kg / m2. Obesity has wide- ranging consequences on the health and wellbeing of individuals. The metabolic consequences of obesity include, but are not limited to, T2DM, MASH, hypercholesterolemia, chronic kidney disease, atherosclerotic cardiovascular disease, heart failure, osteoarthritis and sleep apnea. In the United States, 58 % of adults with obesity have high blood pressure, a risk factor for heart disease and approximately 23 % of adults with obesity have diabetes. According to the Centers for Disease Control and Prevention, the prevalence of overweight and obesity in the United States between 2017 – 2020 was more than 100 million adults, representing approximately 42 % of the population. During the same time, the prevalence of severe obesity was more than 22 million adults, representing approximately 9 % of the population. Globally, obesity affects more than 890 million** (**13 %** ~~" IND "~~) ~~application~~ **adults and has continued** to **increase in prevalence worldwide since** the ~~FDA to support~~ **World Health Organization declared a global obesity epidemic. This deeply rooted and global health crisis represents a total addressable market of more than $ 100 billion annually. 7Global Obesity Epidemic: Prevalence of Obesity and Overweight and Total Addressable MarketCurrently Approved Peptide Treatments have** ~~initiation~~ - **Limitations** ~~of a Phase 1b study~~ **Currently approved GLP- 1R agonists provide multiple beneficial effects** in **patients with** T2DM ~~and obesity and received FDA allowance in September 2022. We initiated the Phase 1b multiple ascending dose (" MAD ") study of 6GSBR- 1290 in January 2023 and completed dosing in otherwise healthy overweight subjects in March 2023. In May 2023~~ , **including excellent glycemic control** ~~we submitted a protocol amendment to the FDA and initiated dosing of the Phase 2a proof- of- concept study in T2DM and obesity. We reported topline data for the 28- day Phase 1b MAD study in September 2023, in which GSBR- 1290 was generally well- tolerated~~ with **low risk of hypoglycemia,** ~~no adverse event (" AE ")- related discontinuations and demonstrated an encouraging safety profile and significant~~ weight loss ~~of up to 4~~ **and protection against cardiovascular and renal complications** . **However** ~~9 % placebo- adjusted~~ , ~~supporting once~~ **approved GLP** - ~~daily~~ **1R agonists have several shortcomings in terms of patient convenience, ease of** dosing **and cost. Injectable peptide GLP- 1R agonists require patients to self- inject, require inconvenient refrigerated storage and are costly** . In **addition** ~~December 2023~~ , **long acting GLP- 1R agonists typically require long titration periods to reach** ~~we reported clinically meaningful topline data from our Phase 2a T2DM cohort, interim results from our Phase 2a obesity cohort and~~ - **an optimal dose for disease management in order to avoid** ~~topline data from a Japanese~~

~~ethno- bridging study of GSBR- 1290. These data demonstrated that GSBR- 1290 was generally well- tolerated, with no~~ treatment- **associated gastrointestinal** ~~related SAEs over 12 weeks, with only one participant discontinuing the study due to adverse events in the T2DM cohort and none in the obesity cohort. GSBR- 1290 also showed significant reductions in weight in the obesity cohort at 8 weeks, and significant reductions in hemoglobin A1c (" HbA1c ") and weight in the T2DM cohort. We expect to report the full 12- week Phase 2a obesity data in the latter half of the second quarter of 2024 with additional 24 participant data. We also fully enrolled a formulation bridging and titration optimization study to evaluate capsule versus tablet PK and explore different titration regimens of GSBR- 1290. We expect to report topline results from this study in the latter half of the second quarter of 2024, in preparation for the global Phase 2b study for obesity which we expect to initiate in the second half of 2024. A Phase 2 study in T2DM is also planned for the fourth quarter of 2024. A number of GPCR properties contribute to its importance as a drug target class, including interaction with a diverse set of signaling molecules, involvement in a vast array of physiological and pathological processes, and cell surface expression that enables extracellular drug binding. As such, GPCRs have emerged as the largest family of targets for approved drugs, have provided significant benefit to patients and have achieved blockbuster sales in a number of therapeutic indications, including diabetes (Victoza), bipolar disorders (Abilify, Seroquel), asthma (Singulair), hypertension (Diovan, Lopressor), and cardiovascular disease (Plavix). Despite this success, there remain a number of challenges to continued innovation in this target class, including (i) low expression levels on cell surfaces, (ii) the complexity of the multi- subunit peptide GPCR receptor, (iii) difficulties in obtaining relevant crystal structures as a basis for drug design, and (iv) non- specific signaling through multiple intracellular signaling pathways, a concept known as non- biased signaling, which can limit activity and increase~~ side effects **, including nausea and vomiting. Unfortunately, most patients today do not stay on therapy past a year, with discontinuation rates of 65 % with injectable GLP- 1R agonists after one year and up to 85 % after two years as shown below. This means that patients are not benefitting from sustained weight loss and the long- term cardiometabolic benefits that GLP- 1R agonist can provide. Discontinuation Rates of Approved GLP- 1R Agonist Treatment Over First Two Year of Treatment8Oral Small Molecules: A Solution for Long- Term Maintenance TherapyWe believe there is a significant opportunity for oral small molecules to enable patients to continue GLP- 1R agonist treatment for sustained weight loss and long- term cardiometabolic benefits. For example, oral semaglutide (Rybelsus), the first approved oral GLP- 1R peptide agonist, provides an option for patients who are unable or unwilling to self- administer injectable therapies. However, Rybelsus requires a stringent dosing protocol and dosing with up to four ounces of water and no food or beverage within 30 minutes. Additionally, the product' s absorption enhancer may affect the absorption of other concomitantly administered oral medications. Thus, we believe there is a significant unmet medical need for orally administered GLP- 1R agonists that meet or exceed efficacy and safety parameters of available drugs with less stringent preparation requirements. Existing constraints that should be eliminated or minimized include: restrictive food or fluid dosing protocols, refrigeration and maintenance of effective concentrations throughout the dosing interval without interfering with the absorption of concomitant medications while offering the potential for combination products with other glucose- lowering agents or other commonly co- administered therapies. In addition, the high prevalence of obesity and overweight together with the broad interest in currently approved GLP- 1R peptides have contributed to past drug shortages for Wegovy and Zepbound. Moreover, the scalability of weekly GLP- 1R peptide injectables may be limited by fill- finish capacity and device requirements, while the scalability to large populations of oral GLP- 1R analog peptides, including oral semaglutide, may be limited by large drug substance requirements arising from their poor bioavailability** . We ~~have~~ **believe we are well- positioned to overcome the limitations of existing peptide therapies through the** ~~developed~~ **development of novel oral** ~~a platform designed to address these key challenges, enabling us to discover~~ small molecule **therapeutics via** ~~drugs to effectively target GPCRs. Further,~~ our **differentiated technology** platform **and approach** ~~has been designed to develop novel drugs against other targets where traditional drug discovery methods have not been adequate~~ . Our **Technology Platform and ApproachOur** next generation **,** structure- based drug discovery platform is based on techniques that our founders have evolved ~~for~~ over 25 years, which enables us to generate small molecule product candidates designed to overcome the historical limitations of GPCR drug development **(see subsection titled " Challenges of GPCR Therapeutics Discovery and Development " below)** . As shown below, we believe our insights and ~~capability~~ **capabilities** ~~to~~ **for** ~~visualize~~ **visualizing** ~~the~~ three- dimensional **ligand and target** protein structures ~~of the target and the ligands~~ combined with ~~the~~ computational chemistry capabilities of our co- founder and strategic partner, Schrödinger, give us significant competitive advantages in highly efficient and rational drug design. We design our novel compounds by combining our knowledge of GPCR structures together with advanced physics- based computational methods, which we believe allows us to predict the binding affinity of molecules to the target site with a high degree of accuracy. **9Our Technology Platform Repeatedly Delivers New** ~~7Advantages of GPCR oral small molecule therapeuticCHALLENGES OPPORTUNITIES ● Limited cellular and tissue permeability ● Customizable pharmaceutic properties ● Scalability and costs ● Orally -- **Oral Small MoleculesWe** available, better patient compliance ● Limited stability ● No cold- chain requirements ● Cold supply chain requirements ● Lower costs ● Higher costs ● Large scale manufacturing capabilityWe~~ believe the strengths of our platform position us to develop oral small molecule drugs that can deliver biologic- like activity and specificity. Oral small molecules can address many of the key limitations of biologic and peptide drugs, thereby significantly improving patient access. We believe this is particularly important for the most prevalent chronic diseases including those involving the metabolic, cardiovascular ~~,~~ and pulmonary systems. ~~Our lead product candidate, GSBR- 1290, is an oral~~ **Oral** ~~and biased~~ small ~~molecule~~ **molecules have large** ~~agonist of GLP -~~ **scale manufacturing advantages** ~~1R, a validated GPCR drug target for T2DM~~ and ~~obesity, currently in Phase 2 development. There~~ are ~~currently ten marketed peptide molecules that target GLP- 1R; collectively, these peptide therapies generated worldwide sales of $ 65 billion in 2023. However, there are currently no approved oral small molecule therapies targeting GLP- 1R. In non- human primate (" NHP "), studies, GSBR- 1290 demonstrated glucose- dependent insulin secretion and suppressed food intake, resulting in weight~~

reduction. Given these findings and other compelling preclinical data, we completed a Phase 1 study in healthy volunteers for GSBR- 1290 in September 2022, a Phase 2a study development in diabetes in December 2023 and expect to complete a Phase 2a study in obesity in the latter half of the second quarter of 2024. To date GSBR- 1290 has demonstrated generally **more cost** favorable safety, tolerability and efficacy results in clinical trials. Beyond GSBR- **effective** 1290, we are developing next generation GLP- 1R candidates, including dual GLP- 1R / glucose- dependent insulinotropic polypeptide receptor (" GIPR ") agonists and amylin agonists, each designed with customized properties to **produce** achieve additional benefit. 8We are also developing oral small molecule therapeutics targeting other GPCRs for the treatment of pulmonary and cardiovascular diseases. Specifically, we are advancing ANPA- 0073, our biased agonist, targeting the apelin receptor (" APJR, ") a GPCR that **than** has been implicated in idiopathic pulmonary fibrosis..... targets that historically have been limited to peptides or biologies . **As shown below** ● Advance our GLP- 1R franchise of metabolic focused assets, establishing a foundation for additional opportunities. Our franchise approach involves developing next generation GLP- 1R agonists, including dual GLP- 1R / GIPR agonists, each designed with customized properties to achieve maximum benefit. Based on compelling data generated from our preclinical studies, we believe that our lead GLP- 1R candidate, GSBR- 1290, has the potential to be a differentiated treatment for T2DM and obesity. In obesity, we expect to complete the Phase 2a study in the latter half of the second quarter of 2024 and initiate a Phase 2b study in the fourth quarter of 2024. In T2DM , we have completed the Phase 2a study and expect to initiate a **current manufacturing capacity** Phase 2 study in the second half of **6** 2024. In addition , our next generation GLP- 1R program **000 tons / year of aleniglipron, which** is focused **enough to supply treatment to more than 120 million patients per year. Potential Differentiation for Aleniglipron** on **Scalable Manufacturing10Our** the development of orally- available small....., or other complementary capabilities. Our Pipeline and ProgramsWe pursue opportunities to target GPCRs in human diseases on the basis of validated biology, safety, development feasibility and market potential. We are building a pipeline of wholly- owned oral small molecule drugs targeting chronic diseases with unmet medical need and commercial potential. Our initial focus is in areas of metabolic, cardiovascular and pulmonary diseases. The following table summarizes key information on our current product candidates: **Our StrategyOur mission** Metabolic DiseasesWe are initially advancing our GLP- 1R franchise as a treatment for obesity and T2DM, conditions affecting approximately 764 million and 537 million people worldwide, respectively. We believe our GLP- 1R programs have demonstrated qualities that offer the potential to differentiate them from current approved and development stage programs. ● Selective GLP- 1R Program. GSBR- 1290 is a biased GLP- 1R agonist which has demonstrated dose- dependent activation of the G- protein pathway. GSBR- 1290 has also demonstrated glucose- dependent insulin secretion and suppressed food intake with similar activity to **discover** an **and develop broadly accessible** approved injectable peptide GLP- 1R agonist in preclinical models. The product candidate is designed to be orally administered, without restrictions on diet or concomitant therapy. ● GLP- 1R Combination. Our combination and next generation small molecule program is focused on GLP- 1R candidates, including GLP- 1R / GIPR agonists and amylin agonists, each designed with customized properties to achieve additional benefits like enhanced metabolic control. Our APJR agonist, ANPA- 0073, is being evaluated for selective or muscle- sparing weight loss. ANPA- 0073, is a G- protein biased APJR agonist for which we completed a Phase 1 SAD and MAD study, in which it was generally well tolerated as a single dose from 2mg to 600 mg, and at doses from 75 mg to 500 mg once daily dosing for seven days, with no SAEs reported. 10Pulmonary and Cardiovascular DiseasesWe are evaluating our LPA1R program, LTSE- 2578 for IPF and PPF. Our LPA1R program, LTSE- 2578, is an investigational oral small molecule LPA1R antagonist. We believe LTSE- 2578 is a differentiated molecule because it demonstrated potent in vitro and in vivo activity in preclinical IPF models and dose dependent inhibition of histamine release as the PD marker. We plan to initiate a first- in- human study in the second quarter of 2024. GPCRs as a Therapeutic Target FamilyGPCRs form the largest human membrane protein family, consisting of approximately 800 identified members as illustrated below. GPCRs are involved in several vital physiological functions, such as immune system regulation and inflammation, autonomic nervous system transmission, behavioral and mood regulation, sensory transmission, and maintenance of homeostasis, making them important targets for numerous therapeutics . To date, there are approximately..... cell membranes. Their primary function is to **treat** recognize extracellular substances, primarily ligands, and transmit signals across the cell membrane to the inside of the cell. Schematic of a GPCRAs shown above, the binding of extracellular ligands to GPCRs elicits conformational changes that impact the intracellular side **wide** of the receptor, resulting in the formation of a GPCR complex with signal transducers, particularly G- proteins. These signal transducers go on to interact with second messengers, ultimately either stimulating or inhibiting certain cellular processes. GPCRs signal not only through G- proteins, but also through β- arrestins and other non- G- protein transducers. B- arrestins play an essential role in many physiological and pathological processes, and are involved in the desensitization, internalization, sequestration, and trafficking of GPCRs. Certain GPCR ligands are capable of simultaneously activating both G- protein and non- G- protein mediated signaling pathways, which can lead to a variety of physiologic as well as pathologic effects. Challenges of GPCR Therapeutic Discovery and DevelopmentDespite tremendous advancements in structure- based drug design and development, GPCR drug discovery and development remains challenging. ● Similarity between the binding sites of GPCRs and related receptors can cause off- target toxicities: All GPCRs have the same overall three- dimensional architecture but the specific endogenous binding site is unique due to the placement of amino acid side chains shaping the binding site. For instance, the early sphingosine- 1- phosphate 1 receptor (" S1P1R ") agonist Gilenya led to the development of a new class of therapy for the treatment of multiple sclerosis, but had exhibited bradycardia as a side effect due in part to sphingosine- 1- phosphate 3 receptor (" S1P3R ") activity, a very closely related S1P1 receptor subtype. The next- generation S1P1R agonist Zeposia was designed using structural information by Receptos, Inc. to remove the S1P3 and other activities and therefore did not have the same side effect profile as Gilenya. ● GPCRs are involved in diverse downstream signaling pathways which can result in side effects: GPCRs interact with a range of molecules, including G- protein and..... is particularly important for the most prevalent chronic diseases including those involving the endocrine,..... chronic metabolic, cardiovascular, and pulmonary diseases with unmet medical need . Our GLP

through advancements in structure - ~~1R Focused Franchise for Metabolic DisordersTo unlock the full potential~~ **based drug discovery and computational chemistry. The key pillars** of our **business strategy to achieve this mission include: • Invest in and leverage our next generation structure- based** drug discovery platform ~~across~~ **to drive innovations in GPCR targeted therapies and beyond. Our platform has the potential to transform the treatment paradigm for** a ~~broad~~ **wide** range of ~~paradigm for a wide range of~~ chronic diseases with unmet medical need.We are continually growing our position as a leader in structure- based drug discovery and development by incorporating platform innovations that have the potential to expand the therapeutic opportunity of this field.We are integrating advancements in computational chemistry,molecular imaging technologies,structural biology techniques ~~,~~and machine learning while continuing to deepen our understanding of GPCR signaling pathways and pharmacology.We intend to expand into other key emerging areas where we can leverage our platform to develop orally- available molecules against targets that historically have been limited to **peptides or biologics.• Advance our** metabolic ~~indications, we intend to build out our~~ franchise ~~approach~~ **including our GLP- 1R and amylin backbone therapies, establishing a foundation** for **additional opportunities** ~~GLP- 1R~~ . Our franchise approach involves developing next generation GLP- 1R ~~candidates~~ **and amylin receptor agonists** , **designed** with ~~each exhibiting~~ customized properties to achieve ~~additional~~ **maximum** benefit. ~~Our~~ **Based on compelling data generated from our clinical and preclinical studies, we believe that our** lead GLP- 1R ~~product~~ candidate, **aleniglipron** ~~GSBR- 1290~~ , has the potential to be a differentiated treatment for ~~T2DM and~~ obesity **.** ~~based~~ **Based** on preclinical data **, we believe that our lead oral small molecule amylin development candidate, ACCG- 2671, has the potential to be the first- in- class oral small molecule amylin treatment option for obesity** . **In addition,our program is 11focused on the development of orally- available small molecules in combination with GLP- 1R and / or amylin,including glucose- dependent insulinotropic polypeptide receptor (“ GIPR ”),GCG receptor (“ GCGR ”),** as well as the ~~APJR~~ - **APJ receptor** for selective or muscle- sparing weight loss. ~~●~~ • Pursue additional opportunities in chronic diseases.Chronic diseases pose a major burden to patients and healthcare systems worldwide and there is an urgent need for effective and more accessible treatment options. **We** ~~Our APJR agonist product candidate,ANPA- 0073 is in development for the treatment of cardiopulmonary and cardiometabolic conditions.In addition,we~~ are evaluating LPA1R antagonism in **idiopathic pulmonary fibrosis,or** IPF ~~,~~and ~~selected~~ **are currently conducting** a **Phase 1** ~~development candidate (LTSE- 2578) in January 2023 and expect to initiate a~~ first- in- human study ~~in the second quarter of 2024~~ .We plan to continue to harness insights on GPCR targets,particularly among metabolic,endocrine,pulmonary ~~,~~and cardiovascular indications,and leverage our platform to fuel our pipeline ~~through our discovery engine at Basecamp Bio Inc~~ . • ~~(“ Basecamp Bio ”).9 ●~~ Maximize the potential of our platform and portfolio through strategic partnerships.We have established value- and capability- enhancing collaborations with Schrödinger,our co- founder and strategic partner.We intend to continue to explore additional collaborations with third parties to further strengthen our platform capabilities and enable expansion of our portfolio.We plan to leverage our platform for external opportunities where partners bring additional disease biology understanding,drug development and commercial expertise,regional insights ~~,~~or other **complementary capabilities.Our ProgramsAleniglipron (** GSBR- 1290 **) – Oral Small Molecule Selective GLP- 1R Agonist for Obesity Overview and TimelineOur most advanced product candidate, aleniglipron,** is an oral and biased **small molecule** agonist of ~~the~~ GLP- 1R, a validated GPCR drug target ~~involved~~ **for obesity, currently** in ~~a variety~~ **two Phase 2 clinical studies for the treatment** of ~~metabolic~~ **obesity, overweight and related** conditions. We completed ~~a~~ **our** Phase 1 **single ascending dose (“** SAD **”)** study **of aleniglipron** ~~for GSBR- 1290 in healthy volunteers~~ in September 2022. **Aleniglipron was generally well tolerated and demonstrated dose- dependent pharmacokinetic (“ PK ”) and pharmacodynamic (“ PD ”) activity. We submitted an IND application to the FDA to support initiation of a Phase 1b study in T2DM and obesity and received FDA allowance in September 2022.** We initiated the Phase 1b **multiple ascending dose (“** MAD **”)** study **of aleniglipron** in January 2023 and completed dosing in otherwise healthy overweight subjects in March 2023. In May 2023, we submitted a protocol amendment to the FDA and initiated dosing of the Phase 2a proof- of- concept study in T2DM and obesity. We reported topline data for the 28- day Phase 1b MAD study in September 2023, in which **aleniglipron** ~~GSBR- 1290~~ was generally well- tolerated with no adverse event- related discontinuations and demonstrated an encouraging safety profile and significant weight loss of up to 4. 9 % placebo- adjusted, supporting once- daily dosing. In December 2023, we reported clinically meaningful topline ~~data~~ **12data** from our Phase 2a T2DM cohort, interim results from our Phase 2a obesity cohort and topline data from ~~our~~ **a** Japanese ethno- bridging study of **aleniglipron** ~~GSBR- 1290~~ . These data demonstrated ~~18that~~ -- **that aleniglipron** ~~GSBR- 1290~~ was generally well- tolerated, with no treatment- related **serious adverse events (“** SAEs **”)** over 12 weeks, with only one participant discontinuing the study due to adverse events in the T2DM cohort and none in the obesity cohort. **Aleniglipron** ~~GSBR- 1290~~ also showed significant reduction in weight in the obesity cohort ~~,~~ **at 8 weeks** and significant reductions in **hemoglobin A1c (“** HbA1c **”)** and weight in the T2DM cohort. ~~We expect to~~ **In June 2024, we** ~~report~~ **reported** ~~the full 12- week~~ **positive topline data from our** Phase 2a obesity ~~data~~ **study,** in **which aleniglipron demonstrated** ~~the latter half of the second quarter of 2024 with additional 24 participant data. We also fully enrolled~~ a **clinically meaningful and statistically significant placebo- adjusted mean decrease in weight of 6. 2 % at 12 weeks (p < 0. 0001, using least- squares means (“ LSM ”) and analyzed based on the primary efficacy estimand using a mixed model for repeated measures) and demonstrated generally favorable safety and tolerability results following repeated, daily dosing up to 120 mg. Furthermore, we explored a new tablet** formulation **of aleniglipron in a** ~~bridging and titration optimization study to evaluate~~ capsule ~~versus~~ **to** tablet PK ~~and explore different titration regimens of GSBR- 1290. This~~ study ~~is~~ **, which demonstrated a placebo- adjusted mean weight loss of up to 6. 9 % with the tablet formulation at 12 weeks (p < 0. 0001, using LSM and analyzed based on the primary efficacy estimand using a mixed model for** ~~expected~~ - **repeated measures). In July** ~~to be completed in the latter half of the second quarter of~~ 2024, ~~in preparation for~~ **we submitted an IND to** the ~~global~~ **FDA to support the initiation of a** Phase 2b study ~~for obesity which we expect to initiate~~ in **chronic weight management and received FDA allowance in August 2024. In** the fourth quarter of 2024 ~~. A~~ **, we initiated the** Phase ~~2~~ **2b ACCESS** study ~~in T2DM is also planned for the second half of~~

2024. Based on our preclinical and clinical data , **a randomized** we believe that GSBR- 1290 and our next- generation product candidates have the potential to have highly differentiated profiles versus currently approved therapies and those in development. Diabetes Disease BackgroundDiabetes mellitus (" DM ") is an endocrine related disorder of glucose regulation with subsequent hyperglycemia , **double** or high blood sugar, which develops following pancreatic β - **blind** cell destruction or dysfunction resulting in severe loss of insulin production , **placebo** also known as type 1 diabetes, or β - **controlled** cell dysfunction and loss of insulin sensitivity , **dose- range finding study of aleniglipron** also known as T2DM. T2DM is more common in **approximately 220** adults - **adult participants** and accounts for around 90 % of all diabetes cases. In T2DM, the loss of insulin sensitivity is often preceded by being overweight or obese, and manifests along with hypertension and dyslipidemia. Regardless of etiology, once hyperglycemia develops, patients with diabetes share a common disease course characterized by atherosclerotic diseases such as coronary heart disease, stroke, peripheral vascular disease and / or, microvascular diseases such as nephropathy, retinopathy, and neuropathy. Additionally, hyperglycemia is associated with metabolic dysfunction, chronic inflammation, and an increase in infections. According to the 2021 International Diabetes Federation Diabetes Atlas, more than one in ten adults are now living with **obesity** diabetes globally. The estimated prevalence of diabetes in adults aged 20 to 79 years has more than tripled since 2000, from an estimated 151 million (4. 6 % of the global population in this age group at the time) to 537 million (10. 5 %) today. If trends continue, the number will jump to a staggering 783 million (12. 2 %) by 2045. The number of adults with diabetes in the United States reached 32. 2 million in 2021, while China has the largest numbers of adults with diabetes at 140. 9 million. In 2021, approximately 6. 7 million adults aged 20 to 79 are estimated to have died as a result of diabetes or its complications. According to American Diabetes Association (" ADA "), the total estimated cost of diagnosed diabetes in the United States increased to $ 327 billion in 2017, which included $ 237 billion in direct medical costs and $ 90 billion in reduced productivity. In newly diagnosed T2DM patients, treatment is focused on improving modifiable risk factors such as obesity, low physical activity and high calorie diet through patient education that includes instruction on maintaining a healthy lifestyle including nutritional counseling, avoiding excessive calories and rapidly absorbed carbohydrates, and physical exercise. Patients who are unable to achieve glycemic control through weight loss and / or lifestyle modifications should be started on single or combination glucose- lowering medications to lower their glycemic burden and reduce the risk of cardiovascular and other complications. Obesity Disease BackgroundObesity, defined as a body mass index (" BMI **≥** ") of > 30 kg / m2 **)** , is a major independent risk factor for - **or** T2DM. Approximately 90 % of T2DM patients are considered either overweight **(** with a BMI **≥ 27** between 25. 0 kg / m2 **)** and 29. 9 kg / m2, or obese with **at least one weight- related comorbidity** a BMI of 30 kg / m2 or greater . Worldwide **Participants start at 5 mg of aleniglipron (or placebo) with a 4- week titration schedule, reaching target doses of 45 mg, 90 mg and 120 mg. The primary endpoint is percent change in body weight from baseline to week 36. Secondary endpoints include safety and tolerability of the monthly titration scheme, as well as PK of aleniglipron. In the fourth quarter of 2024, we initiated a randomized, double- blind, placebo- controlled dose- range finding Phase 2 study of aleniglipron, known as ACCESS II, in approximately 82 adult participants living with** obesity **or** has nearly tripled between 1975 and 2016. As of 2020, 1. 9 billion (39 %) adults were overweight **with at least** , including over 764 million (15 %) adults who were obese. In men, being slightly overweight increased diabetes risk seven- fold and in women, being slightly overweight increased diabetes risk twelve- fold. Being obese increased the risk to 60- fold. Obesity affects nearly one **weight- related comorbidity. The study** third of all adults in the United States and is **designed** associated with a range of comorbidities, such as T2DM, cardiovascular disease, obstructive sleep apnea, and cancer. Importantly, even 19modest weight reduction, on the order of five to **evaluate** ten percent, can significantly reduce comorbidities and improve health- related outcomes and has been recently recommended by the major scientific societies (European Association of the Study of Diabetes (" EASD ") and ADA). Obesity therefore represents an immense commercial opportunity with very few approved therapies on the market. The GLP- 1R agonist semaglutide, approved for use in T2DM, has also been approved for weight management for which it is marketed under the brand name Wegovy, which is estimated to reach peak sales of $ 6. 7 billion in 2026. Relationship Between T2DM and ObesityT2DM and obesity are not independent conditions, as the majority of patients with T2DM are obese. Observed increases in the prevalence of T2DM are related to the increasing prevalence of obesity and multiple mechanisms have been proposed through which they may be linked pathophysiologically. Upper body and visceral fat are associated with T2DM, metabolic syndrome and cardiovascular disease. Obesity is a major contributor to poor metabolic control in patients with T2DM. Increasingly, weight reduction is seen as an important goal of therapy for patients with T2DM. Weight loss in the first year of treatment of T2DM has been associated with an increase in life expectancy. According to the ADA Standards of Medical Care in Diabetes — 2022, management of obesity is an important factor in the treatment of diabetes since even a small degree of weight loss can improve control of blood sugar levels, resulting in a decreased need for glucose- lowering medications. Given this information, a therapy that can both lower blood glucose and help with weight management in T2DM could have near- term benefits in glycemic control and longer- term benefits in increased insulin sensitivity and reduction of cardiovascular risk. Current Treatments for T2DM and ObesityFirst- line treatment for patients with T2DM involves lifestyle modifications and metformin. If glycemic control remains inadequate, an additional oral glucose lowering medication should be added. Options include sodium- glucose transport protein 2 inhibitors, dipeptidyl peptidase- 4 inhibitors, and GLP- 1R agonists. Current treatment algorithms suggest that GLP- 1R agonists should be preferentially used after metformin failure in patients who are at high risk for, or who have established, atherosclerotic cardiovascular disease. Several scientific societies, including the EASD and ADA, recommend GLP- 1R agonists as first line therapy in patients with established atherosclerotic cardiovascular disease or in those at high risk of developing disease. According to Global Data, Eli Lilly and Company (" Eli Lilly "), Novo Nordisk, Merck and Sanofi S. A. (" Sanofi "), have captured significant market share in the approximately $ 65. 4 billion market for glucose- lowering agents in 2023, which is projected to grow to $ 115. 4 billion by 2027 as depicted below. 20Historical and projected global obesity and type- 2 diabetes drug sales by classOverview of GLP- 1R Signaling Pathway and Target BiologyGLP- 1 is an incretin peptide

secreted in the intestinal tract in response to food intake. GLP- 1 stimulates insulin secretion from pancreatic β- cells and inhibits glucagon secretion from pancreatic α- cells. GLP- 1 receptors are located on various cell and tissue types including pancreatic β- cells, central and peripheral neurons, cells of the intestinal tract, vascular smooth muscle and endothelial cells, coronary arteries, and the sino- atrial node of the heart. Through actions at these receptors, GLP- 1 and GLP- 1R agonists have demonstrated widespread therapeutic effects in patients with diabetes, including stimulating insulin secretion and lowering blood glucose levels, slowing gastric emptying, reducing calorie intake, promoting weight loss, improving lipoprotein metabolism, lowering systolic blood pressure, improving complications from arteriosclerotic cardiovascular diseases, and reducing cardiovascular disease morbidity and mortality, as illustrated below. 21GLP- 1R pathway and target biologyEndogenous GLP- 1 is rapidly degraded in vivo by DPP- 4, with a half- life of one to two minutes. The development of GLP- 1R agonists for the treatment of diabetes and obesity has involved modifications to the GLP- 1 peptide and / or conjugation to carrier compounds or matrices that delay degradation after subcutaneous administration. The six marketed GLP- 1R and GLP- 1R / GIPR agonists are synthetic peptides and include liraglutide and semaglutide marketed by Novo Nordisk; dulaglutide and tirzepatide marketed by Eli Lilly; exenatide marketed primarily by AstraZeneca plc (" AstraZeneca "); and lixisenatide marketed by Sanofi. According to Global Data, these six GLP- 1R and GLP- 1R / GIPR peptides approved for T2DM and obesity collectively generated approximately $ 65. 4 billion in worldwide sales in 2023, which is projected to reach $ 115 billion by 2027. Rybelsus is an oral formulation of semaglutide co- formulated with sodium N- 8- (2- hydroxybenzoyl) amino caprylate to limit degradation and improve oral absorption. To date, there are no approved oral small molecule therapies targeting this pathway. Common side effects of GLP- 1R and GLP- 1R / GIPR agonists include nausea, vomiting, and diarrhea, which are most pronounced when starting therapy or increasing the dose. Generally, these effects correlate with times of maximum drug concentrations and ameliorate with continued therapy. Typically, slow up- titration to the desired dose can mitigate these side effects. However, once- weekly injectable GLP- 1R and GLP- 1R / GIPR agonists typically require a long titration period to achieve an optimal dose, potentially delaying therapeutic benefit. Once- daily therapy with an oral small molecule may provide flexibility in titration and allow a combined approach with other oral therapies. The Unmet Medical Need for Improved GLP- 1R Therapeutics in Diabetes and ObesityGLP- 1R agonists provide multiple beneficial effects in patients with T2DM, including excellent glycemic control with low risk of hypoglycemia, weight loss and protection against cardiovascular and renal complications. However, we believe approved GLP- 1R agonists have shortcomings in terms of patient convenience, ease of dosing, and cost. Injectable peptide GLP- 1R agonist peptides require patients to self- inject, require inconvenient refrigerated storage and are costly. In addition, long acting GLP- 1R agonists typically require long titration periods to 22reach an optimal dose for disease management in order to avoid treatment- associated gastrointestinal side effects. Oral semaglutide (Rybelsus), the first approved oral GLP- 1R peptide agonist, provides an option for patients who are unable or unwilling to self- administer. However, Rybelsus requires a stringent dosing protocol and dosing with up to four ounces of water with no food or beverage within 30 minutes. Additionally, the product' s absorption enhancer may affect the absorption of other concomitantly administered oral medications. We believe there is an unmet medical need for orally administered GLP- 1R agonists that meet or exceed efficacy and safety parameters of available drugs with less stringent preparation requirements. Such existing constraints include restrictive food or fluid dosing protocols, refrigeration, maintenance of effective concentrations throughout the dosing interval, without interfering with the absorption of concomitant medications and that offer the potential for combination products with other glucose lowering agents or other commonly co- administered therapies. In addition to glycemic control, weight management is increasingly viewed as important to the management of T2DM. Injectable GLP- 1R agonists, liraglutide and semaglutide result in weight loss at doses approved for treatment of T2DM, while higher doses of each drug, indicated **aleniglipron. Participants start at 5 mg of aleniglipron (** for -- **or placebo)** chronic weight management, result in greater weight loss. At an **and** appropriate **follow a 4- week titration schedule up to target** dose **doses of 120 mg** , **180 mg** an **and** oral GLP- 1R agonist may play a role **240 mg. In February 2025, we completed enrollment** in managing **the ACCESS and ACCESS II studies, and we expect to report topline data from** both **studies** blood glucose and weight. Our Solution: Small Molecule GLP- 1R AgonistGLP- 1, along with GIPR, comprise the incretin family, peptide hormones secreted into the blood by enteroendocrine cells in the gut, which play a role in glycemic control. We are taking a franchise approach to our GLP- 1R programs by developing next generation GLP- 1 agonists and potential GIPR modulators. Leveraging the depth of our GLP- 1R / GIPR structure platform, proprietary compound library and deep biology and disease insights, we are advancing multiple generations of structurally distinct GLP- 1R agonist molecules through lead optimization. Each molecule is designed to have a different tissue penetration profile and other -- **the fourth quarter of 2025** incretin activities in order to maximize the value and / or realize the full potential offered by our in- house platform . **Aleniglipron Design and DiscoveryWe** GSBR- 1290 Selective GLP- 1R Agonist ProgramWe are developing **aleniglipron** GSBR- 1290 , a biased orally- available small molecule GLP- 1R agonist, initially as a treatment for T2DM and obesity **and related diseases** . Due to its significant preclinical activity and oral availability, we believe that **aleniglipron** GSBR- 1290 has the potential to be a differentiated treatment with no restrictions on diet or concomitant therapies. **Aleniglipron** 23GSBR- 1290 analog **Analog** bound **Bound** GLP- 1R cryo **Cryo** - EM **Structure13Aleniglipron** structureGSBR- 1290 was designed through our internal structure- based drug discovery platform. As shown above, multiple small molecules bound to GLP- 1R structures have been generated to guide iterative chemistry design efforts. **Aleniglipron** GSBR- 1290 is also designed to be a biased GPCR agonist, which only activates the G- protein pathway without β- arrestin signaling at therapeutic doses, thereby avoiding receptor internalization and de- sensitization. In an intravenous glucose tolerance test **in non- human primates** (" ivGTT **NHPs** ") in NHPs , **aleniglipron** GSBR- 1290 increased glucose- dependent insulin secretion to a similar level achieved by liraglutide, an approved injectable GLP- 1R agonist. In a repeat food intake study in NHPs, **aleniglipron** GSBR- 1290 showed a significant decrease in body weight relative to the placebo and surpassed that seen with liraglutide. **Aleniglipron** GSBR- 1290 Preclinical Data, Pharmacology, and Biomarker DataIn NHP ivGTT studies, glucose was injected five minutes following intravenous administration of either GSBR- 1290 (0. 05 mg / kg) or liraglutide (0. 1 mg / kg). Plasma samples were

taken at indicated timepoints to evaluate insulin and glucose levels. GSBR- 1290 demonstrated statistically significant decreases in blood glucose concentration via stimulation of insulin secretion in a glucose- dependent manner, similar to liraglutide which was dosed at an equivalent approved human dose. Robust activity in non- human primate acute ivGTT studies24Data were presented as mean ± standard error of the mean (" SEM "); one- way ANOVA followed by Dunnett' s multiple comparisons test. * p < 0. 05, * * p < 0. 01, * * * p < 0. 001 vs vehicleAs shown below, in a seven day repeat oral dosing study in NHPs, GSBR- 1290 was evaluated at once- daily oral doses of 2 mg / kg, 6 mg / kg, and 10 mg / kg and compared to placebo and liraglutide. Food intake was measured each day over the first six days of the study and reported as an average of these measurements. ivGTT and body weight were performed before dosing and on the sixth day (body weight) or seventh day (ivGTT) of post- dosing. At all doses of GSBR- 1290, glucose reduction was shown to be statistically significantly different versus vehicle and comparable to liraglutide. Similarly, all doses increased insulin secretion significantly except at 6 mg / kg dose, which only achieved statistical p value at 0. 055 due to a slightly greater data variability. At 6 mg / kg and 10 mg / kg, a statistically significant reduction of average food intake measured over the first six days of the study compared to vehicle was observed. At 10 mg / kg of GSBR- 1290, the average food intake from Day 1 to Day 6 was only 59 % relative to liraglutide group. GSBR- 1290 at 6 mg / kg and 10 mg / kg also showed a significant decrease in body weight relative to placebo and surpassed liraglutide, with the highest dose of GSBR- 1290 achieving more than eight percent reduction in average body weight versus baseline in one week. Seven day repeat oral dosing study in non- human primatesData were presented as mean ± SEM; one- way ANOVA followed by Dunnett' s multiple comparisons test. * p < 0. 05, * * p < 0. 01, * * * p < 0. 001 vs vehicleIn the description of our clinical trials and preclinical studies below and elsewhere in this Annual Report, n represents the number of participants in a particular group and p or p- values represent the probability that random chance caused the result (e. g., a p- value of 0. 01 means that there is a 0. 1 % probability that the difference between the placebo group and the treatment group is purely due to random chance). A p- value of less than or equal to 0. 05 is a commonly used criterion for statistical significance, and may be supportive of a finding of efficacy by regulatory authorities. In addition, we conducted a preclinical comparison study of GSBR- 1290 and PF- 06882961, a clinical stage compound in development by Pfizer. Unlike GSBR- 1290, PF- 06882961 is a partially biased GLP- 1R agonist, which could lead to de- sensitization of the receptor in vivo. In an experiment conducted in- house, GSBR- 1290 demonstrated comparable in vivo activity to PF- 06882961 at a lower exposure. In the acute ivGTT studies, GSBR- 1290 achieved similar activity to liraglutide at average concentration around 34 nanomolar (" nM ") (0. 05 mg intravenous), comparing to a similar activity achieved by PF- 06882961 in an in- house experiment at an average concentration around 442 nM (0. 3 mg intravenous). This suggests that the concentration needed to achieve full activity for GSBR- 1290 is at a level much lower than that for PF- 06882961. PF- 06882961 has been studied in SAD and MAD studies with a maximum dose of 200 mg / BID to achieve maximum HbA1c activity and weight management. 25In- house data showed that PF- 06882961 was positive in a glutathione trapping assay. GSBR- 1290 was inactive in this assay, suggesting reduced risks with long- term use. In addition, GSBR- 1290 also did not show activity as a time dependent inhibitor (" TDI ") for cytochrome P450 3A4 (" CYP3A4 "). PF- 06882961 was reported as a CYP3A4 TDI, which, if confirmed in clinical trials, suggests the potential for interactions with the 30 – 50 % of marketed drugs metabolized through this pathway. GSBR- 1290 Phase 1 Healthy Volunteer TrialIn September 2022, we completed a first- in- human Phase 1 SAD study for GSBR- 1290 in 48 healthy adult volunteers between the ages of 18 and 55. The objective was to assess drug safety, tolerability and PK. The study enrolled six cohorts of eight participants assigned to receive a single dose of GSBR- 1290 or placebo in a 3: 1 ratio. Doses ranged from 1 mg to 90 mg across the six cohorts. The fourth cohort received 15 mg administered either under a fed condition, which consisted of a standardized high fat breakfast, and under a fasted condition, in each case to characterize the effect of food on the PK of GSBR- 1290. A schema of our Phase 1 SAD study is presented below: Schema of our GSBR- 1290 Phase 1 SAD study in healthy volunteersGSBR- 1290 Phase 1 PK and PD Data in Healthy VolunteersIn the study, PK parameters of systemic exposure, Cmax and AUC, increased with doses of GSBR- 1290 across the dose range from 1 mg to 90 mg GSBR- 1290. GSBR- 1290 exhibited supra dose proportionality from 1 mg to 30 mg followed by less than dose- proportional from 30 mg to 90 mg. The 30mg dose AUC provided more than double the effective AUC0- 24h required for glycemic control, derived from non- human primate PK / PD data. Food intake (high fat meal) was associated with a ~ 36 % decrease in the geometric mean Cmax but no significant change in mean AUC value, with 80 % relative bioavailability, based on AUC compared with the fasted state. 26GSBR- 1290 Phase 1 Safety Data in Healthy VolunteersGSBR- 1290 was shown to be generally well tolerated at all dose levels administrated in this Phase 1 SAD study. No SAEs and no adverse changes in laboratory tests (including hematology, chemistry and coagulation) were observed. No trial stopping criteria were met. Adverse events (" AEs ") did not result in any early terminations or subject discontinuations from participation in this study. Treatment- emergent AEs (" TEAEs ") were reported for 32 of 36 participants (89 %) following fasted administration of GSBR- 1290 and for 7 of 12 participants (58 %) following administration of placebo, with a total of 109 TEAEs. Following administration of GSBR- 1290 in the fasted state, most TEAEs were classified as mild (69 of 109, or 63 % of all TEAEs) in severity, with 34 TEAEs (31 % of all TEAEs) classified as moderate in severity. Six TEAEs (6 %) were classified as severe, including four events of vomiting, one event of nausea and one event of catheter site infection. There was an apparent dose- related trend in the severity of TEAEs following single doses of GSBR- 1290, with severe TEAEs reported following the 60 mg and 90 mg doses of GSBR- 1290, but not following low doses (1 mg, 10 mg, 15 mg). Occurrences in TEAEs of moderate intensity were also higher following higher dose range of GSBR- 1290. The following table shows an overall summary of TEAEs that were reported in the study. Low dose GSBR- 1290 includes 1 mg, 10 mg and 15 mg fasted and high dose GSBR- 1290 includes 30 mg, 60 mg and 90 mg fasted. If a participant had multiple occurrences of a TEAE, the participant was presented only once in the Participant count for a given Preferred Term. Occurrences were counted each time. There was no notable difference in the overall incidence or severity of treatment- related AEs under fasted and fed administration of GSBR- 1290 at a dose level of 15 mg. There was a higher incidence of related TEAEs of vomiting and headache following fasted administration (three of six participants, or 50 %)

~~compared to fed administration (one of six participants, or 17 %). The most common TEAEs reported in at least four of 36 participants (> 10 %) who received GSBR- 1290 were nausea, headache, vomiting, dehydration, decreased appetite, dizziness, and diarrhea. Across the various dose levels, there were apparent dose- related trends in the overall incidence of common TEAEs. The incidence of the TEAEs described above was notably higher following fasted administration of the high dose GSBR- 1290 treatments (30 mg, 60 mg, 90 mg) than the low dose GSBR- 1290 treatments (1 27mg, 10 mg, 15 mg) and placebo, with a similar observation in treatment- related AEs of nausea, vomiting, dehydration, and headache of at least moderate severity. We believe all TEAEs observed during the study are in line with the proposed treatment mechanism and typically derive from impacts on appetite, nausea, and vomiting. There was an apparent increasing trend in heart rate over time in both low (1 mg, 10 mg, 15 mg) and high dose (30 mg, 60 mg, 90 mg) GSBR- 1290 groups. This increase appeared to peak at 12 hours post- dose and was notably larger in the high dose GSBR- 1290 groups. Increases in heart rate over time were observed in the pooled placebo group but to a much lesser extent. In summary, GSBR- 1290 was shown to be generally well tolerated when administered as a single dose of up to 90 mg. However, there were dose- related trends in the incidence, severity and causality of TEAEs, particularly GI related TEAEs, consistent with what has been previously reported in clinical trials involving the GLP- 1RA class of drugs. There were no treatment- related AEs reported in patients who received placebo. PK parameters of systemic exposure increased with dose of GSBR- 1290 across the dose range from 1 mg to 90 mg GSBR- 1290. GSBR- 1290~~ Non-clinical Safety Pharmacology and Toxicology StudiesA standard battery of nonclinical safety pharmacology studies (central nervous system, cardiovascular and respiratory) has been completed with **aleniglipron** ~~GSBR- 1290~~ with no findings anticipated to be of clinical relevance. Genotoxicity assessments demonstrated an absence of genotoxicity potential. In the 4- week and 13- week GLP toxicology study in rats, the no- observed- adverse- effect level (“ NOAEL ”) dose was considered to be 1000 mg / kg / day, the highest dose tested. In the 4- week and 13- week GLP toxicology study in NHPs, **aleniglipron** ~~GSBR- 1290~~ showed pharmacologically related events such as inappetence and bodyweight loss, which were reversible with sufficient recovery periods. There were no **aleniglipron** ~~GSBR- 1290-~~ related deaths during the course of study and no **aleniglipron** ~~GSBR- 1290-~~ related changes in organ weights, gross and histopathology examinations at the end of the dosing and recovery periods. In the 13- week study, NHPs of both sexes in all dose groups, including in the control group, had minimal to moderate multifocal necrosis / infiltration in the liver. The root cause of these liver abnormalities was not determined, but these findings were considered unrelated to **aleniglipron** ~~GSBR- 1290~~ . The FDA reviewed our 13- week GLP toxicology studies in rats and NHPs and agreed that these liver abnormalities were not considered a new non- clinical safety signal related to **aleniglipron** ~~GSBR- 1290~~ . In nonclinical animal models, **aleniglipron** ~~GSBR- 1290~~ demonstrated statistically significant decreases in blood glucose concentration and increases of insulin secretion. In a recent 6- month GLP toxicology study in rats, **aleniglipron** ~~GSBR- 1290~~ demonstrated a NOAEL dose at 1000 mg / kg / day, which supports an estimated more than 100 **-** fold safety window up to 120 mg human dose. We also conducted a 9- month ~~non- human primate (~~ NHP ~~)~~ GLP toxicology study and found no test article-related change in heart rates or QTc intervals. No meaningful increases in the liver enzymes, ALT / AST, were observed in either the rat or NHP study. There were no significant findings in embryo- fetal developmental toxicology studies in rats and rabbits. **Aleniglipron** ~~GSBR- 1290~~ Phase ~~1b MAD studyThe~~ **2a Study in Obesity and DiabetesIn June 2024, the Company reported positive topline data from the** Phase ~~1b MAD~~ **2a obesity** study ~~focused on the safety and tolerability of GSBR- 1290~~ in **which** ~~24 healthy overweight or obese individuals. Participants were randomized 3: 1 to GSBR- 1290 or placebo across three dose cohorts with target doses of 30mg, 60mg or 90mg.~~ GSBR- 1290 demonstrated ~~reductions in~~ **a clinically meaningful and statistically significant placebo- adjusted** mean ~~body~~ weight ~~ranging~~ **loss of 6. 2 % at 12 weeks (p < 0. 0001) and generally favorable safety and tolerability results following repeated, daily dosing** up to ~~4~~ **120 mg** . ~~9 kg compared~~ **The Company also reported data from a new tablet formulation of GSBR- 1290 in a capsule** to ~~baseline~~ **tablet PK study** , ~~and~~ **which demonstrated a placebo- adjusted mean weight loss of** up to ~~4~~ **6** . 9 % ~~placebo- adjusted~~ **with the tablet formulation at 12 weeks** . ~~28 Percent~~ **PK data support proportional exposure between 60 and 120 mg and once- daily oral dosing of GSBR- 1290. 14Phase 2a Body** Weight Change from ~~Baseline~~ **BaselineCapsule** to **Tablet PK Study Body** ~~Day 28 Placebo (n = 5) GSBR- 1290 30 mg (n = 6) GSBR- 1290 60 mg (n = 6) GSBR- 1290 90 mg (n = 5) % weight~~ **Weight** ~~change~~ **Change** from **BaselineAleniglipron** ~~baseline- 0. 5 %- 1. 6 %- 5. 2 %- 5. 4 % % weight change placebo- adjusted (90 % CI) — - 1. 1 % (- 3. 8 to 1. 7)- 4. 6 % (- 6. 6 to- 2. 7)- 4. 9 % (- 7. 8 to- 1. 9) Exploratory p- value vs. placebo — 0. 4940. 0020. 013 GSBR- 1290 demonstrated an encouraging safety and tolerability profile following once- daily dosing. No participants discontinued the study drug due to adverse events. The majority of adverse events reported were mild, with no severe or serious adverse events observed. As expected for this class, leading adverse events were gastrointestinal- related, with the two most common gastrointestinal adverse events being nausea and diarrhea, with higher incidences observed in all three cohorts compared to placebo. There were no clinically meaningful changes in liver function tests. Summary of Treatment Emergent Adverse Events Placebo pooled Event, N (%) 90 mg (n = 6) Any TEAE 5 (83) 6 (100) 4 (67) Any TEAE by maximum severity Mild 3 (50) Moderate 1 (17) 2 (33) Severe Any Serious Adverse Events GSBR- 1290 Phase 2a study in diabetes and obesity The randomized, double- blind, 12- week placebo- controlled Phase 2a clinical trial has enrolled a total of 94 participants to date, including 60 participants randomized to GSBR- 1290. The T2DM cohort enrolled 54 participants, randomized to GSBR- 1290 at 45 mg (n = 10) or 90 mg (n = 26), or placebo (n = 18), dosed once daily. The obesity cohort initially enrolled 40 participants randomized to GSBR- 1290 at 120 mg (n = 24) or placebo (n = 16), dosed once- daily. An additional 24 participants have been enrolled in the obesity arm as previously announced in September 2023 to replace those for whom 12- week weight data was not collected as a result of a data collection omission. These replacement participants have also been randomized 3: 2 to GSBR- 1290 or placebo. The primary endpoints of the Phase 2a study are safety and tolerability of GSBR- 1290. Key secondary endpoints include reduction in weight for both obesity and T2DM cohorts, as well as reduction in HbA1c for the T2DM cohort. GSBR- 1290~~ Safety and ~~tolerability~~ **Tolerability ResultsAleniglipron** ~~results GSBR- 1290~~ demonstrated an encouraging safety and tolerability profile following repeated, daily dosing for all doses studied (up to 120 mg) in the obesity and T2DM cohorts,

with results summarized as follows: ● • The majority (88 to 96 %, depending on study arm) of **adverse events (“** AEs **”)** reported were mild to moderate. ● • There were no SAEs related to study drug. ● • As expected for this mechanism of action, leading AEs were gastrointestinal- related. The two most common AEs were nausea and vomiting. ● **15 •** There were no cases of elevated liver enzymes in the obesity cohort. One participant in the T2DM treatment group experienced an event of elevated liver enzymes without an increase in bilirubin initially at day 8 while receiving 5 mg of study drug. This participant was diagnosed with fatty liver disease while in the study. ● • Of the 60 participants dosed with **aleniglipron** GSBR- 1290 , only one participant discontinued the study due to AEs related to study drug (none in the obesity cohort and one (2. 8 %) in the T2DM cohort). Summary of Treatment Emergent Adverse Events (**“** TEAEs **”**) Phase 2a TDM Cohort Phase 2a Obesity Cohort (12- week data) (12- week interim data) 45 mg **90 mg Placebo** 120 mg **Event, N (%) (n = 10) (n = 26) (n = 18) (n = 24) (n = 16) Any TEAE** 10 (100) 25 (96. 2) 8 (44. 4) 23 (95. 8) 11 (68. 8) **Any TEAE by maximum severity Mild** 2 (20) 6 (23. 1) 6 (33. 3) 6 (25) 9 (56. 3) **Moderate** 7 (70) 17 (65. 4) 2 (11. 1) 17 (70. 8) 2 (12. 5) **Severe** 2 (7. 7) Any SAEs 1 (10) 1 (3. 8) Any SAEs related to study drug **Aleniglipron** GSBR- 1290 Efficacy results **Results Aleniglipron** GSBR- 1290 demonstrated clinically meaningful activity in both T2DM and obesity cohorts, with results summarized as follows: ● In the T2DM cohort , **.** there **There** was a statistically significant HbA1c reduction (- 1. 01 to- 1. 02 %, placebo- adjusted) at Week 12 (Table 1). The study demonstrated a statistically significant and clinically meaningful reduction in weight at Week 12 (- 3. 26 % to- 3. 51 %, placebo- adjusted) (Table 2). Weight loss continued to decrease through Week 12. ● Results of the interim analysis in the obesity cohort showed a statistically significant and clinically meaningful decrease in weight at Week 8 (- 4. 74 %, placebo- adjusted) (Table 3). Weight loss continued to decrease throughout the eight weeks of treatment. Table 1: Diabetes **T2DM** cohort **Cohort** least **Least** square **Square** means **Means** difference **Difference** (**“** LSM **”**) change **Change** in HbA1c from baseline **Baseline** to 12 weeks **Weeks** (%) *** AleniglipronAleniglipron** GSBR- 1290GSBR- 1290 45 mg 90 mg Placebo (n = 10) (n = 26) (n = 18) LSM HbA1c change from baseline (%)- 0. 79- 0. 840. 18 % HbA1c change placebo- adjusted (LSM,- 1. 01- 1. 0295 % confidence interval (CI)) (- 1. 73,- 0. 29) (- 1. 59,- 0. 44) P- value vs. placebop = 0. 008p = 0. 001 * LSM, CI and p- value from Mixed Model for Repeated MeasuresTable ----- **Measures Table** 2: Diabetes **T2DM** cohort **Cohort** LSM change **Change** in weight **Weight** from baseline **Baseline** (%) *** Aleniglipron Aleniglipron45** GSBR- 1290 GSBR- 129045 mg 90 mg Placebo (n = 10) (n = 26) (n = 18) LSM weight change from baseline (%)- 3. 32- 3. 220. 04 % weight change placebo- adjusted (LSM,- 3. 51- 3. 26 — 95 % CI) (- 5. 58,- 1. 43) (- 5. 17,- 1. 36) P- value vs. placebop = 0. 0019p = 0. 0013 — **ACCG** * LSM, CI and p - **2671 – Oral** value from Mixed Model for Repeated MeasuresTable 3: Obesity Cohort LSM change in weight from baseline (%) 8 week interim results % GSBR- 1290 120 mg Placebo (n = 24) (n = 16) LSM weight change from baseline (%)- 5. 5- 0. 82 % weight change placebo- adjusted (LSM, 90 %- 4. 74CI) (- 6. 74,- 3. 10) P- value vs. placebop < 0. 0001GSBR- 1290 Phase 1 Japanese Bridging StudyThe 4- week Phase 1 Japanese ethnobridging study included healthy lean Japanese participants randomized to GSBR- 1290 (n = 9) and placebo (n = 3), and healthy lean non- Japanese participants receiving GSBR- 1290 (n = 6). GSBR- 1290 demonstrated a substantial weight reduction in Japanese participants (- 3. 91 % on GSBR- 1290 vs- 1. 67 % placebo) and in non- Japanese participants (- 5. 13 % not placebo- adjusted), with no discontinuations or dose reductions, and no SAEs. These data will be used for regulatory interactions in Japan in preparation for potential future global studies of GSBR- 1290. GSBR- 1290 Six- and Nine- Month Toxicology StudiesIn preparation for Phase 2b development with longer durations of treatment, we have completed six- month (rodent) and nine- month (non- human primate) toxicology studies to evaluate the safety of GSBR- 1290. No major findings were observed in either study, with no test article- related changes observed in the liver, including ALT / AST, at all **Small Molecule** doses, and a more than 100 fold safety window at the 120 mg therapeutic dose. Amylin Receptor Agonist **for ObesityOverviewWe are advancing our amylin oral small molecule program and have declared our development candidate, ACCG** - Combination GLP **2671. In preclinical studies, ACCG** - 1R ProgramAmylin **2671 demonstrated sub- nanomolar in vitro functional activity on amylin and calcitonin receptors, and in vivo reduction in food intake, resulting in weight loss. We expect to initiate Phase 1 clinical study of ACCG- 2671 in the fourth quarter of 2025. The amylin receptor system is complex, and its complexity is present at various levels as shown here and in the figure below: • First (starting from left figure panel): At the receptor level, there are three amylin receptors, AMY1 / 2 / 3 receptors. They are heterodimers formed by the calcitonin receptor CTR and the co- receptor RAMP1 / 2 / 3. There is an equilibrium between calcitonin receptor and Amylin receptors. • Second: At the agonist level, there are two types of agonists: DACRA and SARAoDACRA, stands for Dual Amylin and Calcitonin Receptor Agonists, which binds both the amylin receptor and calcitonin receptor. oSARA, stands for Selective Amylin Receptor Agonist, which preferentially binds to the amylin receptor. • Third: Different agonists bind to the amylin receptor or calcitonin receptor and form different receptor- agonist complexes. These complexes could differ in stability, conformation, G protein / b- arrestin recruitment and activation status and cAMP signaling. The amylin receptor pocket is large, making small molecule discovery challenging. The amylin receptor pocket is large, making small molecule discovery challenging. Despite these challenges, we have successfully discovered what we believe is the first amylin small molecule agonist. Amylin** is co- secreted with insulin from β pancreatic cells upon nutrient delivery to the small intestine as a satiety signal, acts upon sub- cortical homeostatic and hedonic brain regions, slows gastric emptying , and 31suppresses -- **suppresses** post- prandial glucagon **GCG** responses to meals. Therefore, new pharmacological amylin analogues can be used as potential anti- obesity medications in individuals who are overweight or obese. Amylin **17Amylin** tool **Tool** compound **Compound** showed **Showed** add **Add** - on effects **Effects** when **When** used **Used** with semaglutide **SemaglutideIn** In collaboration with Schrödinger, we are taking a structure- based drug discovery approach to identify oral small molecule amylin agonists for daily use either alone or in combination with GLP- 1R agonists to treat obesity and T2DM. We have identified two novel lead series with promising potency and PK profiles. We have obtained multiple high quality Cryo- EM structures and established in- house in vivo animal models, which enable us to advance our lead optimization effort with high efficiency. In an in- house proof- of- concept study in rats, our small molecule amylin tool compound (ACCG- 0184) showed additional beneficial effects when used as an add- on

treatment to a GLP- 1R agonist. ~~We~~ **In December 2024, we announced the selection of ACCG- 2671 as our lead oral amylin agonist for the treatment of obesity. ACCG- 2671 was designed as an oral small molecule DACRA and is expected to enter Phase 1 clinical development in the fourth quarter of 2025. In addition, we have initiated GMP manufacturing to support GLP toxicology studies and early clinical development. In preclinical studies, ACCG- 2671 demonstrated potent and balanced in vitro activities toward amylin and the calcitonin receptors. ACCG- 2671 also further demonstrated robust in vivo efficacy and a PK and safety profile supporting once- daily oral dosing in humans. ACCG- 2671 Demonstrated Sub- nanomolar Potency of DACRA Activity18ACCG- 2671 Achieved Cagrilintide- like Efficacy in Preclinical DIO Rat ModelLastly, given our most advanced oral small molecule amylin position, we** are ~~planning~~ **continuing** to ~~select a~~ **work on multiple generations, and we expect to declare additional** development ~~candidate~~ **candidates** in the **future** ~~second half of 2024~~. ~~GenerationGIPR Modulator- Combination~~ **GIP and GCG Receptor Oral Small Molecule Obesity ProgramsOverviewBeyond our** GLP- 1R ~~ProgramIn~~ **and amylin receptor programs, we are developing next generation oral incretins for potential combination therapy with GLP- 1R or amylin candidates. These include small molecule candidates targeting GIPR and GCGR, each designed with customized properties to achieve additional benefit. In** our GIPR program, we have identified multiple GIPR agonist, dual GLP- 1R / ~~GIRP~~ - **GIPR** agonist and GIPR antagonist hits for small molecule GIPR modulation. We believe GLP ~~-~~-1R / GIPR modulation has the potential to provide a differentiated treatment in ~~diabetes and~~ obesity. Recent third- party clinical data showed tirzepatide, a GLP- 1R / GIPR modulator, was superior to semaglutide with respect to glycemic control. The glycated hemoglobin level target of less than 5. 7 % (normoglycemia) was met in 27 **%** to 46 % of the T2DM patients who received tirzepatide compared to 19 % of those who received semaglutide. The body weight reduction and gastrointestinal **-** related side effects were similar to the GLP- 1R agonists. In addition, many patients who received tirzepatide were noted to have improved biomarkers of insulin sensitivity. We have obtained both GIP and tirzepatide bound GIPR structures along with GLP- 1R structures to guide our small molecular design. ~~32Multiple~~ **19Multiple** Structures of ~~ligand~~ **Ligand** ~~bound~~ **Bound** GLP- 1R, GIPR, GCGRAs shown above, representative three- dimensional structures of the incretin GPCRs (e. g., GIPR, GLP- 1R, Glucagon receptor) are available for structure- based drug discovery. This structural data enables the ~~ability to~~ design **of** dual and tri modulators of this important class of metabolic GPCRs. The GIPR model shown below suggests that one of our dual GLP- 1 / GIPR agonists may extend to fill the pocket (highlighted in color) occupied by our GLP- 1 / GIPR agonist hits. Multiple approaches were applied for hit identification, including a screen of our proprietary incretin compound library. Weak antagonists and agonists were identified. After several rounds of structure activity relationship evolution, a full potential GLP- 1R / GIPR antagonist and initial dual GLP- 1R / GIPR agonist hit leading to the discovery of an optimized dual GLP- 1R / GIPR agonist hit. While displaying different GIPR activity, both compounds still maintained certain levels of GLP- 1R activities. We are planning to select a development candidate in ~~the first half of~~ 2025. GIPR ~~agonist~~ **Agonist** / dual ~~agonist~~ **Agonist** / antagonist **Hits Identified for Potential GLP- 1R CombinationsIn our GCG program, we have identified multiple GCGR agonist and dual GLP- 1R / GCGR agonist** hits ~~identified~~ for ~~potential~~ **small molecule GCGR modulation. GCG is primarily expressed in the liver and therefore GCGR agonists could play an important role in liver- mediated diseases, specifically MASH. 20ANPA- 0073- Oral Small Molecule APJ Receptor Agonist for Selective Weight Loss ANPA- 0073 is our biased APJ receptor agonist. In September 2022, we completed a Phase 1 SAD and MAD study evaluating ANPA- 0073 in healthy human volunteers, in which it was generally well tolerated. We are currently conducting long term** GLP- ~~1R~~ **toxicology studies of ANPA- 0073, which is Phase 2 ready, to be used in** ~~combinationsOur~~ ~~----~~ ~~type studied,~~ **inflammatory score as shown below.** ~~APJ~~ **APJR agonist demonstrated anti** ~~receptor activation enhances extracellular signal~~ - ~~regulated kinases~~ **fibrosis efficacy in therapeutic IPF mouse modelFurthermore** , ~~AMPK,AKT~~ **ANPA- 137 also demonstrated anti- fibrotic activity in** ~~and~~ - **an** ~~p70S6 kinases and the inhibition of cAMP production.Activation of these pathways would result~~ in **vivo bleomycin** ~~worthwhile increases in the protein content of skeletal muscles.Apelin has in fact proved beneficial in maintaining muscle and could potentially counteract age~~ - **induced rat** ~~associated atrophy.We are currently conducting long~~ **lung fibrosis model.Similar** ~~term GLP- toxicology studies of ANPA- 0073,which is Phase 2 ready,~~ to ~~be used in combination with weight loss medicines~~ **mouse bleomycin study design,seven days after bleomycin challenges,rats 39received 15 mpk of oral ANPA- 137** for **two weeks** ~~selective or muscle- sparing weight loss~~. ~~APJ Receptor Biased Agonism is a Potential Differentiator for ANPA- 0073BIASED SELECTIVITYβ- ARRESTINCOMPOUND IDSIGNALING / cAMPINTERNALIZATION / cAMPApelin Peptide 1.331.47AMG- 986 0.861.00BMS- 986224 3.803.80ANPA~~ -- **ANPA** ~~- 0073 18.023,074ANPA~~ - 137 ~~28~~ **significantly reduced lung fibrosis as quantified by Ashcroft score as shown below** . ~~201,411ANPA~~ **APJR agonist demonstrated anti** - **fibrosis efficacy** ~~0073 Phase 1 Safety Data~~ in **therapeutic IPF rat modelANPA- 0073 Phase 1** Healthy ~~VolunteersIn~~ --- **Volunteer Trial DesignIn** September 2022,we completed a two- part,96 subject,first- in- human Phase 1 SAD and MAD study for ANPA- 0073 in 48 healthy adult volunteers between the ages of 18 and 55.The objective was to assess drug safety and PK.The first part of this study was a SAD study,involving eight cohorts of eight participants assigned to receive a single dose of ANPA- 0073 or placebo in a 3:1 ratio.Doses from 2 mg to 600 mg across the eight cohorts were evaluated.The second part of the ~~study~~ **trial** was a MAD study,including four cohorts of eight subjects receiving sequential ascending doses of ANPA- 0073 daily for seven days,increasing from 75 mg to 500 mg once daily. **A schema of our Phase 1 study is presented below:Schema of our** ANPA **- 0073 Phase 1 study in healthy volunteersANPA- 0073- 01 Part A SAD Schema40ANPA- 0073- 01 Part B MAD SchemaANPA- 0073 Phase 1 Safety Data in Healthy VolunteersANPA** - 0073 was generally well tolerated at all dose levels administrated in the SAD and MAD parts of this Phase 1 study.In the study,PK parameters of systemic exposure,Cmax and AUC,increased with doses of ANPA- 0073 across the dose range from 75 mg to 500 mg. ~~21In~~ **In** the SAD cohorts,no SAEs and no adverse changes in laboratory tests were observed.Among the AEs reported,five were considered moderate ~~TEAEs~~ **treatment emergent adverse events** and the remaining were mild in severity.AEs did not result in any early terminations or subject discontinuations from participation in this study.No ~~study~~ **trial** stopping criteria were met and no significant changes or

trends in hematology,blood ~~chemistries~~ **41chemistries** ,vital signs or electrocardiogram (“ ECG ”) measurements were noted.The following table shows all TEAEs that were reported:ANPA- 0073 Phase 1 SAD ~~TEAEsIn~~ **Treatment Emergent Adverse EventsIn** the MAD portion of the Phase 1 study,no SAEs and no adverse changes in laboratory tests were observed.Among the AEs reported,twelve were considered moderate TEAEs and the remaining were mild in severity.AEs did not result in any early terminations or subject discontinuations from participation in this study.No ~~study~~ **trial** stopping criteria were met and no significant changes or trends in hematology,blood chemistries,vital signs or ECG measurements were noted.The following table shows all TEAEs that were reported: ~~22ANPA -~~ **ANPA** - 0073 Phase 1 MAD ~~TEAEsWe have~~ **Treatment Emergent Adverse EventsWe will** ~~initiated -~~ **initiate** the 26- week chronic GLP- toxicology studies in rats and 39- week studies in dogs that we believe will be required by regulatory agencies to continue dosing beyond 13 weeks in Phase 2.We are also evaluating ANPA- 0073 for selective or **muscle- sparing weight loss** LPA1R **Antagonist** ~~and APJR Program~~ for **IPFAdditionally, we** ~~the Treatment of IPFWe~~ are developing **an antagonist that targets lysophosphatidic acid 1 receptor (“ LPA1R ”), a GPCR implicated in responses to tissue injury and pro- fibrotic processes, for the treatment of IPF. We have demonstrated substantial anti- fibrotic activity of our LPA1R antagonists in mouse models of fibrotic lung disease and we selected a development candidate,** LTSE- 2578, ~~an investigational oral small molecule LPA1R antagonist for the treatment~~ **in January 2023. In June 2024, we initiated our first- in- human Phase 1 study** of ~~IPF~~ **LTSE- 2578** . We believe LTSE- 2578 is a differentiated molecule because it demonstrated potent in vitro and in vivo activity in preclinical IPF models and dose dependent inhibition of histamine release as the pharmacodynamic marker. We have completed IND- enabling studies including 28 **-** day GLP- toxicology studies in dogs and rats. ~~33We are planning to~~ **In June 2024, we** ~~initiate~~ **initiated** a ~~first- in- human~~ Phase 1 **clinical study of LTSE- 2578. This randomized, double- blind, placebo- controlled first- in- human clinical study is designed to investigate the safety, tolerability and PK of** single and multiple ascending ~~dose~~ **doses** ~~study~~ **of LTSE- 2578** in **approximately 64** healthy **participants** ~~volunteers in the second quarter of 2024. In addition, we are developing ANPA- 0073, an~~ **and** ~~investigational oral small molecule APJR agonist, for the treatment of IPF. When compared to a non- biased APJR agonist (Apelin- 12) in a preclinical study, ANPA- 0073 avoided hypotension. In September 2022, we completed a Phase 1 SAD and MAD study evaluating ANPA- 0073, in which it was generally well tolerated in healthy human volunteers. We~~ expect to **report** ~~conduct additional preclinical studies and are evaluating plans to initiate~~ **initial data** ~~a Phase 2 study~~ in ~~IPF~~ **2025** . IPF Disease BackgroundIPF is a life- threatening chronic interstitial lung disease characterized by progressive fibrosis of lung tissue leading to impaired blood oxygenation, progressive deterioration in lung function ~~,~~and ultimately respiratory failure. IPF occurs primarily among patients between the ages of 50 and 70 years and is associated with high mortality, with median survival time between three- and five- years following diagnosis. Estimated prevalence of IPF is 13 to 20 per 100, 000 people worldwide. In the United States, approximately 100, 000 people are affected, and 30, 000 to 40, 000 new cases are diagnosed each year. ~~Normal~~ **23Normal** ~~lungs~~ **Lungs** (A) and ~~lungs~~ **Lungs** with IPF (B) The etiology of IPF remains unknown. IPF is a progressive disease, beginning with inflammation followed by fibrotic buildup as damaged epithelial cells surrounding the alveoli are replaced by fibroblasts, as shown above. Buildup of fibroblasts cause the lungs to thicken over time, becoming stiff and unable to properly function. In addition to complications from the disease itself, IPF can lead to other severe co- morbidities, including lung cancer, pulmonary embolisms, pneumonia or PH. The most common symptoms of IPF are shortness of breath, persistent cough, fatigue ~~,~~and weight loss, severely impacting quality of life. Given the non- specific nature of these symptoms, IPF is challenging to diagnose, particularly in the early stages of disease. Current Treatments for IPF and Unmet Medical NeedCurrently, there are two FDA- approved drugs for the treatment of IPF, Esbriet (pirfenidone) and Ofev (nintedanib). Pirfenidone exhibits anti- fibrotic, anti- inflammatory and antioxidant properties through down- regulation of key pro- fibrotic growth factors including TGF- β, inhibition of inflammatory cytokines production and release and reduction of lipid peroxidation and oxidative stress. In Phase 3 ~~trials~~ **studies** , pirfenidone slowed disease progression and functional decline in patients with IPF and showed a reduced risk of mortality. Common adverse effects of pirfenidone include gastrointestinal intolerance such as nausea, diarrhea and dyspepsia and skin reactions, including rash and photosensitivity. ~~34Nintedanib -~~ **Nintedanib** is an intracellular inhibitor that targets multiple tyrosine kinase growth factor receptors (vascular endothelial growth factor receptors 1 ~~–~~3, fibroblast growth factor receptors 1 ~~–~~3 ~~,~~and platelet- derived growth factor receptors α and β). By inhibiting these receptors, nintedanib interferes with processes implicated in IPF pathogenesis, including proliferation and migration of lung fibroblasts ~~,~~and differentiation of fibroblasts to myofibroblasts. Nintedanib may also have a mortality benefit. Its most frequent side effects are diarrhea and nausea. Both drugs are recommended by the most recent treatment guidelines from 2015. These therapeutics slow disease progression, but do not offer a cure. The two- year mortality rate is 36 % and 39 % after treatment of nintedanib and pirfenidone **,** respectively. Safety and tolerability concerns, which resulted in a 20 % to 30 % discontinuation rate due to side effects, limit therapeutic usage and there remains an unmet medical need for IPF patients. Despite these limitations, these two drugs have generated total sales of $ 3. 6 billion in 2020. ~~Overview of~~ LPA1R Pathway and Target BiologyLysophosphatidic acid (“ LPA ”) is a bioactive lipid ~~which~~ **that** exerts potent extracellular signaling through its interaction with several GPCRs, mediating important cellular responses, such as proliferation, migration ~~,~~and cytoskeletal reorganization. ~~LPA~~ **24LPA** / LPA1R in IPF ~~pathogenesisAs~~ **PathogenesisAs** shown above, upon injury to certain cells in the lung, LPA levels increase and activate LPA1R. In published third- party preclinical studies, LPA1R activation promoted pro- fibrotic processes, including accumulation of fibroblasts; genetic or PD inhibition of LPA1R attenuated bleomycin induced lung fibrosis by mediating fibroblast recruitment and vascular leak. We believe that LPA1R has been clinically validated as a potential target based on proof- of- concept data from a third party, randomized, double blind, placebo- controlled Phase 2 ~~trial~~ **study** of an LPA1R antagonist (BMS ~~–~~986020) in patients with IPF. Patients in the ~~600mg -~~ **600 mg** BID cohort exhibited significantly slower rates of forced vital capacity decline from baseline to 26 weeks versus placebo. Although the compound was generally well tolerated, dose- related hepatobiliary toxicity in some patients led to early termination of the ~~trial~~ **study** . After conducting additional toxicology investigations, BMS reported that hepatobiliary toxicity was likely caused by inhibition

of bile acids efflux transporters such as Bile Salt Export Pump (“ BSEP ”). Second ~~35generation --~~ **generation** LPA1R antagonists (BMS ~~–~~986278) with minimal BSEP inhibition by BMS are currently in clinical development. We believe that LPA1R can also be used to treat progressive pulmonary fibrosis (“ PPF ”), which is defined as the presence of at least two of the three criteria, which are worsening respiratory symptoms, functional decline ~~,~~and radiological progression in patients with interstitial lung disease with radiological pulmonary fibrosis for known or unknown reasons other than IPF, within the previous year. A conditional recommendation has been made for nintedanib in the treatment of PPF, and further studies are needed for pirfenidone. As illustrated below, we utilized the available protein structural information to collaborate with Schrödinger. After validation and customization with an initial set of compounds for retrospective analysis, Schrödinger’ s **Free Energy Perturbation (“** FEP **”)** was utilized and suggested potency in the prospective analysis. This customized model greatly expedited the iterative lead optimization process and helped us to achieve candidate selection efficiently. ~~Iterative~~ **25Iterative** LPA1R Structure- ~~Based~~ **based** Drug DiscoveryLTSE- 2578 Preclinical DataIn an in vivo PK and PD study, mice were orally dosed with LTSE- 2578 and challenged by LPA at one hour and at 12 hours after dosing. Plasma was collected at two minutes post- LPA challenge and histamine level was measured as a pharmacodynamics biomarker. As shown below, LTSE- 2578 demonstrated reductions in histamine release at doses ≥ 0. 06 mg / kg, as compared to approximately 45 ng / mL and approximately 201 ng / mL for BMS’ s first generation (BMS ~~–~~986020) and second generation (BMS ~~–~~986278) LPA1R antagonists, respectively. ~~36LTSE --~~ **LTSE** - 2578 ~~demonstrated~~ **Demonstrated** ~~dose~~ **Dose** ~~dependent~~ **Dependent** ~~inhibition~~ **Inhibition** of ~~histamine~~ **Histamine** ~~releaseLTSE~~ **ReleaseLTSE** - 2578 showed limited inhibition (IC50 > 50 μ M) of efflux transporters including BSEP, MRP3 and MRP4, potentially reducing the likelihood of hepatobiliary toxicity caused by efflux transporter inhibition. One month GLP toxicity studies of LTSE- 2578 in rats and dogs have been completed to enable the upcoming first time in human study. **26GPCRs as a Therapeutic** ~~Overview of APJR Pathway and~~ Target ~~BiologyThe apelinergic~~ **FamilyGPCRs form the largest human membrane protein family, consisting of approximately 800 identified members as illustrated below. GPCRs are involved in several vital physiological functions, such as immune** system ~~with~~ **.To date,there are** approximately 475 drugs on the market ~~to date~~ acting at over 100 unique GPCRs. ~~Importantly~~ **Additionally** ,more than 220 GPCRs have not yet been explored as clinical targets,hence representing ~~a~~ broad ~~and~~ untapped therapeutic potential for addressing global healthcare needs.Phylogenetic ~~Tree~~ **tree** of GPCR ~~TargetsGPCR~~ **targetsGPCR** targeting drugs have successfully delivered significant patient benefit resulting in large market opportunities in many therapeutic areas.Examples include liraglutide (Victoza for T2DM),aripiprazole (Abilify for schizophrenia,bipolar disorder and depression),montelukast (Singulair for asthma),valsartan (Diovan for hypertension),metoprolol (Lopressor for hypertension,angina **,** and myocardial infarction) **,** and clopidogrel (Plavix for myocardial infarction and stroke).GPCR related drugs are the largest drug class accounting for approximately 27 % of global pharmaceutical sales with estimated aggregate sales of $ 890 billion between 2011 and 2015. ~~GPCRs~~ **11GPCRs** are proteins that span the entire width of cell membranes.Their primary function is ~~to recognize extracellular plays --~~ **play** ~~a key~~ **an essential** role in **many physiological and pathological processes, and** ~~the~~ **they** ~~maintenance~~ **are involved in the desensitization, internalization, sequestration and trafficking of GPCRs. Certain GPCR ligands are capable of simultaneously activating both G- protein and non- G- protein mediated signaling pathways, which can lead to a variety of physiologic as well as pathologic effects. Challenges of GPCR Therapeutic Discovery and DevelopmentDespite tremendous advancements in structure- based drug design and development, GPCR drug discovery and development remains challenging. • Similarity between the binding sites of GPCRs and related receptors can cause** ~~of~~ **off** ~~vascular health and function through regulation of fibrosis, cell proliferation and inflammation. APJR~~ **- target toxicities: All GPCRs have the same overall three- dimensional architecture but the specific endogenous binding site** is **unique due** ~~highly expressed in the pulmonary vascular endothelium and is upregulated on endothelial cells in IPF patients. Further, activation of the apelinergic system through APJR has been shown~~ to ~~protect endothelial cell survival, and is critical for regeneration of~~ the **placement of amino acid side chains shaping** ~~small capillary blood vessels. These findings support~~ the ~~possibility that an APJR agonist may play a beneficial role in interstitial lung disease. Apelin~~ binding **site. For instance, the early sphingosine 1** ~~to APJR activates G- protein second messenger signaling and leads to reduced production of cyclic adenosine monophosphate ----~~ **phosphate 1 receptor** (“ ~~cAMP~~ **S1P1R** ”) ~~. Apelin binding~~ **agonist Gilenya led** to ~~APJR also initiates~~ **the development of** a ~~feedback loop that eventually downregulates apelin- APJR~~ **new class of therapy for the treatment of multiple sclerosis, but had exhibited bradycardia as a side effect due in part to sphingosine 1 phosphate 3 receptor (“ S1P3R ”) activity, a very closely related S1P1 receptor subtype. The next generation S1P1R agonist Zeposia was designed using structural information by Receptos, Inc. to remove the S1P3 and other activities and therefore did not have the same side effect profile as Gilenya. • GPCRs are involved in diverse downstream** signaling ~~by recruitment~~ **pathways which can result in side effects: GPCRs interact with a range** of **molecules, including G- protein and non- G- protein transducers including** β- arrestin ~~and subsequent internalization of APJR . In addition, recruitment of β~~ **Signaling pathway selectivity results from agonist** - ~~arrestin triggers downstream~~ **induced specific receptor conformation and when targeting GPCRs involved in multiple signaling** pathways ~~that induce vasorelaxation and cardiomyocyte hypertrophy. Therefore , the degree of activation by designed ligands of G- protein and β- arrestin signaling pathway may lead to~~ both therapeutic ~~benefit~~ **benefits** and ~~undesirable~~ **side** effect issues may arise. ~~●~~ **28 •** Expression levels of GPCRs are low and create significant hurdles to structural and PD characterization:Recombinant protein expression of GPCRs remains extremely challenging.Expression levels of GPCRs are low and improvement of expression level continues to be mainly empirical and resource- consuming.GPCRs are complex membrane proteins that require a stable membrane environment throughout the purification process to avoid destabilization and aggregation. ~~●~~ • GPCR structural visualization is complex making GPCR structure- based drug discovery challenging:Structure- based drug design requires rapid iterations of GPCR structures in complex with specific new ligands to determine their ~~effects on~~ effects ~~. 37Importance of endothelial cells~~ on **conformation. This is** ~~pulmonary fibrosisAs shown above, while epithelial cell~~ **well** ~~damage and~~

established through robust crystallography platforms for soluble drug targets. Cryo- EM has helped accelerate the ~~inflammatory~~ membrane protein field, but the methods still require substantial expertise and execution. Drug discovery approaches targeting GPCRs have evolved from traditional approaches including high throughput screening to rational design for enhanced activity, tailor- made signaling response and improved selectivity, which leads to improved safety and tolerability profiles. Our Structure- Based Drug Discovery Technology PlatformOur platform is based on techniques that our founders have been evolving for over 25 years, which have enabled them to deliver multiple marketed medicines. Our approach enables us to generate small molecule product candidates that are designed ~~known contributors~~ to ~~fibrosis, recent studies have highlighted~~ overcome the historical limitations of GPCR drug development. Our insights and capabilities enable us to visualize the ~~the~~ three ~~importance~~ - dimensional protein structures of ~~endothelial cells on pulmonary fibrosis~~ the target and the ligands . We believe this visualization combined ~~Microvascular injuries are observed in patients~~ with ~~pulmonary fibrosis. Persistent vascular leak may support a pro- inflammatory and pro- fibrotic environment. Endothelial senescence is found in~~ the ~~lung~~ computational chemistry capabilities of Schrödinger gives us significant competitive advantages ~~IPF patients. Senescent endothelial cells could secrete factors that directly stimulate fibroblast activation. Targeting apelin pathway may promote capillary regeneration, ameliorate the inflammatory environment, and reduce endothelial senescence,~~ in highly efficient ~~this way reducing lung fibrosis. Since an~~ and ~~APJR agonist mainly targets endothelial cells~~ rational drug design. We design our novel compounds by combining our knowledge of GPCR structures together with advanced physics- based computational methods , which we believe ~~it could be easily combined~~ allows us to predict the binding affinity of molecules to the target site with the current standard of care, pirfenidone..... to suppress cAMP production through activation of a high degree ~~G- protein- mediated signaling without significant activation~~ of accuracy ~~the β- arrestin pathway in order to avoid APJ internalization, and thereby potentially avoid any desensitization effects of an unbiased APJR agonist. We conducted preclinical in vitro studies on our compounds and third- party compounds to assess arrestin signaling and internalization~~ . As shown below, ~~apelin~~ our technology platform allows us to determine feasibility, optimize the design of and efficiently generate families of potent and highly selective small molecule candidates. 29Structure Therapeutics Integrated Technology Platform from Target to INDOral small molecules have the potential to address the key limitations of biologic and peptide drugs ~~and clinically tested competitor compounds including AMG- 986 and 38BMS- 986224 are all non- biased APJR agonists in these in vitro studies, with low β- arrestin / cAMP and internalization / cAMP ratios. Our molecules~~ , such as high cost ~~ANPA- 0073~~ and patient inconvenience ~~ANPA- 137~~ , thereby significantly improving patient access.We believe this is particularly important for the most prevalent chronic diseases including those involving the endocrine,cardiovascular ~~,~~and pulmonary systems.We believe the strengths of our technology platform will enable us to develop oral small molecule drugs that can deliver biologic- like activity and specificity. ~~Strategic~~ GPCR Target PrioritizationWe start with target prioritization by focusing on validated GPCR targets that do not have attractive small molecule solutions.We then prioritize by assessing the feasibility of a small molecule solution for these targets and market opportunities of their respective target indication.Expertise in GPCR Structure- Based Drug DiscoveryGPCRs ~~are difficult to characterize structurally because they are composed of seven transmembrane domains,have~~ are difficult to characterize structurally because they are composed of seven transmembrane domains,have low expression ~~,~~and are unstable outside of the cell membrane environment.While structure- based approaches have been utilized for decades in soluble protein drug discovery,recent breakthrough advancements in computational chemistry,artificial intelligence,machine learning and electron microscopy are redefining the field of GPCR structure- based drug discovery. ~~14Visualization~~ 30Visualization of GPCR Structure and ~~binding~~ Binding ~~site~~ Site ~~interactionsAs~~ InteractionsAs shown above,our structure- based technology platform combines direct visualization of protein receptor binding interactions with advanced simulation of molecular motion and signal transduction.Site 1 is considered to be the orthosteric or primary binding site for receptor activation.Site 2 is on the surface of the receptor,often referred to as the allosteric site and may potentially regulate receptor activation signaling.By visualizing and analyzing how different ligands bind to a particular target and specific sites and affect their conformational dynamics,we believe we are able to efficiently convert biologics and peptides into more accessible,patient- accommodating oral small molecules.In addition,we can enhance the pharmaceutic properties of our small molecules with the aim ~~to~~ of ~~elicit~~ eliciting the desired function while maintaining superior pharmaceutical properties.Non- biased vs ~~biased~~ Biased GPCR ~~agonistsAdditionally~~ AgonistsAdditionally ,GPCR signaling can follow several pathways and molecules can be designed such that their pharmacology is selected to ~~be~~ create " biased signaling " as illustrated above.GPCRs are known to signal not only through G- proteins,but also through β- arrestins,intracellular proteins that " arrest " the signal and stop the receptor from becoming over- stimulated through a receptor internalization mechanism.Using the three- dimensional structures of GPCRs and selection methods,we can potentially design highly selective " biased " ~~15molecules~~ 31molecules that preferentially activate G- protein and not β- arrestin pathways,which could lead to enhanced clinical activity as well as an improved safety profile due to lower dosage requirements. Robust ~~GPCR ExperienceRobust~~ and Integrated Medicinal Chemistry to Generate and Optimize Hits on GPCR TargetsWe have extensive medicinal chemistry know- how on the discovery and development of novel molecules that target GPCRs.When coupled with ~~much higher β- arrestin / cAMP~~ our deep understanding of GPCR biology, we have the potential to design appropriate chemotypes for each GPCR function as illustrated below. Family Members with Determined Structures are Highlighted within the Tree, and ~~internalization / cAMP ratios than apelin peptide and the~~ their ~~competitor~~ Binding Pockets with the LigandFour Character Code at End of Each Image is Protein Data Bank ID. Further optimization of compounds powered by our excellence in medicinal chemistry ~~lead~~ led us to identify potent and selective oral small molecule product candidates.Partnership with Schrödinger Leveraging its Cutting- Edge Computational Chemistry CapabilityWe have collaborations with Schrödinger on the iteration and optimization of GPCR lead compounds using various next- generation physics- based computational technologies.Schrödinger is a scientific leader in chemical simulation,accurate physics- based methods,which includes among many technologies, ~~Free Energy Perturbation (" FEP ")~~ and

in silico drug discovery.Its ’ computational platforms integrate predictive physics- based methods with machine learning to evaluate billions of compounds in silico,achieving experimental accuracy on properties such as binding affinity and solubility.Through this iterative process,we can accelerate evaluation and optimization of molecules in silico ahead of synthesis and assay ,-and then further optimize them through additional cycles of computation analysis **.32Structure Therapeutics Integrated PlatformAs** shown ~~below~~ **above, our collaborations with Schrödinger in our computational and chemistry module enables us to accelerate our lead optimization drug discovery process and reduce development costs** . ~~APJR~~ **In our partnership with Schrödinger on GPCR drug discovery, we retain the full product rights on the compounds under development. Safety AssaysWe have proactively used cell and animal-** ~~biased -~~ **based safety assays to better screen out unwanted side effects** ~~agonism is a potential differentiator for ANPA- 0073BIASED SELECTIVITYβ-ARRESTINCOMPOUND IDSIGNALING / cAMPINTERNALIZATION / cAMPApelin Peptide 1. 331. 47AMG- 986 0. 861. 00BMS- 986224 4. 481. 94ANPA- 0073 18. 023 -~~ , **such as liver** ~~074ANPA- 137 28. 201 -~~ **cardiovascular** ~~411ANPA- 0073 Preclinical DataIn an~~ **and central nervous system toxicity at** ~~in vitro study, ANPA- 0073 demonstrated high potency in suppressing cAMP production through~~ the ~~G~~ **initial stages of lead optimization, and we have designed molecules to help minimize safety risks at every step. Our in** ~~- protein- mediated~~ **depth understanding of GPCR** signaling pathway **provides us insights to design biased molecules when necessary to mitigate any unwanted liabilities while maintaining the desired activities.** ~~with a half maximal excitatory concentration (EC50) value of less than 10 nM (n = 15), but less potency in triggering the~~ **Other** ~~β~~ **Proprietary In** ~~- arrestin pathway~~ **House Development Tools for Drug Synthesis** and **ScreeningIn addition to our robust iterative structure** ~~APJR internalization respectively. These data suggest ANPA -~~ ~~0073~~ **based drug discovery platform shown above, Basecamp Bio** is **optimizing proprietary in** ~~highly biased. The G -~~ ~~protein agonist potency of ANPA~~ **house drug discovery tools including DNA** ~~-~~ **Encoded Library technology** ~~0073 was similar across different species (rat, dog and monkey). Anti- fibrosis effect of an~~ **and Affinity Mass Spectrometry technology** ~~APJ agonist ANPA- 0137 was evaluated in bleomycin- induced lung fibrosis model. Seven days after bleomycin challenges, mice received oral ANPA- 137 for two -~~ **to enable the synthesis** ~~weeks. ANPA- 137 significantly reduced lung fibrosis Ashcroft scores~~ and ~~inflammatory cells infiltration into lung as quantified~~ **screening of vast numbers of small molecule product candidates at a scale that is not possible to achieve** by **traditional methods** inflammatory score as shown below. APJR..... selective or muscle- sparing weight loss . Intellectual PropertyOur success depends in part on our ability to obtain and maintain proprietary protection for our product candidates and other discoveries, inventions, trade secrets and know- how that are critical to our business operations. Our success also depends in part on our ability to operate without infringing the proprietary rights of others, and in part on our ability to prevent others from infringing our proprietary rights. A comprehensive ~~42discussion --~~ **discussion** on risks relating to intellectual property is provided under Part I. Item 1A. “ Risk Factors — Risks Related to Our Intellectual Property. ” **33For our product candidates, we will, in general, initially pursue patent protection covering compounds, compositions of matter and methods of use. Throughout the development of our product candidates, we seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through additional methods of use, process of making, formulation and dosing regimen- related claims as appropriate. In total, our patent portfolio comprises over 350 patents and patent applications, as of December 31, 2024, filed in various jurisdictions worldwide. This includes over 95 issued patents that are owned by our wholly- owned subsidiaries. Our patent portfolio for our product candidates is outlined below. In addition to patent protection, we also rely on trade secrets, know- how, trademarks, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. However, such confidentiality agreements can be breached, and we may not have adequate remedies for any such breach.** For **more information regarding the risks related to our intellectual property, see Part I. Item 1A. “ Risk Factors — Risks Related to Our Intellectual Property. ” Aleniglipron (GSBR- 1290): GLP- 1 Receptor ProgramFor** our GLP- 1R program ~~, as of December 31, 2023 -~~ , our wholly- owned subsidiary Gasherbrum Bio, Inc. ~~,~~ is the sole owner of **24** ~~one granted U. S.~~ patent **families** ~~and 11 pending U -~~ ~~S.~~ **These include patents and** patent applications **directed to our lead product candidate aleniglipron** ~~, 14 Patent Cooperation Treaty (“ PCT ”), applications,~~ and **its analogs** ~~94 pending foreign patent applications in Argentina~~ , **solid forms** ~~the African Regional Intellectual Property Organization (“ ARIPO ”), Australia, Brazil, Canada, Chile, the People’ s Republic of China (“ PRC ”), Colombia, Costa Rica, Dominican Republic, Egypt, the Eurasian Patent Office (the “ EAPO ”), the European Patent Office (the “ EPO ”), Guatemala, Hong Kong, Indonesia, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Panama, Peru, Philippines, Saudi Arabia, Singapore, Thailand, Taiwan, Ukraine, Vietnam,~~ and ~~South Africa~~ **methods of treating conditions associated with GLP- 1R activity** . These **patents and** patent applications, to the extent they issue (or in the case of priority applications, if issued from future non- provisional applications that we file), are expected to expire between 2041 and ~~2044~~ **2045** , without accounting for potentially available patent term adjustments or extensions. **ACCG** ~~These patent applications relate to compositions of matter of heterocyclic GLP -~~ **2671: Amylin Receptor ProgramFor** ~~1 agonists, including GSBR- 1290 and its analogs, solid forms and methods of treating conditions associated with GLP- 1R activity. We intend to strengthen the patent protection of our product candidates and other discoveries, inventions, trade secrets and know- how that are critical to our business operations through additional patent application filings. For~~ our oral small molecule ~~APJR~~ **Amylin** program ~~, as of~~

December 31, 2023 , our wholly- owned subsidiary Annapurna **Aconcagua** Bio, Inc. **(“ Aconcagua ”)** is the sole owner of **6** two granted U. S. patents **patent families** and three pending U . S. **These include** patent applications , one PCT application, one granted European patent and 24 pending foreign patent applications in Argentina, Australia, Brazil, Canada, the PRC, the EAPO, the EPO, Hong Kong, Israel, India, Japan, South Korea, Mexico, New Zealand, Singapore, Taiwan, and South Africa relating to compounds and compositions of matter for treating conditions associated with Apelin **amylin** receptor activity, including ANPA **ACCG** - 0073 **2671** and its analogs , solid forms and methods of treating conditions associated with Apelin **amylin** receptor activity. Any patents issuing from these patent applications (or in the case of priority applications, if issued from future non- provisional applications that we file) are expected to expire between 2039 and 2043 **2044 and 2045** , without accounting for potentially available patent term adjustments or extensions. For **GIP and GCG Receptor ProgramsFor** our LPA1R **oral small molecule GIPR** program , as of December 31, 2023 , our wholly- owned subsidiary Lhotse **Gimigela** Bio, Inc. (“ Lhotse ”) is the sole owner of three pending U **3 patent families** . S. **These include** patent applications , four PCT applications and seven pending foreign patent applications in Argentina, the PRC, the EPO, Japan, and Taiwan relating to compounds and compositions of matter for treating conditions associated with **GIPR** LPA receptor activity , including LTSE- 2578 and its analogs, and methods of treating conditions associated with **GIPR** LPA receptor activity. Any patents issuing from these patent applications (or in the case of priority applications, if issued from future non- provisional applications that we file) are expected to expire between **in** 2041 **2045** and 2044 , without accounting for potentially available patent term adjustments or extensions. For **34ANPA- 0073: APJ Receptor ProgramFor** our **APJ receptor** oral small molecule Amylin program , as of December 31, 2023 , our wholly- owned subsidiary Aconcagua **Annapurna** Bio, Inc. (“ Aconcagua ”) is the sole owner of two PCT **5 patent families. These include patents and patent** applications relating **directed** to compounds **our lead product candidate ANPA- 0073** and compositions of matter **its analogs, solid** for **forms and methods of** treating conditions associated with Amylin **APJ** receptor activity and methods of treating conditions associated with Amylin receptor activity . Any **These** patents **and** issuing from these patent applications **, to the extent they issue** (or in the case of priority applications, if issued from future non- provisional applications that we file) **,** are expected to expire in **between 2039 and** 2044 **2045** , without accounting for potentially available patent term adjustments or extensions. **LTSE- 2578: LPA1 Receptor ProgramFor our LPA1R program, our wholly- owned subsidiary Lhotse Bio,** In **Inc** addition to **. (“ Lhotse ”) is the sole owner of 5** patent **families. These include patents** protection, we also rely on trade secrets, know- how, trademarks, other proprietary information and continuing technological innovation **patent applications relating** to develop **compounds** and maintain our competitive position **compositions** . We seek to protect **of matter for treating conditions associated with LPA1R activity, including LTSE- 2578** and maintain **its analogs and methods of treating conditions associated with LPA1R activity. These patents and patent applications, to the extent** the **they issue (** confidentiality of proprietary information to protect aspects of our business that are not amenable to **in the case of priority applications** , or **if issued from future non- provisional applications** that we do not consider appropriate **file), are expected to expire between 2041 and 2044, without accounting** for , **potentially available** patent **term adjustments** protection. Although we take steps to protect our **or extensions** proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology . Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. 43However, such confidentiality agreements can be breached, and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see Part I. Item 1A. “ Risk Factors — Risks Related to Our Intellectual Property. ” Lhotse Collaboration Agreement with Schrödinger, LLCIn October 2020, Lhotse, our wholly- owned subsidiary, entered into a collaboration agreement with Schrödinger (the “ Lhotse- Schrödinger Agreement ”) to discover and develop novel, orally bioavailable, small molecule inhibitors of LPA1R. Under the Lhotse- Schrödinger Agreement, Schrödinger is obligated to provide computational modeling and design support, including by using its technology platform to perform virtual screens, and Lhotse is obligated to provide day- to- day chemistry and biology support. Pursuant to the Lhotse- Schrödinger Agreement, a joint steering committee comprised of representatives from both parties oversees the research performed under the agreement. During the term of the Lhotse- Schrödinger Agreement and for a specified period thereafter while Lhotse is engaged in active development of any compound having activity against LPA1R that is discovered or developed under the Lhotse- Schrödinger Agreement, Schrödinger is obligated to work exclusively with Lhotse on the design, research, development and commercialization of compounds that inhibit LPA1R. Lhotse will solely own the research results, work product, inventions and other intellectual property generated under the Lhotse- Schrödinger Agreement that are directed to LPA1R. Under the Lhotse- Schrödinger Agreement, Lhotse is obligated to pay Schrödinger a quarterly active program payment in the low six digits for each successive three- month period during which Schrödinger continues to perform research work as agreed by the parties, and as of December 31, 2023 **2024** , we have paid to Schrödinger an aggregate of $ 0. 8 million. If Lhotse develops and commercializes a product containing a compound (“ Collaboration Compound ”) that is discovered or developed under the Lhotse- Schrödinger Agreement (“ Collaboration Product ”), Lhotse is obligated to pay Schrödinger development and regulatory milestone payments of up to an aggregate of $ 17. 0 million, regardless of the number of Collaboration Products that reach such milestones. Lhotse will also be obligated to pay Schrödinger tiered royalties in the low single digit range on aggregate worldwide net sales of all Collaboration Products, subject to specified reductions and offsets. Lhotse’ s obligation to pay royalties to Schrödinger will expire on a Collaboration Product- by- Collaboration Product and country- by- country basis on the later of (i) the expiration of the last- to- expire Lhotse owned patent claim covering the composition of matter of the Collaboration Compound contained in such Collaboration Product in such country, (ii) the expiration of regulatory, pediatric, orphan drug, or data exclusivity with respect to such Collaboration Product in such country, and (iii) ten years after the first

commercial sale of such Collaboration Product in such country (“ Royalty Term ”). Unless terminated earlier, the Lhotse- Schrödinger Agreement will continue for three years, subject to extension by mutual written agreement of the parties. Either party may terminate the Lhotse- Schrödinger Agreement for the other party’ s uncured material breach, subject to certain notice and cure periods, or for the other party’ s bankruptcy or insolvency. Lhotse’ s obligation to make milestone and royalty payments (subject ~~to~~ **35to** the Royalty Term) to Schrödinger continues after the expiration or termination of the Lhotse- Schrödinger Agreement. Aconcagua Collaboration Agreement with SchrödingerIn November 2023, Aconcagua, our wholly- owned subsidiary, entered into a collaboration agreement (the “ Aconcagua- Schrödinger Agreement ”) with Schrödinger to discover and develop novel, small molecule modulators of a specific target. Under the Aconcagua- Schrödinger Agreement, Schrödinger is obligated to provide computational modeling and design support, including by using its technology platform to perform virtual screens, and Aconcagua is obligated to provide day- to- day chemistry and biology support. Pursuant to the Aconcagua- Schrödinger Agreement, a joint steering committee comprised of representatives from both parties oversees the research performed under the agreement. During the term of the Aconcagua- Schrödinger Agreement or if longer, for a specified number of years after the effective date of the Aconcagua- Schrödinger Agreement, Schrödinger is obligated, subject to certain exceptions, to work exclusively with Aconcagua on the design, research, development and commercialization of compounds that inhibit the target. Aconcagua will solely own the research results, work product, inventions and other intellectual property ~~44generated~~ -- **generated** under the Aconcagua- Schrödinger Agreement other than improvements to Schrödinger’ s background intellectual property. During the term of the Aconcagua- Schrödinger Agreement, Aconcagua is obligated to pay Schrödinger a monthly active program payment in the low six digits, which payment includes fees payable for certain Schrödinger software employed in the Collaboration, and as of December 31, ~~2023~~ **2024** , we have paid to Schrödinger an aggregate of $ ~~0~~ **3** . 3 million. If Aconcagua develops and commercializes a product containing a compound (“ Aconcagua Collaboration Compound ”) that is discovered or developed under the Aconcagua- Schrödinger Agreement or a derivative thereof (“ Aconcagua Collaboration Product ”), Aconcagua is obligated to pay Schrödinger development, regulatory and commercialization milestone payments of up to an aggregate of $ 89. 0 million for the first Aconcagua Collaboration Product to achieve a particular milestone event, regardless of the number of Aconcagua Collaboration Products that reach such milestones. Aconcagua will also be obligated to pay Schrödinger tiered royalties in the low single digit range on aggregate worldwide net sales of all Aconcagua Collaboration Products, subject to specified reductions and offsets. Aconcagua’ s obligation to pay royalties to Schrödinger will expire on a Aconcagua Collaboration Product- by- Aconcagua Collaboration Product and country- by- country basis on the later of (i) the expiration of the last- to- expire Aconcagua owned patent claim covering the composition of matter of the Aconcagua Collaboration Compound contained in such Aconcagua Collaboration Product in such country and (ii) ten years after the first commercial sale of such Aconcagua Collaboration Product in such country (“ Aconcagua Royalty Term ”). Unless terminated earlier, the Aconcagua- Schrödinger Agreement will continue for three years, subject to extension by mutual written agreement of the parties. Either party may terminate the Aconcagua- Schrödinger Agreement for convenience after a specified period or for the other party’ s uncured material breach. Aconcagua’ s obligation to make milestone and royalty payments (subject to the Aconcagua Royalty Term) to Schrödinger continues after the expiration or termination of the Aconcagua- Schrödinger Agreement, unless the Aconcagua- Schrödinger Agreement is terminated under specified circumstances. ManufacturingWe do not own or operate manufacturing facilities for the production of our product candidates and currently have no immediate plans to build our own clinical or commercial scale manufacturing capabilities. We currently engage with third- party contract manufacturing organizations (“ CMOs ”) in multiple geographies for the manufacture of our product candidates. We rely on and expect to continue to engage third- party manufacturers for the production of both drug substance and finished drug product. We currently obtain our supplies from these manufacturers on a purchase order basis and do not have long- term supply arrangements in place. Should any of these manufacturers become unavailable to us for any reason, we believe that there are a number of potential replacements. ~~CompetitionThe~~ **36CompetitionThe** biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. While we believe that our platform and our knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. If any of our product candidates are approved for the indications for which we expect to conduct clinical ~~trials~~ **studies** , they will compete with the foregoing therapies and currently marketed drugs, as well as any drugs potentially in development. It is also possible that we will face competition from other pharmaceutical approaches as well as other types of therapies. The key competitive factors affecting the success of all our programs, if approved, are likely to be their efficacy, safety, convenience, price, level of generic competition, and availability of reimbursement. Despite significant biopharmaceutical industry investment, no oral small molecule therapy targeting GLP- 1R has been approved for the treatment of diabetes or obesity. We are aware of GLP- 1R small molecules in ~~45development~~ -- **development** by **Pfizer, Eli Lilly, Qilu Regor Therapeutics, AstraZeneca /** Eccogene ~~(licensed by Astrazeneca in November 2023)~~ **, Terns Pharmaceuticals, Jiangsu Hengrui Medicine, Huadong, Sciwind Biosciences, Ascletis, Gilead, Kallyope, MindRank, vTv Therapeutics,** Carmot Therapeutics (acquired by Roche **Group** in January 2024), **Kailera** ~~Terns Pharmaceuticals, Pfizer, Eli Lilly, and Qilu Regor~~ Therapeutics ~~Inc.~~ **, formerly Hercules CM Newco (licensed HRS- 7535, an oral small molecule GLP- 1; HRS- 9531 a GLP- 1 / GIP; and preclinical asset HRS- 4729 from Jiangsu Hengrui Medicine), and Merck (licensed HS- 10535, an oral small molecule GLP- 1, from Hansoh Pharma)** . There are currently approved GLP- 1R peptides for the ~~Pfizer, Eli Lilly, and Qilu Regor Therapeutics Inc. There are currently approved GLP- 1R peptides for the~~ treatment of diabetes and obesity marketed by Novo Nordisk, Eli Lilly, AstraZeneca, ~~and~~ Sanofi **and Kailera Therapeutics, formerly Hercules CM Newco** . We are aware of other GLP- 1R plus dual / tri incretin targeting peptides in development by Eli Lilly, Jiangsu Hansoh Pharmaceutical Group ~~Co., Ltd.~~ , Boehringer Ingelheim, Altimmune, ~~Inc.,~~ Carmot Therapeutics, ~~Inc., and~~ Sciwind Biosciences ~~Co.~~ , ~~Ltd~~ **Novo Nordisk, Viking Therapeutics, Amgen, Merck, Zealand**

Pharma, D & D Pharmatech, GMAX Biopharma, Jiangsu Hengrui Medicine, BrightGene, Innovent Biologics, PegBio, NeuroBo Pharmaceuticals, Hanmi Phamaceuticals, Progen Holdings, Pep2Tango, Metsera, QL Biopharma, Lexaria Bioscience, Sun Pharmaceutical, Gan & Lee, Innogen Biomed Industries and Verdiva Bio . In addition, there are a number of companies developing product candidates for diabetes and obesity utilizing approaches with different mechanisms of action, including but not limited to sodium- glucose cotransporter- 2 inhibitors. We are aware of ~~APJR~~ **APJ receptor** targeted product candidates in development for ~~COVID- 19 acute respiratory distress syndrome by CohBar, Inc.;~~ IPF ~~,~~ **and** systemic sclerosis interstitial lung disease ~~, and kidney nephrotic syndrome~~ by Apie Therapeutics ~~; and muscle atrophy by BioAge Labs, Inc~~ . Both Amgen and Bristol Myers Squibb (" BMS ") have ~~APJR~~ **APJ receptor** targeted product candidates for heart failure. ~~In addition, there are a number of companies developing product candidates for PAH utilizing approaches with different mechanisms of action, including but not limited to FibroGen, Inc., Galapagos NV, Galecto, Inc., Pliant Therapeutics, Inc., Gilead Sciences, Inc., Roche Holding AG and Boehringer Ingelheim.~~ We are aware of LPA1R targeted product candidates in development for IPF by BMS, Horizon Therapeutics ~~plc~~ (acquired by Amgen in October 2023) ~~,~~ and DJS Antibodies ~~Ltd~~ ; and myelin restoration and neuroinflammation by Pipeline Therapeutics. In addition, there are a number of companies developing product candidates for IPF utilizing approaches with different mechanisms of action, including Roche Holding AG and Boehringer Ingelheim. Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical ~~trials~~ **studies** , obtaining regulatory approvals, and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical ~~trials~~ **studies** , as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical 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. ~~Our~~ **37Our** 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 products that we may develop. Our competitors also may obtain FDA or other applicable regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products. Data Privacy and Security LawsNumerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health- related and other personal or sensitive information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations **have been enacted or proposed that** govern the collection, use, disclosure, and protection of health- related and other personal information **. For example, California passed the California Consumer Privacy Act of 2018 (" CCPA ") as amended by the Consumer Privacy Rights Act of 2020 (" CPRA "), Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act** . In addition, certain foreign laws govern the privacy and security of personal data, including health- related data. For example, the European Union General Data Protection Regulation (" EU GDPR ") imposes strict requirements for processing the personal data of individuals within ~~46the~~ **the** European Economic Area (" EEA "). Companies that must comply with the EU 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. Further, from January 1, 2021, companies have had to comply with the GDPR and also the United Kingdom (" UK ") GDPR (" UK GDPR ") which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR relating to fines up to the greater of £ 17. 5 million or 4 % of global turnover. **The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business' s collecting, using, and disclosing personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business' s personal data processing activities, to delete the individual' s personal data, and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for data breaches which may include an award of statutory damages. In addition, the California Privacy Rights Act of 2020 (" CPRA "), effective January 1, 2023, will expand the CCPA. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal data, establish restrictions on personal data retention, expand the types of data breaches that are subject to the CCPA' s private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law.** Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and / or criminal penalties and restrictions on data processing. ~~RegulationGovernment~~ **38RegulationGovernment** Regulation of Pharmaceutical Product Development and ApprovalU. S. Regulation of Pharmaceutical Product Development and ApprovalIn the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (" FDCA ") and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining marketing approvals and the subsequent compliance with

appropriate federal, state and local rules and regulations requires the expenditure of substantial time and financial resources. Our drug candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following: ● completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies all performed in compliance with applicable regulations, including the FDA' s good laboratory practices (" GLP ") regulations; ● submission to the FDA of an Investigational IND which must become effective before human clinical ~~trials~~ **studies** may begin; ● approval by an institutional review board (" IRB ") or ethics committee representing each clinical site before each clinical trial may be initiated; ● performance of adequate and well- controlled human clinical ~~trials~~ **studies** in accordance with applicable good clinical practices (" GCPs ") and other clinical trial- related regulations, to establish the safety and efficacy of the proposed drug product for its proposed indication; ● preparation and submission to the FDA of an NDA together with payment of user fees; ● a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review; ● review by an FDA advisory committee, where appropriate or if applicable; ● satisfactory completion of an FDA pre- approval inspection of the manufacturing facility or facilities at which the active pharmaceutical ingredient (" API ") and finished drug product are produced to assess compliance with the FDA' s current Good Manufacturing Practices (" cGMP "); ● potential FDA audit of the preclinical and / or clinical trial sites that generated the data in support of the NDA; and ● FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States. Preclinical Studies and Clinical ~~Trials~~**StudiesThe** preclinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, evaluating purity and stability, as well as carrying out ~~47non~~ -- **non** - human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the preclinical tests must comply with federal regulations, including GLPs where applicable. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol (s) for human ~~trials~~ **studies** . The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical ~~trials~~ **studies** and places the IND on clinical hold within that 30- day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Some long- term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue ~~after~~ **39after** the IND is submitted. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical ~~trials~~ **studies** due to safety concerns or non- compliance. Accordingly, submission of an IND does not guarantee the FDA will allow clinical ~~trials~~ **studies** to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated. The clinical stage of development involves the administration of the drug product to human subjects or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor' s control, in accordance with GCPs, which establish standards for conducting, recording data from, and reporting the results of clinical ~~trials~~ **studies** , and are intended to assure that the rights, safety, and well- being of study participants are protected. GCPs also include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical ~~trials~~ **studies** are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active and before approval, progress reports summarizing the results of the clinical ~~trials~~ **studies** and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. Further, each clinical trial must be reviewed and approved by each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical ~~trials~~ **studies** are minimized and are reasonable in relation to anticipated benefits. The IRB also reviews and approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical ~~trials~~ **studies** and completed clinical trial results to public registries. Clinical ~~trials~~ **studies** are generally conducted in three sequential phases that may overlap or be combined, known as Phase I, Phase II and Phase III clinical ~~trials~~ **studies** . ● Phase I: The drug is initially introduced into a small number of healthy volunteers or patients with the target disease or condition who are initially exposed to a single dose and then multiple doses of ~~48the~~ -- **the** drug candidate. These studies are designed to assess the metabolism, pharmacologic action, dosage tolerance, side effects associated with increasing doses, and safety of the drug, and if possible, to gain early evidence on effectiveness. ● Phase II: The drug is administered to a limited patient population with a specified disease or condition to evaluate optimal dosage and dosing schedule. At the same time, safety and further PK and PD information is collected, as well

as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. ● Phase III: The drug is administered to an expanded number of patients, generally at multiple sites that are geographically dispersed, in well- controlled clinical ~~trials~~ **studies** to generate enough data to demonstrate the efficacy of the drug for its intended use, its safety profile, and to establish the overall ~~benefit~~ **40benefit** / risk profile of the drug and provide an adequate basis for drug approval and labeling of the drug product. Post- approval ~~trials~~ **studies** , sometimes referred to as Phase IV clinical ~~trials~~ **studies** , may be conducted after initial marketing approval. These ~~trials~~ **studies** are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase IV clinical ~~trials~~ **studies** as a condition of NDA approval. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB' s requirements or if the drug has been associated with unexpected serious harm to patients. Concurrent with clinical ~~trials~~ **studies** , companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, cGMPs impose extensive procedural, substantive and recordkeeping requirements to ensure and preserve the long- term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life. NDA Submission and FDA Review ProcessAssuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of non- clinical studies and of the clinical ~~trials~~ **studies** , together with other detailed information, including extensive manufacturing information and information on the composition of the drug and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. Data can come from company- sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. Under the Prescription Drug User Fee Act, as amended (" PDUFA ") each NDA must be accompanied by an application user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual prescription drug program fee for human drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non- orphan indication. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA has a goal of ten months from the filing date to complete a standard review of an NDA for a drug that is a new molecular entity. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a " filing " ~~49decision~~ -- **decision** after it the application is submitted. The FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMP to assure and preserve the drug' s identity, strength, quality and purity. The FDA may refer applications for novel drugs or drug candidates that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. ~~Before~~ **41Before** approving an NDA, the FDA will conduct a pre- approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the FDA may re- analyze clinical trial data and may also audit data from clinical ~~trials~~ **studies** to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities where the drug product and / or its API will be produced, it may issue an approval letter or a Complete Response Letter (" CRL ") An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL usually describes all of the specific deficiencies in the NDA identified by the FDA. The CRL may require additional clinical data and / or an additional pivotal clinical trial (s), and / or other significant, expensive and time- consuming requirements related to clinical ~~trials~~ **studies** , preclinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. If a drug receives marketing approval, such approval will be granted for particular indications and may be significantly limited to specific diseases, dosages, or patient populations. Further, the FDA may require that certain contraindications, warnings or precautions be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post- market testing or clinical ~~trials~~ **studies** and surveillance to monitor the effects of approved drugs. For example, the FDA may require so- called Phase IV testing which involves clinical ~~trials~~ **studies** designed to further assess a drug' s safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy (" REMS ") to ensure that the benefits of a drug or biological product outweigh its risks. A REMS is a

safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of drugs. Drug approvals may be withdrawn for non- compliance with regulatory standards or if problems occur following initial marketing. Pediatric ~~TrialsUnder~~ **StudiesUnder** the Pediatric Research Equity Act, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit an initial Pediatric Study Plan (“ PSP ”) within sixty days of an end- of- Phase II ~~50meeting~~ -- **meeting** or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed- upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical ~~trials~~ **studies** , and / or other clinical development programs. ~~Orphan~~ **42Orphan** Drug Designation and ExclusivityUnder the Orphan Drug Act, the FDA may designate a drug product as an “ orphan drug ” if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200, 000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will publicly disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, meaning that the FDA may not approve any other applications for the same product for the same indication for seven years, including a full NDA, except in certain limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee. 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. In addition, 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, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Post- Marketing RequirementsFollowing approval of a new drug, the NDA sponsor and the approved drug are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the drug, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, and complying with applicable promotion and advertising requirements. Modifications or enhancements to the drug or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. FDA regulations also require that approved drug products be manufactured in specific facilities identified in the approved application for marketing and in accordance with cGMP. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any ~~51deviations~~ -- **deviations** from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing ~~processes~~ **43processes** , or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical ~~trials~~ **studies** to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: ● restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls; ● fines, warning letters, or untitled letters; ● clinical holds on clinical ~~trials~~ **studies** ; ● refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals; ● product seizure or detention, or refusal to permit the import or export of products; ● consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; ● mandated modification of promotional materials and labeling and the issuance of

corrective information; ● the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or ● injunctions or the imposition of civil or criminal penalties. The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product' s labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off- label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer' s communications on the subject of off- label use of their products. However, companies may share truthful and not misleading information that is otherwise consistent with a product' s FDA- approved labeling. Marketing ExclusivityMarket exclusivity provisions under the FDCA can delay the acceptance by the FDA for review, or the approval, of certain marketing applications. The FDCA provides a five- year period of non- patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (" ANDA "), or ~~52an~~ **an** NDA submitted under Section 505 (b) (2), or 505 (b) (2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original reference drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be accepted for review after four years if it contains a certification of patent invalidity or non- infringement to one of the patents listed with the FDA for the reference drug. The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or ~~sponsored~~ **44sponsored** by the applicant are deemed by the FDA to be essential to the approval of the application, such as new indications, dosages or strengths of an existing drug. This three- year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving abbreviated NDAs or 505 (b) (2) NDAs for drugs containing the active agent for the original indication or condition of use. Five- year and three- year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well- controlled clinical ~~trials~~ **studies** necessary to demonstrate safety and effectiveness. Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical ~~trials~~ **studies** in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical ~~trials~~ **studies** . Other U. S. Regulatory MattersManufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services (" CMS "), other divisions of the Department of Health and Human Services, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, the activities of pharmaceutical manufacturers are subject to federal and state laws designed to prevent fraud and abuse in the healthcare industry. The laws generally limit financial interactions between manufacturers and health care providers or other participants in the healthcare industry and / or require disclosure to the government and public of such interactions. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Pharmaceutical manufacturers are also required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. Participation in such programs may require tracking and reporting of certain drug prices. Manufacturers are subject to fines and other penalties if such prices are not reported accurately. Drugs must meet applicable child- resistant packaging requirements under the U. S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws. The distribution of pharmaceutical drugs is subject to additional requirements and regulations, including extensive record- keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical drugs. The failure to comply with regulatory requirements subjects manufacturers to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines, civil monetary or other penalties, injunctions, recall or seizure of drugs, total or partial suspension of production, denial or withdrawal of product approvals, additional regulatory oversight and integrity monitoring, exclusion from participation in government healthcare programs or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with ~~53FDA~~ -- **FDA** and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way. Chinese Regulation of Pharmaceutical Product Development and ApprovalSince China' s entry into the World Trade Organization in 2001, the Chinese government has made significant efforts to standardize regulations, develop its pharmaceutical regulatory system and strengthen intellectual property protection. ~~In~~ **45In** October 2017, China' s drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Office of the Communist Party of China Central Committee jointly issued the Opinion on Deepening the Reform of the Regulatory Approval System to Encourage Innovation in Drugs and Medical Devices, or the Innovation Opinion, which is a

mandatory plan to further reform the review and approval system and to encourage the innovation of drugs and medical devices. Under the Innovation Opinion and other recent reforms, the expedited programs and other advantages encourage drug manufacturers to seek marketing approval in China first and to develop drugs in high priority disease areas, such as oncology or rare disease. To implement the regulatory reform introduced by the Innovation Opinion, the Standing Committee of the National People' s Congress of the PRC (" SCNPC ") and the National Medical Products Administration (" NMPA ") have revised the fundamental laws, regulations and rules governing pharmaceutical products and the pharmaceutical industry, including the amendment of the framework law known as the People' s Republic of China Drug Administration Law (" PRC Drug Administration Law "), which became effective on December 1, 2019. The State Administration for Market Regulation (" SAMR ") has promulgated two key implementing regulations for the PRC Drug Administration Law: (i) the amended Administrative Measures for Drug Registration and (ii) the amended Measures on the Supervision and Administration of the Manufacture of Drugs. Both regulations took effect on July 1, 2020. Rest of the World Regulation of Pharmaceutical Product Development and ApprovalFor other countries outside of Asia and the United States, such as countries in Europe, Latin America or other parts of Asia, the requirements governing the conduct of clinical ~~trials~~ **studies** , drug licensing, pricing and reimbursement vary from country to country. In all cases the clinical ~~trials~~ **studies** must be conducted in accordance with applicable GCP requirements and the applicable regulatory requirements and ethical principles. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Other Healthcare LawsOther U. S. Healthcare LawsWe may also be subject to healthcare regulation and enforcement by the U. S. federal government and the states where we may market our drug candidates, if approved. These laws include, without limitation, state and federal anti- kickback, fraud and abuse, false claims, privacy and security and transparency laws, such as the following: ● federal Anti- Kickback Statute, which prohibit, among other things, persons from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal 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; ~~54~~ ● federal false claims laws, including the False Claim Act and the Civil Monetary Penalties Law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third- party payors that are false or fraudulent. In addition, a claim including items or services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act; ● the federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program (including private health plans) or making false statements relating to healthcare matters. ~~Similar~~ **46Similar** 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; ● the Federal Food, Drug, and Cosmetic Act (" FDCA "), which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for off- label use and regulates the distribution of samples; ● 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; ● the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to ~~the~~ CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (" HITECH "), and their implementing regulations, imposes obligations, including mandatory contractual terms, on " covered entities, " including certain healthcare providers, health plans, healthcare clearinghouses, and their respective " business associates, " and their subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ● state law equivalents of the above federal laws, such as anti- kickback and false claims laws, which may apply to items or services reimbursed by any third- party payor, including private insurers, state transparency laws, state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts. We may also be subject to federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers. Efforts to ensure that our activities comply with applicable healthcare laws may involve substantial costs. Many of these laws and their implementing regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to challenge. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we could be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, additional regulatory oversight and integrity monitoring, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. ~~55Coverage~~ -- **Coverage** and ReimbursementU. S. Coverage and ReimbursementSuccessful sales of our drug candidates in the U. S. market, if approved, will depend, in part, on the extent to which our drugs will be covered by third- party payors, such as government health programs or private health insurance (including managed care plans). Patients who are

provided with prescriptions as part of their medical treatment generally rely on such third- party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third- party payors are critical to new and ongoing product acceptance. Coverage and reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug ~~products~~ **47products** among third- party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly. Further, third- party payors are increasingly reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage) **. Further, coverage policies and third- party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future** . Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U. S. government, state legislatures and foreign governments have shown significant interest in implementing cost- containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption or expansion of price controls and cost-containment measures could further limit our net revenue and results. Decreases in third- party reimbursement for our drug candidates, if approved, or a decision by a third- party payor to not cover our drug candidates could have a material adverse effect on our sales, results of operations and financial condition. General legislative cost control measures may also affect reimbursement for our products. If we obtain approval to market a drug candidate in the United States, we may be subject to spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs and / or any significant taxes or fees. U. S. Health Care ReformThe United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government- paid healthcare costs, including price- controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, in March 2010, the Affordable Care Act (“ ACA ”) was passed which substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U. S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal health care programs. There have been judicial, Congressional and executive branch challenges **and amendments** to certain aspects of the ACA, including efforts to repeal or replace certain aspects of the ACA. For example, on ~~June 17, 2021 the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. In addition, on~~ August 16, 2022, ~~President Biden signed~~ the Inflation Reduction Act of 2022 (“ IRA ”) **was signed** into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “ donut hole ” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and through a newly established manufacturer discount program. Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries, presidential executive orders and proposed and enacted federal and state ~~56legislation~~ -- **legislation** designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, **the IRA** ~~in July 2021~~ , **among** ~~the~~ **other things** ~~Biden administration released an executive order with multiple provisions aimed at prescription drugs. In response to Biden’ s executive order~~ , **(1) directs** ~~on September 9, 2021,~~ the U. S. Department of Health and Human Services (“ HHS ”) ~~released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs the HHS~~ to negotiate the price of certain **high-expenditure,** single- source drugs ~~and biologics~~ covered under Medicare **that have been on the market for at least 7 years (the “ Medicare Drug Price Negotiation Program ”)** and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~will~~ **began to** take effect progressively ~~starting~~ in fiscal year 2023. On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list~~ **agreed- upon price** of the first ten drugs that **were** ~~will be~~ subject to price negotiations, although the Medicare ~~drug~~ **Drug** ~~price~~ **Price** ~~negotiation~~ **Negotiation** ~~program~~ **Program** is currently subject to legal challenges. ~~In response to the Biden administration’ s October 2022 executive order, on February 14, 2023,~~ HHS ~~released a report outlining three new models~~ **will select up to fifteen additional drugs covered under Part D** for ~~testing by the CMS Innovation Center which~~ **price negotiation in 2025. Each year 48thereafter more Part B and Part D products** will ~~be evaluated on~~ **become subject to** ~~their~~ -- **the Medicare Drug Price Negotiation Program** ~~ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future~~ . Further, on December 7, 2023, ~~the Biden administration announced~~ an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act **was announced** . On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework **. Additional healthcare reform initiatives may be adopted in the future, particularly in light of the upcoming recent U. S. presidential and Congressional elections** . Other Significant Chinese Regulation Affecting Our Business Activities in ChinaChinese Regulation of Foreign InvestmentThe establishment, operation and management of corporate entities in China are governed by the Company Law of the People’ s Republic of China (the “

PRC Company Law "), which was adopted by the SCNPC in December 1993, implemented in July 1994, and subsequently amended in December 1999, August 2004, October 2005, December 2013 and October 2018. Under the PRC Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The PRC Company Law also applies to foreign- invested limited liability companies. ~~Pursuant to the PRC Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail.~~ The most recent amendment of the PRC Company Law was adopted in December 2023 and ~~will come~~ **came** into effect on July 1, 2024, which introduced multiple updates to the current PRC Company Law with regard to, among others, the capital contribution liability, corporate governance structure and responsibilities of directors, supervisors, senior managers, controlling shareholders and actual controllers. Investment activities in China by foreign investors are governed by the Guiding Foreign Investment Direction, which was promulgated by the State Council on February 11, 2002 and came into effect on April 1, 2002, and the latest Special Administrative Measures (Negative List) for Foreign Investment Access (~~2021~~ **2024**) (the " Negative List "), which was promulgated by the Ministry of Commerce of the People' s Republic of China (" MOFCOM "), and National Development and Reform Commission (" NDRC "), on ~~December 27~~ **September 26** , ~~2021~~ **2024** and took effect on ~~January~~ **November** 1, ~~2022~~ **2024** . The Negative List set out in a unified manner the restrictive measures, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited for foreign investment. The Negative List covers ~~12~~ **11** industries, and any field not falling in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment. The Foreign Investment Law of the People' s Republic of China (the " Foreign Investment Law ") was promulgated by the National People' s Congress (" NPC ") in March 2019 and became effective in January 2020. After the Foreign Investment Law came into force, the Law on Wholly Foreign- Owned Enterprises of the People' s Republic of China, the Law on Sino- foreign Equity Joint Ventures of the People' s Republic of China and the Law on Sino- foreign Contractual Joint Ventures of the People' s Republic of China ~~57have --~~ **have** been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as foreign investors) directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law, including: (i) establishing by foreign investors of foreign- invested enterprises in China alone or jointly with other investors; (ii) acquiring by foreign investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; (iii) investing by foreign investors in new projects in China alone or jointly with other investors; (iv) other forms of investment prescribed by laws, administrative regulations or the State Council. In December 2019, the State Council issued the Regulations on Implementing the Foreign Investment Law, which came into effect in January 2020. After the Regulations on Implementing the Foreign Investment Law came into effect, the Regulation on Implementing the Sino- Foreign Equity Joint Venture Enterprise Law, Provisional Regulations on the Duration of Sino- Foreign Equity Joint Venture Enterprise, the Regulations on Implementing the Wholly Foreign- Owned Enterprise Law and the Regulations on Implementing the Sino- Foreign Cooperative Joint Venture Enterprise Law have been repealed simultaneously. ~~In~~ **49In** December 2019, the MOFCOM and the SAMR issued the Measures for the Reporting of Foreign Investment Information, which came into effect in January 2020. After the Measures for the Reporting of Foreign Investment Information came into effect, the Interim Measures on the Administration of Filing for Establishment and Change of Foreign Investment Enterprises has been repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign- invested enterprises shall submit investment information to the relevant commerce administrative authorities pursuant to these measures. Chinese Regulation of Commercial BriberyPursuant to specific provisions in the amended People' s Republic of China Anti- Unfair Competition Law, commercial bribery is prohibited. Both the bribe giver and bribe recipient are subject to civil and criminal liability. Further, pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by its provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry, which became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for the establishment of Adverse Records of Commercial Briberies. If a pharmaceutical company is listed in the Adverse Records of Commercial Briberies for the first time, their production is not required to be purchased by public medical institutions. A pharmaceutical company will not be penalized by the relevant Chinese government authorities merely by virtue of having contractual relationships with distributors or third- party promoters who are engaged in bribery activities, so long as such pharmaceutical company and its employees are not utilizing the distributors or third- party promoters for the implementation of, or acting in conjunction with them in, the prohibited bribery activities. In addition, a pharmaceutical company is under no legal obligation to monitor the operating activities of its distributors and third- party promoters, and it will not be subject to penalties or sanctions by relevant Chinese government authorities as a result of failure to monitor their operating activities. Chinese Regulation of Product LiabilityIn addition to the strict new drug approval process, certain Chinese laws have been promulgated to protect the rights of consumers and to strengthen the control of medical products in China. Under current Chinese law, manufacturers and vendors of defective products in China may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of the People' s Republic of China (" PRC Civil Law ") promulgated on April 12, 1986 and amended on August 27, 2009, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. The Civil Code of the People' s Republic of China (" PRC Civil Code "), which was promulgated in May 2020 and became effective on January 1, 2021, amalgamates and replaces a series of specialized laws in civil law area, including the PRC Civil Law. The rules on product liability in the PRC Civil Code remain consistent with the rules in the PRC Civil Law. ~~58On~~ **On** February 22, 1993, the Product Quality Law of the People' s Republic of China (" Product Quality Law ") was promulgated to supplement the PRC Civil Law aiming to protect the legitimate rights and interests of the end- users and consumers and to strengthen the supervision and control of the quality of products. The

Product Quality Law was revised on July 8, 2000, August 27, 2009 and December 29, 2018 respectively. Pursuant to the revised Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked. The Law of the People' s Republic of China on the Protection of the Rights and Interests of Consumers was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. According to which, all business operators must comply with this law when they manufacture or sell goods and / or provide services to customers. Under the amendment on October 25, 2013, all business operators shall pay high attention to protect the customers' privacy and strictly keep confidential any consumer information they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators ~~may~~ **50may** be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties. Chinese Tort LawUnder the Tort Law of the People' s Republic of China (" Tort Law "), which became effective on July 1, 2010, if damages to other persons are caused by defective products due to the fault of a third party, such as the parties providing transportation or warehousing, the producers and the sellers of the products have the right to recover their respective losses from such third parties. If defective products are identified after they have been put into circulation, the producers or the sellers shall take remedial measures such as the issuance of a warning, or the recall of products in a timely manner. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages. The PRC Civil Code amalgamated and replaced the Tort Law effective January 1, 2021. The rules on tort in the PRC Civil Code are generally consistent with the Tort Law. Chinese Regulation of Intellectual Property RightsChina has made substantial efforts to adopt comprehensive legislation governing intellectual property rights, including patents, trademarks, copyrights and domain names. PatentsPursuant to the Patent Law of the People' s Republic of China (the " PRC Patent Law "), most recently amended in December 2008 and October 2020, and its implementation rules, most recently amended in January 2024, patents in China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility models and designs are effective for ten and fifteen years, respectively, from the date of application. The PRC Patent Law adopts the principle of " first- to- file " system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first. Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity, and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the PRC Patent Law, novelty means that before a patent application is filed, no ~~59identical~~ -- **identical** invention or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the China National Intellectual Property Administration (" CNIPA "). Normally, the CNIPA publishes an application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the CNIPA for a substantive examination within three years from the date of application. Article 19 of the PRC Patent Law provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, ~~must~~ **51must** first submit it to the CNIPA for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. The PRC Patent Law also sets up the framework and adds the provisions for patent linkage and patent term extension. Patent EnforcementUnauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offenses such as forgery of patents may be subject to criminal penalties. When a dispute arises out of infringement of the patent owner' s patent right, Chinese law requires that the parties first attempt to settle the dispute through mutual consultation. However, if the dispute cannot be settled through mutual consultation, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A Chinese court may issue a preliminary injunction upon the patent owner' s or an interested party' s request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement, or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the calculation standards referenced above. The damage calculation methods shall be applied in the aforementioned order. Generally, the patent owner has the burden of proving that the patent is being infringed. However, if the owner of an invention patent for manufacturing process of a new product alleges infringement of its patent, the alleged infringer has the burden of proof. The most recent amendment to the PRC Patent Law, which was promulgated by the SCNPC in October 2020 and became effective in June 2021, describes the general principles of linking generic drug applications to pharmaceutical patent protection,

also known as Patent Linkage. In July 2021, the NMPA and the CNIPA jointly published the Measures for Implementing an Early- Stage Resolution Mechanism for Pharmaceutical Patent Disputes (Tentative) (“ Measures on Patent Linkage ”), providing an operating mechanism for Patent Linkage. Upon notification of generic applications and certifications, if the patentee or the interested person disagrees, the patentee or the interested person will need to file a claim with the court or the CNIPA within 45 days after the Center for Drug Evaluation (“ CDE’ s ”) publication and must submit a copy of the case acceptance notification to the CDE within 15 working days after the case acceptance date. Otherwise, the NMPA can proceed with the technical review and approval. For chemical drugs, the NMPA would initiate a nine- month approval stay period upon notification. If the patentee or the interested person cannot secure a favorable court judgment or a decision from the CNIPA within the nine- month period, the NMPA can grant marketing authorization to the generic applicant after the nine- month period expires. ~~60Medical~~ **Medical** Patent Compulsory LicenseAccording to the PRC Patent Law, for the purpose of public health, the CNIPA may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which China has acceded. Exemptions for Unlicensed Manufacture, Use, Sale or Import of Patented ProductsThe PRC Patent Law provides five exceptions permitting the unauthorized manufacture, use, sale or import of patented products. None of following circumstances are deemed an infringement of the patent rights, and any person may manufacture, use, sell or import patented products without authorization granted by the patent owner as follows: ● Any person who uses, promises to sell, sells or imports any patented product or product directly obtained in accordance with the patented methods after such product is sold by the patent owner or by its licensed entity or individual; **52** ● Any person who has manufactured an identical product, has used an identical method or has made necessary preparations for manufacture or use prior to the date of patent application and continues to manufacture such product or use such method only within the original scope; ● Any foreign transportation facility that temporarily passes through the territory, territorial waters or territorial airspace of China and uses the relevant patents in its devices and installations for its own needs in accordance with any agreement concluded between China and that country to which the foreign transportation facility belongs, or any international treaty to which both countries are party, or on the basis of the principle of reciprocity; ● Any person who uses the relevant patents solely for the purposes of scientific research and experimentation; or ● Any person who manufactures, uses or imports patented drug or patented medical equipment for the purpose of providing information required for administrative approval, or manufactures, uses or imports patented drugs or patented medical equipment for the abovementioned person. However, if patented drugs are utilized on the ground of exemptions for unauthorized manufacture, use, sale or import of patented drugs prescribed in PRC Patent Law, such patented drugs cannot be manufactured, used, sold or imported for any commercial purposes without authorization granted by the patent owner. Trade SecretsAccording to the People’ s Republic of China Anti- Unfair Competition Law promulgated by the SCNPC on September 2, 1993, as amended on November 4, 2017 and on April 23, 2019 (collectively, the “ PRC Anti- Unfair Competition Law ”), the term “ trade secrets ” refers to technical and business information that is unknown to the public that has utility and may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti- Unfair Competition Law, business persons are prohibited from infringing others’ trade secrets by: (i) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (ii) disclosing, using or permitting others to use the trade secrets obtained illegally under item (i) above; (iii) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (iv) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder’ s requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of such illegal conduct but nevertheless obtains, uses or discloses trade secrets of others trade secrets, the third party may be deemed to have committed a misappropriation of the others’ trade secrets. ~~61Trademarks~~ **Trademarks** and Domain NamesTrademarks. According to the Trademark Law of the People’ s Republic of China, promulgated by the SCNPC in August 1982, as amended in February 1993, October 2001, August 2013 and April 2019 and its implementation rules (collectively, the “ Trademark Law ”), the Trademark Office of the National Intellectual Property Administration is responsible for the registration and administration of trademarks throughout China. The Trademark Law has adopted a “ first- to- file ” principle with respect to trademark registration. Domain Names. Domain names are protected under the Administrative Measures on the Internet Domain Names promulgated by the Ministry of Industry and Information Technology in August 2017 and effective November 2017. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of Chinese internet domain names. **53Chinese Regulation of Labor ProtectionOn July 10, 2021, the Cybersecurity Administration of China (the “ CAC ”) published a draft revision to the existing Cybersecurity Review Measures for public comment (the “ Revised Draft CAC Measures ”). On January 4, 2022, together with 12 other Chinese regulatory authorities, the CAC released the final version of the Revised Draft CAC Measures (the “ Revised CAC Measures ”), which came into effect on February 15, 2022. Pursuant to the Revised CAC Measures, critical information infrastructure operators procuring network products and services, and online platform operators (as opposed to “ data processors ” in the Revised Draft CAC Measures) carrying out data processing activities which affect or may affect national security, shall conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review. On November 14, 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment) for public comment. On September 24, 2024, the State Council released the final version of the Draft Management Regulations (the “ Management Regulations ”), which came into effect on January 1, 2025. Under the Management Regulations, online data processors refer to individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion. The Management Regulations reiterate that online data processors shall be subject to national security**

review pursuant to relevant provisions if they carry out data processing activities which affect or may affect national security. As of the date of this Annual Report, we have not received any notice from any Chinese regulatory authority identifying us as a " critical information infrastructure operator, " " online platform operator ", " online platform service provider " or " online data processor, " or requiring us to go through the cybersecurity review procedures pursuant to the Revised CAC Measures and the Management Regulations. Based on our understanding of the Revised CAC Measures and the Management Regulations, we do not expect to become subject to cybersecurity review by the CAC for issuing securities to foreign investors because: (i) the clinical and preclinical data we handle in our business operations, either by its nature or in scale, do not normally trigger significant concerns over Chinese national security; and (ii) we have not processed, and do not anticipate to process in the foreseeable future, personal information for more than one million users or persons. However, there remains uncertainty as to how the Revised CAC Measures and the Management Regulations will be interpreted or implemented. For example, neither the Revised CAC Measures nor the Management Regulations provides further clarification or interpretation on the criteria for determining those activities that " affect or may affect national security " and relevant Chinese regulatory authorities may interpret it broadly. Furthermore, there remains uncertainty as to whether the Chinese regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Revised CAC Measures and the Management Regulations. While we intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Revised CAC Measures, the Management Regulations or other laws and regulations related to privacy, data protection and information security. For additional information, see the sections titled " Risk Factors — Risks Related to Doing Business in China and Our International Operations — Compliance with China' s new Data Security Law, Cybersecurity Review Measures, Personal Information Protection Law, regulations and guidelines relating to the multi- level protection scheme on cyber security and any other future laws and regulations may entail significant expenses and could affect our business " and " Risk Factors — Risks Related to Doing Business in China and Our International Operations — The approval of, filing or other procedures with the CSRC or other Chinese regulatory agencies may be required in connection with issuing securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures " in this Annual Report. Chinese Regulation of Labor ProtectionUnder the Labor Law of the People' s Republic of China, effective on January 1, 1995 and subsequently amended on August 27, 2009 and December 29, 2018, the Employment Contract Law of the People' s Republic of China, effective on January 1, 2008 and subsequently amended on December 28, 2012 and the Implementing Regulations of the Employment Contract Law, effective on September 18, 2008, employers ~~must~~ **54must** establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions as requested by the Labor Contract Law of the People' s Republic of China. Pursuant to the Law of Manufacturing Safety of the People' s Republic of China effective on November 1, 2002 and amended on August 27, 2009, August 31, 2014 and June 10, 2021, manufacturers must establish a comprehensive management system to ensure manufacturing safety in accordance with applicable laws, regulations, national standards, and industrial standards. Manufacturers not meeting relevant legal requirements are not permitted to commence their manufacturing activities. Pursuant to the Administrative Measures Governing the Production Quality of Pharmaceutical Products effective on March 1, 2011, manufacturers of pharmaceutical products are required to establish production safety and labor protection measures in connection with the operation of their manufacturing equipment and manufacturing process. Pursuant to applicable Chinese laws, rules and regulations, including the Social Insurance Law which became effective on July 1, 2011 and amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds, which became effective on January 22, 1999 and amended on March 24, 2019, Interim Measures concerning the Maternity Insurance of Employees, which became effective on January 1, 1995, and the Regulations on Work- related Injury Insurance, which became effective on January 1, 2004 and was subsequently amended on December 20, 2010, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, work- related injury insurance and maternity insurance. If an employer fails to make social insurance contributions timely and in full, the social insurance collecting authority will order the employer to make up outstanding contributions within the prescribed time period and impose a late payment fee at the rate of 0. 05 % per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount. Regulations Relating to Foreign Exchange Registration of Offshore Investment by Chinese ResidentsIn July 2014, the State Administration of Foreign Exchange (" SAFE "), issued SAFE Circular 37 and its implementation guidelines. Pursuant to SAFE Circular 37 and its implementation guidelines, residents of ~~62China~~ -- **China** (including Chinese institutions and individuals) must register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle (" SPV "), directly established or indirectly controlled by Chinese residents for the purposes of offshore investment and financing with their legally owned assets or interests in domestic enterprises, or their legally owned offshore assets or interests. Such Chinese residents are also required to amend their registrations with SAFE when there is a change to the basic information of the SPV, such as changes of a Chinese resident individual shareholder, the name or operating period of the SPV, or when there is a significant change to the SPV, such as changes of the Chinese individual resident' s increase or decrease of its capital contribution in the SPV, or any share transfer or exchange, merger, division of the SPV. Failure to comply with the registration

procedures set forth in the SAFE Circular 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, the capital inflow from the offshore entities and settlement of foreign exchange capital, and may also subject relevant onshore companies or Chinese residents to penalties under Chinese foreign exchange administration regulations. Regulations Relating to Employee Stock Incentive PlanIn February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the **55** " Stock Option Rules "). In accordance with the Stock Option Rules and relevant rules and regulations, Chinese citizens or non-Chinese citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are Chinese citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan are subject to such regulation. In addition, the State Taxation Administration of the PRC, or SAT, has issued circulars concerning employee stock options or restricted shares. Under these circulars, employees working in China who exercise stock options, or whose restricted shares vest, will be subject to Chinese individual income tax (" IIT "). The Chinese subsidiaries of an overseas listed company have obligations to file documents related to employee stock options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their stock options or restricted shares. If the employees fail to pay, or the Chinese subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the Chinese subsidiaries may face sanctions imposed by the tax authorities or other Chinese government authorities. Regulations Relating to Dividend DistributionPursuant to the PRC Company Law and Foreign Investment Law, and Regulations on Implementing the Foreign Investment Law of the People' s Republic of China, foreign investors may freely remit into or out of China, in RMB or any other foreign currency, their capital contributions, profits, capital gains, income from asset disposal, intellectual property royalties, lawfully acquired compensation, indemnity or liquidation income and so on within the territory of China. In January 2017, SAFE issued the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall provide detailed explanations of the sources of capital and the utilization arrangements and board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.
~~63Regulations~~ -- **Regulations** Relating to Foreign ExchangeThe principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations, most recently amended in August 2008. Under the Foreign Exchange Administration Regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency- denominated loans. In August 2008, SAFE issued the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign- Invested Enterprises (" SAFE Circular 142 "), regulating the conversion by a foreign- invested enterprise of foreign currency- registered capital into RMB by restricting how the converted RMB may be used. SAFE Circular 142 provides that the RMB capital converted from foreign currency registered capital of a foreign- invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investments within China. SAFE also strengthened its oversight of the flow and use of the RMB capital converted from foreign currency registered capital of foreign- invested enterprises. The use of such RMB capital may not be changed without SAFE' s approval, and such RMB capital may not in any case be used to repay RMB loans if the proceeds of such loans have not been used. In March 2015, SAFE issued the Circular of the State Administration of Foreign Exchange on Reforming the ~~Management~~ **56Management** Approach regarding the Settlement of Foreign Exchange Capital of Foreign- invested Enterprises (" SAFE Circular 19 "), which became effective and replaced SAFE Circular 142 on June 1, 2015. Although SAFE Circular 19 allows for the use of RMB converted from the foreign currency- denominated capital for equity investments in China, the restrictions continue to apply as to foreign-invested enterprises' use of the converted RMB for purposes beyond the business scope, for entrusted loans or for inter-company RMB loans. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (" SAFE Circular 16 "), effective on June 9, 2016, which reiterates some of the rules set forth in SAFE Circular 19, but changes the prohibition against using RMB capital converted from foreign currency- denominated registered capital of a foreign- invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to unassociated enterprises. On December 4, 2023, SAFE promulgated the Notice of the State Administration of Foreign Exchange on Further Deepening the Reform and Promoting Facilitation of Cross- border Trade and Investment (" SAFE Circular 28 "), which further updates the restrictions on use of RMB converted from the foreign currency- denominated capital. Violations of SAFE Circular 19, SAFE Circular 16 or SAFE Circular 28 could result in administrative penalties. The Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment was promulgated by SAFE in November 2012 and amended in May 2015, which substantially amends and simplifies the current foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts (e. g., pre- establishment expenses accounts, foreign exchange capital accounts and guarantee accounts), the reinvestment of lawful incomes derived by foreign investors in China (e. g., profit, proceeds of equity transfer, capital reduction, liquidation and early repatriation of investment), and purchase and remittance of

foreign exchange as a result of capital reduction, liquidation, early repatriation or share transfer in a foreign- invested enterprise no longer require SAFE approval, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible before. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in China shall be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in China based on the registration information provided by SAFE and its branches. In February 2015, SAFE promulgated the Circular on Further Simplifying and Improving the Policies Concerning Foreign Exchange Control on Direct Investment (" SAFE Circular 13 "), which took effect on ~~64June~~ -- **June** 1, 2015. SAFE Circular 13 delegates the authority to enforce the foreign exchange registration in connection with the inbound and outbound direct investment under relevant SAFE rules to certain banks and therefore further simplifies the foreign exchange registration procedures for inbound and outbound direct investment. Regulations on Securities Offering and Listing Outside of ChinaOn **July 6, 2021, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly issued the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law. These opinions call for strengthened regulation over illegal securities activities and increased supervision of overseas listings by China- based companies, and propose to take effective measures, such as promoting the construction of relevant regulatory systems to regulate the risks and incidents faced by China- based overseas- listed companies. On** February 17, 2023, the **China Securities Regulatory Commission (" CSRC ")** promulgated a new set of regulations consisting of the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (the " Trial Measures ") and five supporting guidelines which came into effect on March 31, 2023 to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form. ~~The~~ **57The** Trial Measures and supporting guidelines apply to overseas offerings by domestic companies of equity shares, depositary receipts, convertible corporate bonds, or other equity- like securities, and overseas listing of the securities for trading. Both direct and indirect overseas securities offering and listing by domestic companies would be regulated, of which the former refers to securities offering and listing in an overseas market made by a joint- stock company incorporated domestically, and the latter refers to securities offering and listing in an overseas market made in the name of an offshore entity, while based on the underlying equity, assets, earnings or other similar rights of a domestic company which operates its main business domestically. According to the Trial Measures, if an issuer meets the following conditions, the offering and listing shall be determined as an indirect overseas offering and listing by a domestic company: (i) the total assets, net assets, revenues or gross profits of the domestic company (ies) of the issuer in the most recent financial year account for more than 50 % of the corresponding figure in the issuer' s audited consolidated financial statements over the same period; (ii) the majority of the senior management in charge of business operation and management of the issuer are Chinese citizens or habitually reside in China, or its main places of business operation are located in China or main parts of its business activities are conducted in China. Under the Trial Measures and supporting guidelines, a filing- based regulatory system was implemented covering both direct and indirect overseas offering and listing. For an indirect initial public offering and listing in an overseas market, the issuer shall designate a major domestic operating entity to submit the filing documents to the CSRC, including but not limited to the prospectus within three working days after such application of overseas offering and listing is submitted. The CSRC would, within 20 working days if filing documents are complete and in compliance with the stipulated requirements, complete the filing and publish the filing information on the CSRC' s official website. While for confidential filings of overseas offering and listing application documents, the designated filing entity may apply for an extension of the publication of such filing. The issuer shall report to the CSRC within three working days after the overseas offering and listing application documents become public. In addition, subsequent securities offerings of an issuer in the same overseas market where it has previously offered and listed securities shall be filed with the CSRC within three working days after the offering is completed. Meanwhile, overseas offering and listing would be prohibited under certain circumstances, including but not limited to that (i) the offering and listing are expressly forbidden by the Chinese laws, regulations and relevant rules; (ii) the intended overseas securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws or (iii) there are material disputes with regard to the ownership of the equity held by the domestic company' s controlling shareholder or by other shareholders that are controlled by the controlling shareholder and / or actual controller. If a domestic company falls into the circumstances where overseas offering and listing is prohibited prior to the overseas offering and listing, the domestic company shall postpone or terminate the intended overseas offering and listing, and report to the CSRC and competent authorities under the State Council in a timely manner. If domestic companies fail to fulfill the above- mentioned filing procedures or offer and list in an overseas market against the prohibited circumstances, they would be warned and fined up to RMB 10 million. The controlling shareholders and actual controllers of such domestic companies that organize or instruct the ~~65aforementioned~~ -- **aforementioned** violations would be fined up to RMB10 million and directly liable persons- in- charge and other directly liable persons would be each fined up to RMB 5 million. Other Chinese National- and Provincial- Level Laws and RegulationsWe are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients' medical information and the circumstances under which patient medical information may be released for inclusion in our databases, or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future. ~~Employees~~ **58Employees** and Human Capital ResourcesAs of December 31, ~~2023~~ **2024**, we had ~~93~~ **163** full- time employees, ~~35~~ **57** of whom have a Ph. D. or M. D. Of these ~~93~~ **163** employees, ~~66~~ **119** were engaged in research and development activities and ~~27~~ **44** were engaged in business development, finance, information systems, facilities, human resources or administrative support. ~~Four~~ **Seven** of the non- research and development- based employees were based in Shanghai, China and one based in

the UK, while the other ~~22~~ **36** resided in the United States. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity- based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. Corporate InformationWe are a Cayman Islands exempted company incorporated with limited liability. We were initially formed as a Delaware ~~corporation~~ **limited liability company** in 2016 under the name ShouTi Inc., and reorganized as a Cayman Islands exempted company in **February** 2019 ~~. We completed our IPO on February 7, 2023, and our ADS began trading on the Nasdaq Global Market on February 3, 2023~~ . Our principal executive office is located at 601 Gateway Blvd., Suite 900, South San Francisco, California 94080 and our telephone number is (~~628~~ **650**) ~~229~~ **457** - ~~9277~~ **1978** . The principal executive office of our research and development operations is located at Unit 01, 11th floor, Lane 2889, Jinke Road, Pudong New Area, Shanghai, People' s Republic of China, 201203. Our telephone number at this address is 86 21 61215839. Our current registered office in the Cayman Islands is located at the offices of International Corporation Services Ltd., P. O ~~,~~ **.** Box 472, 2nd Floor, Harbour Place, 103 South Church Street, George Town, Grand Cayman KY1- 1106, Cayman Islands. Our website is www. structuretx. com. Information contained on, or accessible through, our website shall not be deemed incorporated into, and is not a part of, this Annual Report. We have included our website in this Annual Report solely as an inactive textual reference. Available InformationOur Annual Report on Form 10- K, Quarterly Reports on Form 10- Q and Current Reports on Form 8- K and amendments to those reports filed or furnished pursuant to Sections 13 (a) or 15 (d) of the Exchange Act are available on our website, free of charge, as soon as reasonably practicable after the reports are electronically filed or furnished to the Securities and Exchange Commission, or SEC. The SEC maintains a website at www. sec. gov that contains reports, proxy and information statements, and other information that we file with the SEC electronically. **We intend to announce material information to the public through filings with the SEC, the investor relations page on our website, which is located at ir. structuretx. com, press releases, public conference calls, and public webcasts. The information disclosed through the foregoing channels could be deemed to be material information. As such, we encourage investors, the media, and others to follow the channels listed above and to review the information disclosed through such channels. The information we post through these channels is not a part of this Annual Report. Any updates to the list of disclosure channels through which we will announce information will be posted on the investor relations page on our website.** ~~66Item --~~ **Item** 1A. Risk Factors. Investing in our securities, involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report, including our consolidated financial statements and their related notes included elsewhere in this Annual ~~Report~~ **59Report** and Part II. Item 7. " Management' s Discussion and Analysis of Financial Condition and Results of Operations " before making an investment decision. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially, the trading price of our ADSs could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may materially and adversely affect our business, prospects, operating results and financial condition. Risks Related to Our Limited Operating History, Financial Position and Capital RequirementsWe have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical ~~-~~stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate the success of our business to date and assess our future viability. Since our inception in 2016, we have focused primarily on organizing and staffing our company, business planning, establishing our intellectual property portfolio, raising capital, developing our structure- based drug discovery platform, identifying and developing our product candidates, conducting preclinical studies and, more recently, clinical ~~trials~~ **studies** , and providing general and administrative support for these operations. Our approach to the discovery and development of product candidates based on our structure- based drug discovery platform is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or commercially. Further, **aleniglipron** ~~GSBR- 1290~~ , our product candidate for ~~T2DM and~~ obesity, **overweight** and **related conditions, ACCG- 2671, our oral small molecule amylin receptor agonist development candidate for the treatment of obesity,** ANPA- 0073, our product candidate for **selective or muscle- sparing weight loss, and LTSE- 2578, our product candidates for** IPF **, and** , are in early clinical development and our other product candidates and programs are in preclinical development or discovery stages. Accordingly, we have not yet demonstrated an ability to successfully obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products. We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses since our inception and expect to continue to incur significant and increasing operating losses for at least the next several years. Our net losses were $ **122. 5 million and $** 89. 6 ~~million and $ 51. 3~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~206~~ **329** . ~~6~~ **1** million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our product candidates will require substantial additional development time and resources **, including additional funding to conduct Phase 3 clinical studies of aleniglipron,** before we would be able to apply for or receive marketing approvals and begin generating revenue

from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate that our expenses will increase substantially as we continue our development of, seek marketing approval for and potentially commercialize any of our product candidates, recruit and maintain key personnel and seek to identify, assess, acquire, in- license or develop additional product candidates. Even if we succeed in developing and obtaining marketing approval for one or more product candidates, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development **(" R & D ")** and other expenditures to develop and market additional product ~~67candidates~~ -- **candidates** . Our failure to become and remain profitable could decrease the value of our ADSs and impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. ~~We~~ **60We** will require substantial additional capital to finance our operations, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development programs, commercialization efforts or other operations. The development of biopharmaceutical product candidates is capital- intensive. We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we conduct our ongoing and planned preclinical studies and clinical ~~trials~~ **studies** of ~~GSBR~~ **aleniglipron, ACCG** - ~~1290~~ **2671** , ANPA- 0073, LTSE- 2578 and any future product candidates we may develop. Our expenses will increase substantially if our product candidates successfully complete early clinical and other studies, and also could increase beyond expectations if the FDA or foreign authorities require us to perform clinical and other studies in addition to those that we currently anticipate. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. In addition, we have and expect to continue to incur additional costs associated with operating as a public company. Furthermore, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Based on our current operating plan, we believe that our cash, cash equivalents and short- term investments **,** as of December 31, ~~2023~~ **2024 ,** will be sufficient to fund our operating expenses and ~~capital expenditure requirements~~ **key clinical milestones** through at least ~~2026~~ **2027 , including all planned aleniglipron studies for Phase 3 readiness but excluding Phase 3 registrational studies** . We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses and other similar arrangements. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any additional capital raising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and, if approved, commercialize our current and any future product candidates. Additional funding may not be available on acceptable terms, or at all. As a result of actual or anticipated changes in interest rates ~~and~~ **,** economic inflation and **tariffs,** the impact of the Russia / Ukraine conflict and Israel- Hamas war, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, including as a result of future bank failures, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Our future funding requirements will depend on many factors, including: ● the progress, costs, design, results of and timing of our planned and ongoing preclinical studies and clinical ~~trials~~ **studies, including Phase 3 clinical studies of aleniglipron** ; ● the willingness of the FDA or applicable foreign authorities to accept our clinical ~~trials~~ **studies** , as well as data from our planned and ongoing preclinical studies and clinical ~~trials~~ **studies** and other work, as the basis for review and approval of our product candidates; ~~68~~ ● the outcome, costs and timing of seeking and obtaining FDA and applicable foreign regulatory approvals; ● the number and characteristics of product candidates that we pursue; **61** ● our need to expand our research and development capabilities, including further development of our structure- based drug discovery platform or in- licensing of complementary technologies; ● the costs and timing associated with manufacturing our product candidates, and establishing commercial supplies and sales, marketing, and distribution capabilities; ● our efforts to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights; ● our need and ability to retain key management and hire scientific, technical, business, and medical personnel; ● our need to implement additional internal systems and infrastructure, including financial and reporting systems; ● the costs associated with operating as a public company; ● the economic and other terms, timing of and success of our current and any future collaboration, licensing or other arrangements which we may enter in the future; and ● the timing, receipt, and amount of sales from our potential products, if approved. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, and our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations. Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. For example, in October

2023, we issued and sold an aggregate of 21, 617, 295 ordinary shares and 2, 401, 920 newly designated non- voting ordinary shares in the Private Placement **. In June 2024, we issued and sold an aggregate of 10, 427, 017 ADSs in the Follow- On Offering** . To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our ADS holders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as limitations on our ability to incur additional debt, make capital expenditures or declare dividends. If we raise funds through collaborations or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. Risks Related to the Discovery, Development and Regulatory Approval of Product CandidatesOur approach to the discovery of product candidates based on our technology platform is unproven, and we do not know whether we will be able to develop any products of commercial value. The success of our business depends primarily upon our ability to identify novel product candidates based on our structure- based drug discovery platform and to successfully develop and commercialize those product candidates. While we have had favorable preclinical study **and topline clinical trial** results for certain of our development programs, ~~69we~~ **we** have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical ~~trials~~ **studies** or in obtaining marketing approvals or in commercializing such product candidates. We also may be unsuccessful in identifying additional product candidates using our ~~platform~~ **62platform** , and any of our product candidates may be shown to have harmful side effects or may have other characteristics that may necessitate additional clinical testing, or make the product candidates unmarketable or unlikely to receive marketing approval. In particular, because all of our product candidates have been derived from our structure- based drug discovery platform, any failure of one of our development programs could create a perception that our other programs are less likely to succeed or that our discovery platform is not viable. Similarly, adverse developments with respect to other companies that attempt to use a similar approach to our approach may adversely impact the actual or perceived value and potential of our discovery platform and resulting product candidates. If any of these events occur, our ability to successfully discover, develop and commercialize any product candidates may be impaired and the value of our company could decline significantly. We are early in our development efforts and only have ~~two~~ **four** product candidates, ~~GSBR~~ **aleniglipron, ACCG** - ~~1290 and~~ **2671,** ANPA- 0073 **and LTSE- 2578** , in early clinical development. All of our other development programs are in the preclinical or discovery stage. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed. We are in the early stages of our development efforts and have ~~two~~ **four** product candidates, ~~GSBR~~ **aleniglipron, ACCG** - ~~1290 and~~ **2671,** ANPA- 0073 **and LTSE- 2578** , in early clinical development. **In June** ~~We completed a Phase 1 SAD study of GSBR- 1290 in healthy volunteers in September 2022~~ **2024** ~~for T2DM and obesity. Furthermore~~ , we **reported positive topline data from our** ~~initiated the Phase 1b MAD study in January 2023 and completed dosing in otherwise healthy overweight subjects in March 2023. We also initiated the dosing of the~~ Phase 2a **obesity** study ~~in May 2023. We reported topline data for the 28- day Phase 1b MAD study in September 2023~~ , in which **aleniglipron** ~~GSBR- 1290 was generally well- tolerated with no adverse event- related discontinuations and~~ demonstrated **a clinically meaningful** ~~an~~ **and statistically** ~~encouraging safety profile and~~ significant **placebo- adjusted mean decrease in** weight **of 6** ~~loss up to 4~~ . ~~9~~ **2** % ~~placebo- adjusted, supporting once- daily dosing. We also reported topline data for the 12- week Phase 2a clinical trial in December 2023, in which GSBR- 1290 was generally well- tolerated with no treatment- related SAEs, no AE- related discontinuation in obesity and only one adverse event- related discontinuation in T2DM. Furthermore, GSBR- 1290 demonstrated significant reductions in HbA1c and weight~~ at 12 weeks ~~in T2DM~~ **(p < 0** . ~~We further~~ **0001, using least- squares means (" LSM ") and analyzed based on the primary efficacy estimand using a mixed model for** ~~reported~~ **repeated measures) and** ~~interim Phase 2a obesity cohort data, in which GSBR- 1290~~ demonstrated **generally favorable safety and tolerability** ~~significant reductions in weight at 8 weeks. We expect to report the full 12- week obesity data in the latter half of the second quarter of 2024. We also reported~~ results **following repeated, daily dosing up** ~~from a Japanese ethno- bridging study and findings from 6- and 9- month toxicology studies demonstrating encouraging safety~~ to **120 mg** ~~support advancing into Phase 2b development~~ . **Furthermore, we explored** ~~The additional formulation bridging study to evaluate~~ a **new** tablet formulation of **aleniglipron** ~~GSBR- 1290 is expected to be completed~~ in **a capsule to tablet PK** ~~the latter half of the second quarter of 2024. Pending supportive data from this bridging~~ study, **which demonstrated a placebo- adjusted mean weight loss of up to 6. 9 % with** the tablet formulation ~~would be used in future GSBR- 1290 studies starting with~~ **at 12 weeks (p < 0. 0001, using LSM and analyzed based on** the **primary efficacy estimand using a mixed model for repeated measures). In July 2024, we submitted an IND to the FDA to support the initiation of a** Phase 2b study ~~for~~ **in chronic weight management and received FDA allowance in August 2024. In the fourth quarter of 2024, we initiated the Phase 2b ACCESS study, a randomized, double- blind, placebo- controlled, dose- range finding study of aleniglipron in approximately 220 adult participants living with** obesity ~~and~~ **(BMI ≥ 30 kg / m2), or overweight (BMI ≥ 27 kg / m2) with at least one weight- related comorbidity. Participants start at 5 mg of aleniglipron (or placebo) with a 4- week titration schedule, reaching target doses of 45 mg, 90 mg** ~~an~~ **and** ~~additional~~ **120 mg. The primary endpoint is percent change in body weight from baseline to week 36. Secondary endpoints include safety and tolerability of the monthly titration scheme, as well as PK of aleniglipron. In the fourth quarter of 2024, we initiated a randomized, double- blind, placebo- controlled dose- range finding** Phase 2 study **of aleniglipron, known as ACCESS II, in approximately 82 adult participants living with obesity** ~~for~~ - **or** ~~T2DM~~ **overweight with at least one weight- related comorbidity. The study is designed to evaluate two higher doses of aleniglipron. Participants start at 5 mg of aleniglipron (or placebo) and follow a 4- week titration schedule up to target doses of 120 mg** , ~~which~~ **180 mg and 240 mg. In February 2025, we completed enrollment in the ACCESS and ACCESS II studies, and** we expect to ~~initiate~~ **report topline data from** both **studies** in the ~~second half~~ **fourth quarter** of **2025. In June** 2024 ~~. Additionally~~ , we ~~completed~~

~~our~~ **initiated a** Phase 1 **clinical trial of LTSE** ~~SAD and MAD study for ANPA- 0073~~ **2578. The randomized, double- blind, placebo- controlled first-** in **- human clinical trial is designed to investigate the safety, tolerability and pharmacokinetics of single and multiple ascending doses of LTSE- 2578 in approximately 64** healthy **participants and** ~~volunteers for IPF in September 2022. We~~ expect to **report initial data** ~~conduct additional preclinical studies of ANPA- 0073 for its effects~~ in **2025** ~~selective weight loss~~. Our other product candidates are still in the preclinical or discovery stages. We will need to progress early product candidates through preclinical studies and submit INDs to the FDA or appropriate regulatory documents to applicable foreign authorities prior to initiating their clinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following: **63** ● completion of preclinical studies with favorable results; ● successful enrollment in, and completion of, clinical ~~trials~~ **studies** ; ● sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical ~~trials~~ **studies** ; ~~70~~ ● allowance to proceed with clinical ~~trials~~ **studies** under INDs by the FDA or under similar regulatory submissions by applicable foreign authorities for the conduct of clinical ~~trials~~ **studies** of our product candidates and our proposed design of future clinical ~~trials~~ **studies** ; ● demonstrating the safety and efficacy of our product candidates to the satisfaction of applicable regulatory authorities; ● receipt of regulatory approvals from applicable regulatory authorities, including NDAs from the FDA and maintaining such approvals; ● making arrangements with third- party manufacturers, or establishing clinical and commercial manufacturing capabilities for our product candidates; ● establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; ● establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates; ● acceptance of any products we develop and their benefits and uses, if and when approved, by patients, the medical community and third- party payors; ● effectively competing with other therapies; ● obtaining and maintaining healthcare coverage and adequate reimbursement from third- party payors; ● maintaining an acceptable safety profile of our products following approval; and ● building and maintaining an organization of people who can successfully develop our product candidates. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical ~~trials~~ **studies** or in obtaining marketing approval thereafter. Given our early stage of development, it will take several years before we can demonstrate the safety and efficacy of a product candidate sufficient to warrant approval for commercialization, if we can do so at all. If we are unable to develop, or obtain marketing approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business. Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes. The results of prior clinical ~~trials~~ **studies** and preclinical studies are not necessarily predictive of future results, and may not be favorable, or receive regulatory approval on a timely basis, if at all. Clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Our clinical ~~trials~~ **studies** may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. For example, we depend on the availability of ~~non- human primates (" NHP~~ **NHPs** ~~")~~ to conduct certain preclinical studies that we are required to complete prior to submitting an IND and initiating clinical development. There is currently a global shortage of NHPs available for drug development. This has caused the cost of obtaining NHPs for our preclinical studies to increase dramatically and, if the shortage continues, could also result in delays to our development timelines. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high. Furthermore, the results from clinical ~~trials~~ **studies** or preclinical studies of a product candidate may not predict the results of later clinical ~~trials~~ **studies** of the product candidate, and interim results of a clinical trial are not necessarily indicative of ~~final~~ **64final** results. For example, **the preliminary** ~~in December 2023, we reported~~ topline ~~data from~~ **nature of aleniglipron results and the length of the study and sample size, may render these results not necessarily indicative of the results for** our **future** ~~12- week Phase 2a~~ clinical **studies for aleniglipron** ~~trial, which focused on safety~~ and **may not be comparable** ~~tolerability of GSBR- 1290 in a total of 94 participants~~ to ~~date~~ **other weight loss products or product candidates** , including **other oral selective GLP** ~~60 participants randomized to GSBR- 1290~~ **1RAs** . **In addition** ~~The results showed GSBR- 1290 was generally well- tolerated with no treatment- related SAEs~~ , **given the size of the** ~~no adverse event- related discontinuation in obesity and only one adverse event- related discontinuation in T2DM. Furthermore, GSBR- 1290 demonstrated 71significant reductions in hemoglobin A1c and weight at 12 weeks in T2DM. We further reported interim~~ Phase 2a obesity cohort **, the primary efficacy endpoint of weight loss was calculated using LSM and analyzed based on the primary efficacy estimand using a mixed model for repeated measures. This means that we drew on all available** data, ~~in which GSBR~~ **including data from patients that did not follow** - **up** ~~1290 demonstrated significant reduction in weight~~ at ~~8~~ **12** weeks. ~~Due to the preliminary nature of these results and the length of~~ **The model estimates how patients with missing data would have responded based on patients who continued** the study and **had similar baseline characteristics (implicit imputation)** ~~sample size, these results are not necessarily indicative of the final results for our clinical trials for GSBR- 1290~~ . Product candidates in later stages of clinical ~~trials~~ **studies** may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical ~~trials~~ **studies** . In particular, while we have conducted, or are conducting certain preclinical studies of our product candidates, the predictive value of these studies with respect to future testing in humans is limited, particularly in indications where animal models are less developed. Even if our clinical ~~trials~~ **studies** are completed, the results may not be sufficient to obtain marketing approval for our product candidates. In clinical ~~trials~~ **studies** that are based on preclinical studies and early clinical ~~trials~~ **studies** , it is not uncommon to observe unexpected results, and many product candidates fail in clinical development despite very promising early results. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. In addition, in

some cases, external experts or regulatory authorities disagreed with such companies' views and interpretations of the data and results from earlier preclinical studies or clinical ~~trials~~ **studies** . As we investigate ~~GSBR~~ **aleniglipron and ACCG** - ~~1290~~ **2671** for ~~T2DM and~~ obesity ~~and~~ **,** ANPA- 0073 for **selective and muscle- sparing weight loss, and LTSE- 2578 for** IPF, we may encounter new and unforeseen difficulties. Similarly **,** any future product candidates we may develop may not be able to progress from preclinical to Phase 1 clinical development. For the foregoing reasons, we cannot be certain that our ongoing and planned clinical ~~trials~~ **studies** and preclinical studies will be successful. Any of the foregoing occurrences may harm our business, financial condition and prospects significantly. Any difficulties or delays in the commencement or completion, or termination or suspension, of our planned clinical ~~trials~~ **studies** could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. In order to obtain FDA approval to market our product candidates, we must demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the FDA. To meet these requirements, we will have to conduct adequate and well- controlled clinical **studies. In addition, before we can initiate clinical studies for any product candidate, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical** ~~trials~~ **trial protocol, as part of an IND or similar regulatory submission, and we are also required to submit comparable applications to foreign regulatory authorities for clinical studies outside of the United States. In July 2024, we submitted an IND to the FDA to support initiation of a Phase 2b study of aleniglipron in chronic weight management and received FDA allowance in August 2024. In the fourth quarter of 2024, we initiated the Phase 2b ACCESS study. We dosed the first patient in the ACCESS II study in the fourth quarter of 2024. We may be required to obtain additional FDA approval prior to evaluating aleniglipron at higher doses of 180 mg and 240 mg under our ACCESS II study. Since we have not previously tested these higher doses, we cannot be certain whether they have a favorable safety or tolerability profile. If we are unable to obtain such additional FDA approval, we may not be able to conduct our ACCESS II study as planned** . Clinical testing is expensive, time- consuming and subject to uncertainty. Conducting preclinical studies and clinical ~~trials~~ **studies** represents a lengthy, time- consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical studies may cause us to incur additional operating expenses. ~~Clinical~~ **65Clinical** ~~trials~~ **studies** may not be conducted as planned or completed on schedule, if at all. For example, in September 2023 **,** we reported that a data collection omission had occurred at a clinical site that impacted the obesity cohort (120 mg dose level) of the Phase 2a study for **aleniglipron** ~~GSBR- 1290~~ , where weight was not collected at the final (week 12) visit for 24 of the 40 enrolled participants ~~. Other safety and laboratory assessments were measured at all visits~~ , **and** ~~including the week 12 visit as per protocol. We have completed the enrollment of additional participants in the Phase 2a obesity cohort to replace those for whom 12- week weight data was not collected. The replacement participants will follow the same study protocol, without changes in the titration schema or target dose (120 mg at once- daily dosing). However,~~ as a result of this data collection omission, we **were delayed and** reported interim Phase 2a obesity cohort data in December 2023, and **topline** ~~we expect to report the full~~ 12- week obesity data in **June** ~~the latter half of the second quarter of~~ 2024. Events that may prevent successful or timely completion of clinical development include: ● delays in reaching a consensus with applicable regulatory authorities on trial design or implementation; ● delays in obtaining regulatory authorization to commence a clinical trial; ~~72~~ ● delays in reaching agreement on acceptable terms with prospective ~~clinical research organizations (" CROs ")~~ , other vendors, or clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different vendors and trial sites; ● delays in obtaining approval from one or more institutional review boards (" IRB ") refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional participants, or withdrawing their approval of the trial; ● delays in recruiting suitable patients to participate in our ongoing and planned clinical ~~trials~~ **studies** ; ● changes to the clinical trial protocol; ● clinical sites deviating from trial protocol such as the data collection omission we experienced at a clinical site as discussed above or dropping out of a trial; ● delays in manufacturing sufficient quantities of our product candidates for use in clinical ~~trials~~ **studies** , or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical ~~trials~~ **studies** ; ● delays in having patients complete participation in a trial or return for post- treatment follow- up; ● participants choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical ~~trials~~ **studies** ; ● lack of adequate funding to continue a clinical trial; ● occurrence of AEs or SAEs associated with the product candidate that are viewed to outweigh its potential benefits; ● occurrence of SAEs in clinical ~~trials~~ **studies** of the same class of agents conducted by other companies; ● imposition of a temporary or permanent clinical hold by regulatory authorities; ● selection of clinical trial end points that require prolonged periods of clinical observation or analysis of the resulting data; ● clinical ~~trials~~ **studies** producing negative or inconclusive results; ● a facility manufacturing our product candidates or any of their components being ordered by the FDA or applicable foreign authorities to temporarily or permanently shut down due to violations of current good manufacturing practice (" cGMP ") regulations or other applicable requirements, or contamination or cross- contaminations of product candidates in the manufacturing process; ● third- party clinical investigators losing the licenses or permits necessary to perform our clinical ~~trials~~ **studies** , not performing our clinical ~~trials~~ **studies** on our anticipated schedule or consistent with the clinical trial protocol or other regulatory requirements or committing fraud; ~~or~~ **or66** ● changes in regulatory requirements, guidance, or feedback from regulatory agencies that require amending or submitting new clinical protocols or otherwise modifying the design of our clinical ~~trials~~ **studies** . We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such ~~trials~~ **studies** are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or applicable foreign authorities. Such authorities may impose such a suspension or termination 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 the FDA or applicable foreign

authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination and approval, which may impact the costs, timing or successful completion of a clinical trial. ~~73Further~~ -- **Further** , conducting clinical ~~trials~~ **studies** in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical ~~trials~~ **studies** . These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory requirements, as well as political, currency exchange and other economic risks relevant to such foreign countries. Investigators and patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff which in turn could adversely impact our clinical trial operations. Additionally, we may experience interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with public health concerns. We have faced and may continue to face delays in meeting our anticipated timelines for our ongoing and planned clinical ~~trials~~ **studies** . We experienced delays in our patient enrollment and our supply chain as a direct result of COVID- 19 on our suppliers' ability to timely manufacture and ship certain supplies such as reagents and other lab consumables and due to the data collection omission at a clinical site as discussed above. These delays have previously impacted and could in the future adversely affect our business, financial condition, results of operations and growth prospects. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales and regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. For example, to facilitate potential commercial- scale manufacturing, we expect to transition from capsule formulations of our product candidates used for early clinical ~~trials~~ **studies** to tablet formulations, including the addition of excipients, in later stage clinical ~~trials~~ **studies** . While these formulation transitions are common for small molecule drug candidates, we cannot guarantee that we will not encounter delays or unexpected results in bridging studies or implementing necessary changes to the manufacturing process. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects. Enrollment and retention of patients in clinical ~~trials~~ **studies** is an expensive and time- consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, which could adversely affect our business, operating results and prospects. Patient enrollment is a significant factor impacting the duration of our clinical ~~trials~~ **studies** , along with treatment duration and completion of required follow- up periods. Clinical ~~trials~~ **studies** may be prolonged, or we may not be able to initiate or continue clinical ~~trials~~ **studies** for our product candidates if we are unable to locate and enroll a ~~sufficient~~ **67sufficient** number of eligible patients to participate as required by the FDA or applicable foreign authorities. For certain of our product candidates, including ANPA- 0073, the conditions which we may evaluate include rare diseases with limited patient pools from which to draw. In some cases, patient populations for rare diseases are located at specific academic sites focused on such indications, often with multiple competing clinical ~~trials~~ **studies** . Potential patients for any planned clinical ~~trials~~ **studies** may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such ~~trials~~ **studies** . We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical ~~trials~~ **studies** and monitoring such patients adequately during and after treatment. As noted above, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical ~~trials~~ **studies** . In addition, the process of finding and diagnosing patients may prove costly. The eligibility criteria of our clinical ~~trials~~ **studies** , once established, may further limit the pool of available trial participants. If the actual number of patients with these diseases is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical ~~trials~~ **studies** , thereby delaying or preventing development and ~~74approval~~ -- **approval** of our product candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our ~~trials~~ **studies** . The timely completion of clinical ~~trials~~ **studies** in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment or retention in our clinical ~~trials~~ **studies** for a variety of reasons. Patient enrollment and retention in clinical ~~trials~~ **studies** depends on many factors, including: ● the size and nature of the patient population; ● the severity of the disease under investigation; ● the design of the trial protocol; ● the existing body of safety and efficacy data for the product candidate; ● the number and nature of competing treatments and ongoing clinical ~~trials~~ **studies** of competing therapies for the same indication; ● the proximity of patients to clinical sites; ● the eligibility criteria for the trial; ● the ability to recruit clinical trial investigators with the appropriate competencies and experience; ● the ability to adequately monitor patients during a trial, clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied; ● the risk that patients will drop out of a trial before completing all site visits; and ● clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical ~~trials~~ **studies** . If we encounter any delays in enrolling such additional participants, this may further delay our clinical trial. In addition, any negative results we may report in clinical ~~trials~~ **studies** of our product candidate may make it difficult or impossible to recruit and retain patients in other clinical ~~trials~~ **studies** of that same product candidate. Delays or failures in planned patient enrollment or

retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. For example, the impact of public health epidemics may delay or prevent patients from enrolling or from receiving treatment in accordance with the protocol and the required timelines, which could delay our clinical ~~trials~~ **studies**, or prevent us or our partners from completing our clinical ~~trials~~ **studies** at all, and harm our ability to obtain approval for such product candidate. Further, if patients drop out of our clinical ~~trials~~ **studies**, miss scheduled doses or follow- up ~~visits~~ **68visits**, or otherwise fail to follow clinical trial protocols, the integrity of data from our clinical ~~trials~~ **studies** may be compromised or not accepted by the FDA or applicable foreign authorities, which would represent a significant setback for the applicable program. In addition, we may rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical ~~trials~~ **studies** and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance. Such delays or failures could adversely affect our business, operating results and prospects. Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing ~~75authorizations~~ -- **authorizations** or limitations on the use of our product candidates, any of which would limit the commercial potential of such product candidate. During the conduct of clinical ~~trials~~ **studies**, patients report changes in their health, including illnesses, injuries and discomforts, to their doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical ~~trials~~ **studies** with a broader group of patients, or as use of these product candidates becomes more widespread if they receive marketing approval, illnesses, injuries, discomforts and other AEs that were observed in earlier ~~trials~~ **studies**, as well as conditions that did not occur or went undetected in previous ~~trials~~ **studies**, will be reported by participants. Many times, side effects are only detectable after investigational product candidates are tested in large- scale, Phase ~~III trials~~ **3 studies** or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our current product candidates and any future product candidates has serious or life- threatening side effects or other side effects that outweigh the potential therapeutic benefit, the development of the product candidate may fail or be delayed, or, if the product candidate has received marketing approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition. In particular, because we are developing our product candidates for chronic indications, the FDA and applicable foreign authorities will likely require that our product candidates demonstrate a higher level of safety over a longer period of time than would be the case for product candidates intended for short- term use. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly. Moreover, if our product candidates are associated with undesirable side effects in clinical ~~trials~~ **studies** or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective, which may limit the commercial value for the product candidate if approved. We may also be required to modify our trial plans based on findings in our ongoing clinical ~~trials~~ **studies**. In our completed Phase 1 SAD and Phase 1b MAD study of **aleniglipron** ~~GSBR- 1290~~, the following adverse events occurred and were considered probably or possibly related to the study drug: nausea, headache, vomiting, dehydration, decreased appetite, dizziness, and diarrhea. In our completed Phase 2a study of **aleniglipron** ~~GSBR- 1290~~, the following adverse events occurred and were considered probably or possibly related to the study drug: nausea, headache, vomiting, decreased appetite, dyspepsia, and diarrhea. In our completed Phase 1 SAD and MAD study of ANPA- 0073, the following adverse events occurred and were considered probably or possibly related to the study drug: blood creatine phosphokinase increase, dizziness, electrocardiogram T wave inversion, diarrhea, headache, lethargy, nausea, vomiting, chills, palpitations, and sinus tachycardia. However, further analysis may reveal AEs inconsistent with the safety results observed. Many compounds that initially showed promise in early- stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations. In addition, if any of our product candidates receive marketing approval, the FDA could require us to include a black box warning in our label or adopt a **risk evaluation and mitigation strategy (“** REMS **”)**, to ensure that the ~~benefits~~ **69benefits** outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients and a communication plan to health care practitioners. For example, the FDA has required that the product labels of approved drugs targeting GLP- 1R include a black box warning related to the risk of thyroid C- cell tumors based on rodent carcinogenicity studies. While we have not yet conducted carcinogenicity studies for **aleniglipron** ~~GSBR- 1290~~, because it also targets GLP- 1R, it is possible that absent compelling data to the contrary, the FDA and applicable foreign authorities will similarly require a black box warning for **aleniglipron** ~~GSBR- 1290~~ if it is approved for marketing. Furthermore, if we or others later identify undesirable side effects caused by our product candidates, several other potentially significant negative consequences could result, including: ● regulatory authorities may suspend or withdraw approvals of such product candidate; ~~76~~ ● regulatory authorities may require additional warnings on the label, including “ boxed ” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product; ● we may be required to change the way a product candidate is administered or conduct additional clinical ~~trials~~ **studies**; ● we could be sued and held liable for harm caused to patients; ● we could be subject to fines, injunctions, or the imposition of criminal or civil penalties; ● we may need to conduct a recall; ● we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace; and ● 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 our product candidates and could significantly harm our business, prospects, financial condition and results of operations. As an organization, we have never conducted later- stage clinical ~~trials~~ **studies** or submitted an NDA, and may be unable to do so for any of our product candidates. We are early in our development efforts for our product candidates, and we will need to successfully complete pivotal clinical ~~trials~~ **studies** in order to seek FDA or applicable foreign authority approval to market ~~GSBR~~ **aleniglipron, ACCG** - ~~1290~~ **2671** , ANPA- 0073 **, LTSE- 2578** and any future product candidates we may develop. Carrying out clinical ~~trials~~ **studies** and the submission of NDAs is complicated ~~. We completed a Phase 1 SAD study for GSBR- 1290 in healthy volunteers in September 2022. We reported topline data for the Phase 1b MAD study in September 2023. We also reported topline data for the 12- week Phase 2a clinical trial in December 2023. We further reported interim Phase 2a obesity cohort data, in which GSBR- 1290 demonstrated significant reductions in weight at 8 weeks. We expect to report the full 12- week obesity data in the latter half of the second quarter of 2024. We also reported results from a Japanese ethno- bridging study and findings from 6- and 9- month toxicology studies demonstrating encouraging safety to support advancing into Phase 2b development. The additional formulation bridging study to evaluate a tablet formulation of GSBR- 1290 is expected to be completed in the latter half of the second quarter of 2024. Additionally, we completed our Phase 1 SAD and MAD study for ANPA- 0073 in healthy volunteers for IPF in September 2022~~ . We have not conducted any later stage or pivotal clinical ~~trials~~ **studies** , have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an NDA or other applicable foreign regulatory submission for any product candidate. We also plan to conduct a number of clinical ~~trials~~ **studies** for multiple product candidates in parallel over the next several years. This may be a difficult process to manage with our limited resources and may divert the attention of management. In addition, we ~~have had no~~ **are currently planning for later stage** interactions with ~~the~~ FDA ~~or applicable~~ **, and other** foreign ~~authorities and~~ **regulatory agencies however we** cannot ~~be certain how many~~ **guarantee timely or shift alignment on our** clinical ~~trials~~ **trial** ~~of our product candidates will be required or how such trials will have to be designed~~ **designs , phase 3 dose rationale and overall size of the data base needed for any future marketing applications** . Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical ~~trials~~ **studies** in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining marketing approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical ~~trials~~ **studies** , could prevent us from or delay us in submitting NDAs for and commercializing our product candidates. ~~The~~ **70The** marketing approval processes of the FDA and applicable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed. The time required to reach approval by the FDA and applicable foreign authorities is unpredictable but typically takes many years following the commencement of clinical ~~trials~~ **studies** and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product ~~77candidate~~ - - **candidate** ' s clinical development and may vary among jurisdictions. We have not obtained marketing approval for any product candidate and it is possible that any product candidates we may seek to develop in the future will never obtain marketing approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive FDA marketing approval of an NDA. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well- controlled clinical ~~trials~~ **studies** , and to the satisfaction of the FDA or applicable foreign authorities, that such product candidates are safe and effective for their intended uses. The number of nonclinical studies and clinical ~~trials~~ **studies** that will be required for FDA approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Results from nonclinical studies and clinical ~~trials~~ **studies** can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA and applicable foreign authorities may also require us to conduct additional preclinical studies or clinical ~~trials~~ **studies** for our product candidates either prior to or post- approval, or could object to elements of our clinical development program. The FDA or applicable foreign authorities can delay, limit or deny approval of our product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for various reasons, including the following: ● the FDA or applicable foreign authorities may disagree with the design or implementation of our clinical ~~trials~~ **studies** ; ● we may be unable to demonstrate to the satisfaction of the FDA or applicable foreign authorities that a product candidate is safe and effective for its proposed indication; ● the results of clinical ~~trials~~ **studies** may not meet the level of statistical significance required by the FDA or applicable foreign authorities for approval; ● serious and unexpected drug- related side effects experienced by participants in our clinical ~~trials~~ **studies** or by individuals using drugs similar to our product candidates; ● we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; ● the FDA or applicable foreign authorities may disagree with our interpretation of data from preclinical studies or clinical ~~trials~~ **studies** ; ● the data collected from clinical ~~trials~~ **studies** of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain marketing approval in the United States or elsewhere, and we may be required to conduct additional clinical ~~trials~~ **studies** ; ● the FDA' s or the applicable foreign authority' s requirement for additional nonclinical studies or clinical ~~trials~~ **studies** ; ● the FDA or the applicable foreign authority may disagree regarding the formulation, labeling and / or the specifications of our product candidates; **71** ● the FDA or applicable foreign authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and ● the approval policies or regulations of the FDA or applicable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of products in development, only a small percentage successfully complete the FDA or foreign marketing approval

processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain marketing approval to market our product candidates, which would significantly harm our business, results of operations and prospects. ~~78We~~ **We** may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on specific product candidates, indications and discovery programs. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. In addition, in recent years, a number of companies have entered the drug discovery industry utilizing different **artificial intelligence (“** AI **”)** approaches. The success of other such AI approaches to drug discovery could create more competition for us. We believe that we must continue to invest a significant amount of time and resources in our platform technologies to maintain and improve our competitive position. We may not be able to obtain or maintain orphan drug designations or exclusivity for our product candidates, which could limit the potential profitability of our product candidates. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States, or a patient population of greater than 200, 000 individuals in the United States but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States alone. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, 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. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the targeted indication, then the drug is entitled to a seven- year period of marketing exclusivity that precludes the applicable regulatory authority from approving another marketing application for the same chemical entity for the same indication for the exclusivity period except in limited situations, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. For purposes of small molecule drugs, the FDA defines “ same drug ” as a drug that contains the same active moiety and is intended for the same use as the drug in question. 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 drug designation. ~~We~~ **72We** intend to pursue orphan drug designation for one or more of our product candidates, as well as for potential other future product candidates. Obtaining orphan drug designations is important to our business strategy; however, obtaining an orphan drug designation can be difficult and we may not be successful in doing so. Even if we were to obtain orphan drug designation for a product candidate, we may not obtain orphan exclusivity and that exclusivity may not effectively protect the drug from the competition of different drugs for the same condition, which could be approved during the exclusivity period. Additionally, after an orphan drug is approved, the FDA could subsequently approve another application for the same drug for the same indication if the FDA concludes that the later drug is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusive marketing rights in the United States also may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or ~~79condition~~ -- **condition** . The failure to obtain an orphan drug designation for any product candidates we may develop, the inability to maintain that designation for the duration of the applicable period, or the inability to obtain or maintain orphan drug exclusivity could reduce our ability to make sufficient sales of the applicable product candidate to balance our expenses incurred to develop it, which would have a negative impact on our operational results and financial condition. We have conducted, or **may** plan to conduct, our initial clinical studies for ~~GSBR~~ **aleniglipron, ACCG** - ~~1290~~ **2671** , ANPA- 0073, LTSE- 2578 and our other product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such ~~trials~~ **studies** , in which case our development plans will be delayed, which could materially harm our business. We have conducted our initial clinical studies for **aleniglipron** ~~GSBR- 1290~~ and ANPA- 0073 in Australia, and **may** ~~will likely~~ conduct our Phase 1 studies for other drug candidates in Australia **, China or other foreign countries** . The acceptance of study data from clinical ~~trials~~ **studies** conducted outside the United States or another jurisdiction by the FDA or applicable foreign authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical ~~trials~~ **studies** are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U. S. population and U. S. medical practice; (ii) the ~~trials~~ **studies** were performed by clinical investigators of recognized competence and pursuant to good clinical practices (“ GCP ”) regulations; and (iii) the data may be considered valid without the need for an on- site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well- designed and well- conducted in accordance with GCP

requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign ~~trials~~ **studies** would be subject to the applicable local laws of the foreign jurisdictions where the ~~trials~~ **studies** are conducted. There can be no assurance that the FDA or any applicable foreign authority will accept data from ~~trials~~ **studies** conducted outside of the United States or the applicable jurisdiction. If the FDA or any applicable foreign authority does not accept such data, it would result in the need for additional ~~trials~~ **studies** , which could be costly and time- consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. We believe that clinical data generated in Australia **and China or other foreign countries** will be accepted by the FDA and its foreign equivalents outside of Australia; however, there can be no assurance the FDA or applicable foreign authorities will accept data from any other clinical studies that we may conduct in Australia **, China or other foreign countries** . If the FDA or applicable foreign authorities do not accept any such data, we would likely be required to conduct additional Phase 1 clinical studies, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business. Conducting clinical ~~trials~~ **studies** outside the United States exposes us to additional risks, including risks associated with: ● additional foreign regulatory requirements; **73** ● foreign exchange fluctuations; ● compliance with foreign manufacturing, customs, shipment and storage requirements; ● cultural differences in medical practice and clinical research; and ● diminished protection of intellectual property in some countries. ~~80Preliminary~~ -- **Preliminary** , topline and interim data from our clinical ~~trials~~ **studies** that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim, preliminary or topline data from our clinical ~~trials~~ **studies** , which are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously made public. As a result, topline and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical ~~trials~~ **studies** . Interim data from clinical ~~trials~~ **studies** that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between topline, preliminary or interim data and final data could significantly harm our business prospects. For example, ~~in December 2023, we reported clinically meaningful~~ topline ~~data from~~ **results and the length of the study and sample size may render the results of** our ~~12- week Phase 2a~~ **prior aleniglipron studies not necessarily indicative of the results for our future** clinical **studies for aleniglipron** ~~trial, which focused on safety~~ and **may not be comparable** ~~tolerability of GSBR- 1290 in a total of 94 participants~~ to ~~date~~ **other weight loss products or product candidates** , including **other oral selective GLP** ~~60 participants randomized to GSBR- 1290~~ **1RAs** . **In addition** ~~The results showed GSBR- 1290 was generally well- tolerated with no treatment- related SAEs~~ , **given the size of the** ~~no adverse event- related discontinuation in obesity and only one adverse event- related discontinuation in T2DM. Furthermore, GSBR- 1290 demonstrated significant reductions in HbA1c and weight at 12 weeks in T2DM. We further reported interim~~ Phase 2a obesity cohort **, the primary efficacy endpoint of weight loss was calculated using LSM and analyzed based on the primary efficacy estimand using a mixed model for repeated measures. This means that we drew on all available** data, ~~in which GSBR~~ **including data from patients that did not follow** - **up** ~~1290 demonstrated significant reductions in weight~~ at ~~8~~ **12** weeks **. The model estimates how patients with missing data would have responded based on patients who continued the study and had similar baseline characteristics (implicit imputation)** . Due to the preliminary nature of these results and the length of the study and sample size, these results are not necessarily indicative of the final results for our clinical ~~trials~~ **studies** for **aleniglipron** ~~GSBR- 1290~~ . If the final data is materially different from the preliminary topline data reported, this could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the topline or preliminary data that we report differ from actual results, or if others, 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, operating results, prospects or financial condition. ~~Obtaining~~ **74Obtaining** and maintaining marketing approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining marketing approval of our product candidates in other jurisdictions. Obtaining and maintaining marketing approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, it does not mean that comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining marketing approval in one jurisdiction may negatively impact the marketing approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies

or clinical ~~trials~~ **studies** as clinical ~~trials~~ **studies** conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. ~~81In~~ **In** many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Obtaining foreign marketing approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which would adversely affect our business, prospects, financial condition, and results of operations. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns 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 applicable foreign authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government shut down several times and certain regulatory agencies, such as the FDA, furloughed critical employees and ceased critical activities. **More recently, such agencies, including the FDA, have conducted layoffs and may, from time to time, conduct additional layoffs.** If a prolonged government shutdown **or significant layoffs** ~~occurs~~ **occur** , it could significantly impact the ability of the FDA and applicable foreign authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or applicable foreign authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or applicable foreign authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Risks Related to Our Reliance on Third PartiesWe rely on third parties for the manufacture of our product candidates for preclinical and clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or ~~such~~ **75such** quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates and related raw materials for preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. Our active pharmaceutical ingredients and drug product for our product candidates are currently provided by a ~~single- source~~ supplier, WuXi STA **, a subsidiary of WuXi AppTec** , and we expect to rely on this supplier for the foreseeable future. **Contract manufacturing organizations** ~~However, certain Chinese biotechnology companies and CMOs~~ may become subject to **legislation,** trade restrictions, sanctions, and other regulatory requirements by the U. S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to ~~82us~~ **us. For example, the House of Representatives of the prior Congress (the 118th Congress) passed the BIOSECURE Act, which proposed prohibiting U. S. government contracts, grants, and loans to entities that use equipment and services from certain named Chinese biotech companies, which currently include WuXi AppTec and WuXi Biologics and certain of their respective subsidiaries and affiliates, and authorizes the U. S. government to include additional Chinese biotechnology companies of concern. This version of the BIOSECURE Act included a grandfathering provision allowing biotechnology equipment and services provided or produced by named biotechnology companies of concern under a contract or agreement entered into before the effective date until January 1, 2032. The BIOSECURE Act did not become law in the 118th Congress. It is unclear whether the current Congress (the 119th Congress) will introduce the BIOSECURE Actor similar legislation in this congressional session and, if so, how the scope, prohibitions, or designated biotechnology companies of concern may differ from the version of the BIOSECURE Act passed by the House in the prior 118th Congress. Any U. S. executive action, legislative action or potential sanctions with China could materially impact entities that work with Chinese biotechnology companies. U. S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. Such disruption could have adverse effects on the development of our product candidates** . We have contracted with, or are in the process of pursuing contracts with, alternative suppliers or manufacturers outside of China for our active pharmaceutical ingredients and drug product for our product candidates. While we believe that our current manufacturing plan will provide us with alternative sources for such supplies, there is a risk that, if supplies are interrupted, or the quality of ingredients provided by such alternative sources is not to our specification, it would cause delays in our supply chain and increase the cost of manufacturing our drugs, which could materially harm our business. Furthermore, we do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third- party manufacturers may not be able to comply with cGMP

regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and others, they will not be able to secure and / or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or an applicable foreign authority does not approve these facilities for the manufacture of our product candidates or if the FDA or applicable foreign authority, withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could ~~significantly~~ **76significantly** and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis. In the event that any of our manufacturers fails to comply with applicable requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, including due to the impact of future global pandemics, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third- party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on our third- party manufacturers or require us to obtain a license from such manufacturers in order to have another third- party manufacture our product candidates. If we are required to or voluntarily change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also need to verify, such as through a manufacturing comparability study, that any product produced by the new manufacturer is equivalent to that produced in a prior facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget. ~~83Our~~ -- **Our** or a third party' s failure to execute on our manufacturing requirements on commercially reasonable terms and timelines, if at all, and comply with cGMP requirements could adversely affect our business in a number of ways, including: ● inability to meet our drug specifications and quality requirements consistently; ● delay or inability to procure or expand sufficient manufacturing capacity; ● issues related to scale- up of manufacturing; ● costs and validation of new equipment and facilities required for scale- up; ● failure to comply with cGMP or similar foreign standards; ● inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all; ● reliance on single source manufacturers for drug substances and drug products; ● lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier; ● misappropriation of proprietary information, including our trade secrets and know- how; ● the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or study drug or placebo not being properly identified; ● clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions; ● operations of our third- party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; ~~and~~ **and77** ● carrier disruptions or increased costs that are beyond our control. In addition, we do not have any long- term commitments or supply agreements with our third- party manufacturers. We may be unable to establish any supply agreements with our third- party manufacturers or do so on acceptable terms, which increases the risk of timely obtaining sufficient quantities of our product candidates or such quantities at an acceptable cost, which may harm our business and results of operations. We rely on third parties to conduct, supervise and monitor our discovery research, preclinical studies and clinical ~~trials~~ **studies** . We have experienced delays due to actions of third parties in the past and if in the future third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We do not currently have the ability to independently conduct certain discovery research, preclinical studies and clinical ~~trials~~ **studies** for our product candidates. We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our preclinical studies and clinical ~~trials~~ **studies** , and we expect to have limited influence over their actual performance. We rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies or clinical ~~trials~~ **studies** are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with the good laboratory practices (" GLPs "), and GCPs, which are regulations and guidelines enforced by the FDA and applicable foreign authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we will rely on CROs to conduct GLP- compliant preclinical studies and GCP- compliant clinical ~~trials~~ **studies** , we remain responsible for ensuring that each ~~84of~~ **of** our GLP preclinical studies and clinical ~~trials~~ **studies** is conducted in accordance with

its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical ~~trials~~ **studies** may be deemed unreliable and the FDA or applicable foreign authorities may require us to perform additional clinical ~~trials~~ **studies** before approving our marketing applications. For example, in September 2023 **,** we announced that topline data from the obesity cohort of our Phase 2a trial of **aleniglipron** ~~GSBR- 1290~~ would be delayed because of a data collection omission by a clinical site, where weight was not collected at the final (week 12) visit for 24 of the 40 enrolled participants. ~~We expect to report the full 12- week obesity data in the latter half of the second quarter of 2024.~~ Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of participants or ensure the collection of requisite data by clinical sites, we may be required to enroll additional participants or repeat clinical ~~trials~~ **studies** , which would delay the marketing approval process. While we will have agreements governing their activities, our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical ~~trials~~ **studies** , or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical ~~trials~~ **studies** may be extended, delayed or terminated, and we may not be able to obtain marketing approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. **78If** ~~In addition, quarantines, shelter- in- place, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, which could disrupt our clinical timelines, which could have a material adverse impact on our business, prospects, financial condition, and results of operations. If~~ our relationship with these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, we may encounter challenges or delays in the future and we cannot assure you that these delays or challenges will not have a negative impact on our business, financial condition and prospects. In addition, principal investigators for our clinical ~~trials~~ **studies** may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or applicable foreign authorities. The FDA or applicable foreign authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or applicable foreign 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. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or applicable foreign authorities and may ultimately lead to the denial of marketing approval of our current and future product candidates. We have entered into, and may in the future enter into, collaboration agreements and strategic alliances to maximize the potential of our structure- based drug discovery platform and product candidates, and we may not realize the anticipated benefits of such collaborations or alliances. We expect to continue to form collaborations in the future with respect to our product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans. ~~85Part~~ -- **Part** of our business strategy is to explore additional collaborations with third parties to further strengthen our platform capabilities and to leverage our platform for external opportunities where partners bring additional disease biology understanding, development and commercial expertise, regional insights or other complementary capabilities. We may therefore form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our structure- based drug discovery platform or our product candidates and any future product candidates that we may develop, including in territories outside the United States or for certain indications. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management' s time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write- downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into acquisition or license agreements or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or other anticipated benefits that led us to enter into the arrangement. Research and development collaborations are subject to numerous risks, which may include the following: ● collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration, and may not commit sufficient efforts and resources, or may misapply those efforts and resources; ● collaborators may not pursue development and commercialization of our structure- based drug discovery platform or collaboration product candidates or may elect not to continue or renew ~~development~~ **79development** or commercialization programs based on clinical trial results or changes in their strategic focus; ●

collaborators may delay, provide insufficient resources to, or modify or stop clinical ~~trials~~ **studies** for our structure- based drug discovery platform or collaboration product candidates; ● collaborators could develop or acquire products outside of the collaboration that compete directly or indirectly with our products or product candidates; ● collaborators may not properly 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; ● disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources; ● collaborations may be terminated and, if terminated, may result in a need for additional capital and personnel to pursue further development or commercialization of our structure- based drug discovery platform or the applicable product candidates; and ● collaborators may own or co- own intellectual property covering our products that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our structure- based drug discovery platform or product ~~86candidates~~ -- **candidates** because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. As a result of these risks, we may not be able to realize the benefit of our existing collaborations or any future collaborations or licensing agreements we may enter into. In addition, there have been a significant number of recent business combinations among large pharmaceutical and biomedical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. In addition, we may face regulatory obstacles in completing such transactions. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our structure- based drug discovery platform or product candidates or bring them to market and generate revenue. ~~Additionally~~ **80Additionally** , we may sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. If collaborations occur, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer. Our products require specific constituents to work effectively and efficiently, and rights to those constituents are, and in the future may be, held by others. We may also seek to in- license third- party technologies to enhance our structure- based drug discovery platform. We may be unable to in- license any rights from constituents, methods of use, processes or other third- party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which could harm our business. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology in order to establish or maintain our competitive position in the market. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates or our structure- based drug discovery platform could delay the development and commercialization of our product candidates in certain geographies or limit our ability to discover and develop new product candidates, which could harm our business prospects, financial condition, and results of operations. ~~87Our~~ -- **Our** existing discovery collaborations with Schrödinger are important to our business. If we are unable to maintain these collaborations, or if these collaborations are not successful, our business could be adversely affected. In October 2020, Lhotse, our wholly- owned subsidiary, entered into the Lhotse- Schrödinger Agreement. In November 2023, Aconcagua, our wholly- owned subsidiary, entered into the Aconcagua- Schrödinger Agreement. Under both agreements, Schrödinger uses its technology platform to perform virtual screens of members of the target class of human integrins, and we and Schrödinger collaborate to facilitate prioritization of targets, perform target validation and analysis, identify leads and perform lead optimization. Schrödinger has granted us an exclusive license to certain intellectual property related to our product candidates discovered under both agreements. See the discussion in Part I. Item 1. " Business — Lhotse Collaboration Agreement with Schrödinger **, LLC** " and Part I. Item 1. " Business — Aconcagua Collaboration Agreement with Schrödinger **, Inc** . " **of this Annual Report.** Because we currently rely on Schrödinger for a substantial portion of our discovery capabilities, if Schrödinger delays or fails to perform its obligations under

the Lhotse- Schrödinger Agreement or Aconcagua- Schrödinger Agreement, disagrees with our interpretation of the terms of the collaborations or our discovery plan or terminates the Lhotse- Schrödinger Agreement or Aconcagua- Schrödinger Agreement, our pipeline of product candidates would be adversely affected. Schrödinger may also fail to properly maintain or defend the intellectual property we have licensed from them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time- consuming and expensive. Additionally, either party has the right to terminate the collaboration pursuant to the terms of the Lhotse- Schrödinger Agreement or Aconcagua- Schrödinger Agreement, as applicable. If either of our collaborations with Schrödinger is terminated, especially during our discovery phase, the development of our product candidates would be materially delayed or harmed. 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. Reliance on third parties to manufacture or commercialize our current or any future product candidates, and on collaborations with additional third parties for the development of our current or any future product ~~candidates~~ **81candidates** , requires us to share trade secrets with these third parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, services agreements, consulting agreements or other similar agreements with our advisors, employees, third- party 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, including our 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 could have an adverse effect on our business and results of operations. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third- party collaborators. A competitor' s discovery of our trade secrets could harm our business. ~~88Confidentiality~~ -- **Confidentiality** agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information. In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidates, technology and product discovery and development processes that involve proprietary know- how, information, or technology that is not covered by patents. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third- party consultants and vendors that we engage to perform research, clinical ~~trials~~ **studies** or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. 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. Trade secrets and confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know- how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information, including to competitors. In addition, competitors or other third- parties may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our ~~intellectual~~ **82intellectual** property by third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition. The adoption and deployment of ~~artificial intelligence (" AI ")~~ in our, and any third- party collaborators' operations, and in particular our and any third- party collaborators' ~~research and development (" R & D ")~~ efforts to explore new targets and develop effective products, may not be effective and may expose us to risk. The industry in which we compete is characterized by rapid technological advancements, frequent introductions of new products and heavy competition. The discovery of new products and targets remain vital to our success and the implementation by us and by any third- party collaborators of **AI** ~~artificial intelligence~~ technologies and processes, including advanced predictive analytics, computational approaches for drug discovery and so- called " generative " AI, has the potential to provide significant benefits in these areas. Use of AI in our efforts may be difficult to deploy successfully due to operational issues inherent in such methods.

In particular, the AI algorithms utilize machine learning and predictive analytics which may lead to flawed, biased, and inaccurate results, which could lead to ineffective product or target candidates and exposure to competitive and reputational harm. We face increased competition from other companies that are using AI and related methods for drug discovery, some of which have more resources than we do and may have developed more effective methods than we and any third- party collaborators have, which may reduce our and any third- party collaborator' s effectiveness in identifying potential targets and attracting additional ~~89collaborators~~ -- **collaborators** to work with us. Even with the successful implementation of AI, we may fail to correctly identify indications and allocate resources efficiently, which could adversely impact our pipeline and ability to compete effectively. Further, AI presents additional risks and challenges, especially as the use of these technologies becomes more important to our operations over time. Generative AI may be used improperly or inappropriately which could lead to the tainting of our proprietary information and render us unable to qualify for patent protection. Their use by people, including our vendors, employees, suppliers and contractors, with access to our proprietary and confidential information, including trade secrets, may continue to increase and may lead to the release of such information, which may impact our ability to realize the benefit of our intellectual property. Our use of generative AI platforms may lead to novel and urgent cybersecurity risks, which may adversely affect our operations and reputation, as well as the operations of any third- party collaborators. Emerging ethical issues surround the use of AI, and we may be subject to reputational and legal risk if our deployment or use of AI becomes controversial. Regulators could limit our, or any third- party collaborator' s ability to develop or implement AI- based technologies as part of measures taken against us or any third- party collaborators in particular or as a consequence of broader legislation, which could have an adverse effect on our or any third- party collaborators' business, results of operations and financial conditions **. Several jurisdictions around the globe, including Europe and certain U. S. states, have proposed, enacted, or are considering laws governing the development and use of AI / Machine Learning, such as the EU' s AI Act. We expect other jurisdictions will adopt similar laws** . Uncertainty in the legal regulatory regime may require significant resources to modify and maintain business practices to comply with U. S. and non- U. S. laws, the nature of which cannot be determined at this time. Risks Related to Commercialization of Our Product CandidatesEven if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved. Even if we obtain any marketing approval for our current or any future product candidates, such approvals will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post- market information. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as on- going compliance with cGMPs and GCPs, for any clinical ~~trials~~ **studies** that we may conduct post- ~~approval~~ **83approval** . Any marketing approvals that we receive for our current or future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 ~~trials~~ **studies** , and surveillance to monitor the quality, safety and efficacy of the drug. In addition, drug manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we or a regulatory authority discover previously unknown problems with a drug, such as AEs of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements following approval of our current or future product candidates, a regulatory authority may, among other things: ● issue an untitled letter or warning letter asserting that we are in violation of the law; ● seek an injunction or impose administrative, civil or criminal penalties or monetary fines; ● suspend or withdraw marketing approval; ~~90~~ ● suspend any ongoing clinical ~~trials~~ **studies** ; ● refuse to approve a pending NDA or NDA supplement, or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners; ● restrict or suspend the marketing or manufacturing of the drug; ● seize or detain the drug or otherwise require the withdrawal of the drug from the market; ● refuse to permit the import or export of product candidates; or ● refuse to allow us to enter into supply contracts, including government contracts. In addition, if any of our product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product' s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The government has also required companies to enter into consent decrees and / or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. The FDA' s policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could cause changes to or delays in the drug review process, or suspend or restrict marketing approval of our product candidates. **For example, the U. S. Supreme Court' s June 2024 decision in Loper Bright Enterprises v. Raimondo overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable**

interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in 84increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability, which would harm our business, financial condition, results of operations and prospects. Even if our current or future product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, third- party payors or others in the medical community necessary for commercial success. Even if our current or future product candidates receive marketing approval, they may fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If they do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our current or future product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to: ● the clinical indications for which the product candidate is approved; ● the efficacy and potential advantages compared to alternative treatments and therapies; ● the timing of market introduction of the product as well as competitive products; ● effectiveness of sales and marketing efforts; ● the strength of our relationships with patient communities; ● the cost of treatment in relation to alternative treatments and therapies, including any similar generic treatments; ● our ability to offer such product for sale at competitive prices; ~~91~~ ● the convenience and ease of administration compared to alternative treatments and therapies; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● the availability of third- party coverage and adequate reimbursement; ● the willingness of patients to pay out- of- pocket in the absence of coverage and adequate reimbursement by third- party payors and government authorities; ● the strength of marketing and distribution support; ● the prevalence and severity of any side effects; and ● any restrictions on the use of the product together with other medications. Our efforts to educate physicians, patients, third- party payors and others in the medical community on the benefits of our product candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates, if approved, to find market acceptance would harm our business and could require us to seek additional financing. ~~Coverage~~ **85Coverage** and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved. Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which coverage and adequate reimbursement for these drugs and related treatments will be available from third- party payors, including government health administration authorities, managed care organizations and other private health insurers. Third- party payors decide which therapies they will pay for and establish reimbursement levels. Commercial payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor- by- payor basis. One third- party payor' s determination to provide coverage for a drug does not assure that other payors will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third- party payor' s decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each third- party payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a third- party payor' s list of covered drugs, or formulary, generally determines the co- payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third- party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop, which could have an adverse effect on our operating results and our overall financial condition. Further, coverage policies and third- party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained for one or more products for which we receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. ~~92We~~ **We** face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us. The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies. Our future success will depend in part on our ability to maintain a competitive position with our structure- based drug discovery platform. If we fail to stay at the forefront of technological change in utilizing our platform to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our approach obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and platform. In addition, we face competition with respect to our current product candidates and will face competition with respect

to any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of the indications that we are pursuing. 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, development, manufacturing and commercialization. ~~We~~ **86We** are aware of GLP- 1R small molecules in development by Pfizer, Eli Lilly, ~~and~~ Qilu Regor Therapeutics ~~Inc.~~ **, AstraZeneca / Eccogene, Terns Pharmaceuticals, Jiangsu Hengrui Medicine, Huadong, Sciwind Biosciences, Ascletis, Gilead, Kallyope, MindRank, vTv Therapeutics, Carmot Therapeutics (acquired by Roche Group in January 2024) and Kailera Therapeutics, formerly Hercules CM Newco (licensed HRS- 7535, an oral small molecule GLP- 1; HRS- 9531 a GLP- 1 / GIP; and preclinical asset HRS- 4729 from Jiangsu Hengrui Medicine)** . There are currently approved GLP- 1R peptides for the treatment of diabetes and obesity marketed by Novo Nordisk, Eli Lilly, AstraZeneca, ~~and~~ Sanofi **and Kailera Therapeutics, formerly Hercules CM Newco** . We are also aware of other GLP- 1R plus dual / tri incretin targeting peptides in development by Eli Lilly, Jiangsu Hansoh Pharmaceutical Group ~~Co., Ltd.~~ , Boehringer Ingelheim, Altimmune, ~~Inc.,~~ Carmot Therapeutics, ~~Inc. (which was acquired by Roche Group in January 2024), and~~ Sciwind Biosciences ~~Co.~~ , ~~Ltd~~ **Novo Nordisk, Viking Therapeutics, Amgen, Merck, Zealand Pharma, D & D Pharmatech, GMAX Biopharma, Jiangsu Hengrui Medicine, BrightGene, Innovent Biologics, PegBio, NeuroBo Pharmaceuticals, Hanmi Phamaceuticals, Progen Holdings, Pep2Tango, Metsera, QL Biopharma, Lexaria Bioscience, Sun Pharmaceutical, Gan & Lee, Innogen and Biomed Industries** . Additionally, we are aware of ~~APJR~~ **APJ receptor** targeted product candidates in development for COVID- 19 acute respiratory distress syndrome by CohBar, Inc.; IPF, systemic sclerosis interstitial lung disease, and kidney nephrotic syndrome by Apie Therapeutics; and muscle atrophy by BioAge Labs, Inc. Both Amgen and **Bristol Myers Squibb (“** BMS **”)** have ~~APJR~~ **APJ receptor** targeted product candidates for heart failure. Furthermore, we are aware of LPA1R targeted product candidates in development for IPF by BMS, Horizon Therapeutics **(** ~~plc, which was recently~~ acquired by Amgen ~~,~~ **in October 2023)** and DJS Antibodies ~~Ltd~~ ; **and** myelin restoration and neuroinflammation by ~~Pipeline~~ **Contineum** Therapeutics. Many of our competitors, either alone or with their collaborators, have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the timing and scope of marketing approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical ~~trials~~ **studies** , as well as in acquiring technologies complementary to, or necessary for, our programs. Any failure to compete effectively could harm our business, financial condition and operating results. In addition, we and any third- party collaborators are facing increasing competition from companies utilizing AI and other computational approaches for drug discovery. Some of these competitors are involved in drug ~~93discovery~~ **discovery** themselves and / or with partners, and others develop software or as well as other tools utilizing AI which can be used, directly or indirectly, in drug discovery. To the extent these other AI approaches to drug discovery prove to be successful, or more successful, than our and any third- party collaborators’ approach, our business, financial condition and operating results could be adversely affected. If the market opportunities for any of our product candidates are smaller than we estimate, even assuming approval of a product candidate, our revenue may be adversely affected, and our business may suffer. The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. 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 product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, ~~including~~ **87including** scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere 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. We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue. We have no internal sales, marketing or distribution capabilities, nor have we as a company commercialized a product. If any of our product candidates ultimately receives marketing approval, we will be required to build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such

product in the markets that we target, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses. Our future growth may depend, in part, on our ability to commercialize products in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive ~~94regulatory --~~ **regulatory** approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical ~~trials~~ **studies**, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including: ● different regulatory requirements for approval of drugs in foreign countries; ● reduced protection for intellectual property rights; ● the existence of additional third- party patent rights of potential relevance to our business; ● unexpected changes in tariffs, trade barriers and regulatory requirements; **88** ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; ● foreign reimbursement, pricing and insurance regimes; ● workforce uncertainty in countries where labor unrest is common; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ● business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires. Risks Related to Our Business Operations and IndustryOur operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide. Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to: ● the timing, degree of success and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our product candidates, which may change from time to time; ● coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; ● the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of our agreements with third- party manufacturers; ● expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies; ● the level of demand for any approved products, which may vary significantly; ● future accounting pronouncements or changes in our accounting policies; ~~and95 --~~ **and** ● the timing and success or failure of preclinical studies or clinical ~~trials~~ **studies** for our product candidates or any competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our ADSs could decline substantially. Such a price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide. ~~We~~ **89We** are highly dependent on the services of our senior management team and if we are not able to retain these members of our management team and recruit and retain additional management, clinical and scientific personnel, our business will be harmed. We are highly dependent on our senior management team. The employment agreements we have with these officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. In addition, we will need to attract, retain and motivate highly qualified additional management, clinical and scientific personnel. If we are not able to retain our management and to attract, on terms acceptable to us, additional qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or grow. We may not be able to attract or retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other pharmaceutical companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer operating history in the industry than we do. They also may provide more diverse

opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality candidates and consultants than what we have to offer. If we are unable to attract, retain and motivate high- quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop product candidates and our business will be limited and we may experience constraints on our development objectives. Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future marketing approvals, sales of our product candidates and our results of operations. Additionally, we do not currently maintain " key person " life insurance on the lives of our executives or any of our employees. We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations. As of December 31, ~~2023~~ **2024**, we had ~~93~~ **163** full- time employees. As we advance our research and development programs, we may need to further increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, discovery biology, chemistry, manufacturing, general and administrative matters related to being a public company, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must: ● identify, recruit, integrate, maintain and motivate additional qualified personnel; ~~96~~ ● manage our development efforts effectively, including the initiation and conduct of clinical ~~trials~~ **studies** for our product candidates; and ● improve our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to develop, manufacture and commercialize our product candidates, if approved, will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day- to- day activities, to managing these growth activities. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. ~~We~~ **90We** conduct certain research and development operations through our Australian wholly- owned subsidiaries. If we lose our ability to operate in Australia, or if any of our subsidiaries are unable to receive the research and development tax credit allowed by Australian regulations, or are required to refund any research and development tax credit previously received or reserve for such credit in our financial statements, our business and results of operations could suffer. In 2021, we formed two wholly- owned Australian subsidiaries, Annapurna Bio Pty Limited (" Annapurna AU ") and Gasherbrum Bio Pty Limited (" Gasherbrum AU "), to conduct various preclinical and clinical activities for our product and development candidates in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop and commercialize our lead products in Australia, including conducting clinical ~~trials~~ **studies**. Furthermore, we have no assurance that the results of any clinical ~~trials~~ **studies** that we conduct for our product candidates in Australia will be accepted by the FDA or applicable foreign authorities. In addition, current Australian tax regulations provide for a refundable research and development tax credit equal to 43. 5 % of qualified expenditures. Although we have previously claimed a refundable research and development tax credit there is a possibility that we may not be able to claim such credit or we might qualify for a lesser credit. If we lose our ability to operate Annapurna AU or Gasherbrum AU in Australia, or if in the future we are ineligible or unable to receive the research and development tax credit or are required to refund any research and development tax credit previously received or have to reserve for such credit in our financial statements, or if the Australian government significantly reduces or eliminates the tax credit, our business and results of operation may be adversely affected. Our relationships with customers, physicians and other healthcare providers, and third- party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, other healthcare laws and regulations and health data privacy and security laws and regulations, contractual obligations and self- regulatory schemes. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti- Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, as well as our proposed sales and marketing programs. In addition, we may be subject to health information privacy and security laws by the federal government, the ~~97states~~ **states** and other jurisdictions in which we may conduct our business. The laws that may affect our operations include, but are not limited to: ● the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to, among other things, arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation; ● federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws, such as the Civil Monetary Penalties Law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal ~~government~~ **91government**. In addition, the government

may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act; ● the Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which created additional federal criminal statutes that prohibit, among other things, a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e. g., public or private). Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH "), and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates ~~and covered contractors~~ , individuals or entities that perform certain services on behalf of a covered entity that involves the use or disclosure of individually identifiable health information and their subcontractors that use, disclose or otherwise process individually identifiable health information; ● The Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ~~(" CMS ")~~ information related to: (i) payments or other " transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members; ● state and foreign law equivalents of each of the above federal laws, state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and / or information regarding drug pricing, state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers, state laws and regulations that require drug manufacturers to file reports relating to drug pricing and marketing information, and state and local laws that require the registration of pharmaceutical sales representatives; ~~and98 --~~ **and** ● state and foreign laws that govern the privacy and security of personal information, including health- related information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Because of the breadth of these laws and the limited statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including certain scientific advisory board agreements with physicians who are compensated in the form of ordinary shares or share options in addition to cash consideration, could be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will 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 of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. ~~If~~ **92If** our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws and the curtailment or restructuring of our operations. Healthcare legislative reform measures may have a negative impact on our business and results of operations. In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post- approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the " ACA, ") was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U. S. pharmaceutical industry. Since its enactment, there have been judicial, Congressional and executive branch challenges **and amendments** to certain aspects of the ACA. **For example** ~~On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states on procedural grounds without specifically ruling on the constitutionality of the ACA. In addition~~ , on August 16, 2022, ~~President Biden signed~~ the Inflation Reduction Act of 2022 (" IRA ") **was signed** into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and through a newly established manufacturer discount program. It is possible the ACA will be subject to judicial or Congressional challenges **and amendments** in the future. Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries, presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug ~~99products --~~ **products**

. For example, ~~at~~ **the IRA, among** ~~the~~ **other things** ~~federal level~~ , **(1) directs** ~~in July 2021, the Biden administration released an executive order with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021,~~ the U. S. Department of Health and Human Services (" HHS ") ~~released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things, (1) directs the HHS~~ to negotiate the price of certain **high- expenditure,** single- source drugs ~~and biologics~~ covered under Medicare **that have been on the market for at least 7 years (the " Medicare Drug Price Negotiation Program ")** and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~take~~ **began to** effect progressively ~~starting~~ in fiscal year 2023. On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list~~ **agreed- upon reimbursement prices** of the first ten drugs that **were** ~~will be~~ subject to price negotiations, although the Medicare ~~drug~~ **Drug** ~~price~~ **Price** ~~negotiation~~ **Negotiation** ~~program~~ **Program** is currently subject to legal challenges. HHS ~~has and~~ will ~~continue~~ **select up** to ~~issue and update guidance as these programs are implemented~~ **fifteen additional drugs covered under Part D for price negotiation in 2025** . ~~It is currently unclear how the IRA~~ **Each year thereafter more Part B and Part D products** will **become subject** ~~be implemented but it is likely~~ to ~~have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three~~ -- **the** ~~new models for testing by the Center for~~ Medicare **Drug Price Negotiation Program** ~~and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future~~ . Further, on December 7, 2023, ~~the Biden administration announced~~ an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act **was announced** . On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure ~~and~~ **93and** transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on January 5, 2024, the FDA approved Florida' s Section 804 Importation Program (" SIP ") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future. We cannot predict what healthcare reform initiatives may be adopted in the future **, particularly in light of the recent U. S. presidential and Congressional elections** . We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. If we or our third- party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third- party manufacturers. Our manufacturers are subject to federal, state, and local laws and regulations in the United States and foreign jurisdictions governing the use, manufacture, storage, handling and disposal of medical, radioactive and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical, radioactive or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with ~~100fines~~ --- **fines** , and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical radioactive or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development, and production efforts, which could harm our business, prospects, financial condition, and results of operations. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop. We face an inherent risk of product liability exposure related to the testing of our current and any future product candidates in clinical ~~trials~~ **studies** and may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for any product candidate that we may develop; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● loss of revenue; ● substantial monetary awards to trial participants or patients; ● significant time and costs to defend the related litigation; ● a diversion of management' s time and our resources; ● withdrawal of clinical trial participants; **94** ● initiation of investigations by regulators; ● the inability to commercialize any product candidate that we may develop; ● injury to our reputation and significant negative media attention; and ● a decline in our ADS price. We currently hold approximately $ 10. 0 million in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical ~~trials~~ **studies** and if we successfully commercialize any product

candidate. Insurance coverage is increasingly expensive. We may not be able to obtain or maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. If our information technology systems or data, or those of third parties upon which we rely, are or were compromised or experienced significant disruptions of our information technology systems or data security incidents, we could experience adverse consequences including but not limited to significant financial, legal, regulatory, business and reputational harm; litigation; fines and penalties; disruptions of our business operations; loss of revenue or profits; loss of customers or sales; or other adverse consequences. We are increasingly dependent on information technology systems and infrastructure, including mobile and third- party, cloud- based technologies, to operate our business. In the ordinary course of our business, we ~~may~~ collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential ~~information. It is critical that we 101do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive~~ information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third- party vendors who may or could have access to our computer networks or our sensitive information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on or transmitted between those systems, make such systems potentially vulnerable to unintentional or malicious, internal and external exploits of our technology environment, including by organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, " hacktivists, " nation states and others. Further, **many** ~~due to the COVID- 19 pandemic, we enabled all~~ of our employees ~~to~~ work remotely, which **increases our** ~~may make us more vulnerable~~ **vulnerability** to cyberattacks. Cyberattacks are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, " hacktivists, " nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, supply chain attacks, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. **Threat** ~~Data security incidents and other inappropriate access can also be difficult to detect, can result from the intentional or inadvertent actions~~ **actors direct** ~~or inactions of those with authorized access to our network and any delay in identifying them may lead to increased harm. In addition, the prevalent use of mobile devices increases the risk of data security incidents. Significant~~ **significant** disruptions of, or cyber incidents ~~directed~~ at, our or our third- party vendors' and / or business partners' information technology systems **that** could adversely affect our business operations and / or result in the loss, misappropriation, and / or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in a variety of adverse effects, including financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development ~~programs~~ **95programs** and our business operations. For example, the loss of clinical trial data from completed or future clinical ~~trials~~ **studies** could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our intellectual property or proprietary business information ~~could~~ **would** require substantial expenditures to remedy. If we or our third- party collaborators, consultants, contractors, suppliers, vendors or service providers were to suffer an actual or likely attack or breach, for example, that involves the unauthorized access to or use or disclosure of personal or health information for which we are responsible may require us, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions (including mandatory corrective action or requirements to verify the correctness of database contents), and consuming, distracting and expensive litigation, any of which could result in increased costs to us, and result in significant legal and financial exposure, or other harm to our business and reputation. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. ~~While~~ **It may be difficult and / or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom** we **work** ~~have no reason~~ to **detect** ~~believe that we have been subject to any significant system failure~~ , ~~accident or~~ **investigate, mitigate, contain, and remediate a** security ~~breach to~~ **incident could result in outages,** ~~date~~ **data losses** , ~~attackers have become very sophisticated in the way they conceal~~ **and disruptions of our business. Threat actors may also gain** access to **other networks and** systems **after a compromise of** ~~, and many companies that have been attacked are not aware that they have been attacked. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or~~ **our networks** ~~remediate incidents or breaches due to attackers increasingly using tools~~ and **systems** ~~techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence~~ . While we have implemented security measures intended to protect our information technology systems and infrastructure, such measures may not successfully prevent service interruptions or security incidents. ~~102Our~~ **We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may**

experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and applicable foreign authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical ~~trials~~ **studies** or interactions with the FDA or applicable foreign authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a negative ~~impact~~ **96impact** on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any. In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low- priced and high- priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product candidate to other available therapies, which is time- consuming and costly. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. We are subject to stringent and evolving U. S. and foreign laws, regulations, rules, industry standards, contractual obligations, policies and other obligations related to data security and privacy. Our **or the third parties with whom we work (including our suppliers)** actual or perceived failure to comply with such obligations could lead to government enforcement actions, which could include civil, criminal or administrative penalties, litigation (including class claims) and arbitration demands, fines and penalties, disruptions of our business operations, reputational harm, adverse publicity, and ~~/ or and~~ other adverse business consequences **,** and could negatively affect our operating results and business, financial condition, results of operations **,** and prospects **, and other adverse business consequences and could negatively affect our operating results and business, financial condition, results of operations and prospects** . ~~103In~~ **In** the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we may collect about trial participants in connection with clinical ~~trials~~ **studies** , sensitive third- party data, business plans, transactions, and financial information. The global data protection landscape is rapidly evolving, and we are or may become subject to or be affected by evolving federal, state and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal and state health information privacy laws, state data breach notification laws, and federal and state consumer protection laws, such as Section 5 of the Federal Trade Commission Act, govern the collection, use, disclosure and protection of health information and other personal information and could apply to our operations. These laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal information. HIPAA, as amended by HITECH, imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA. 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 provider or research institution that has not satisfied HIPAA' s requirements for disclosure of individually identifiable health information. ~~In~~ **97In** the past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-

out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (" CPRA "), (collectively, " CCPA ") applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $ 7, 500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical ~~trials~~ **studies** , the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, also exempt some data processed in the context of clinical ~~trials~~ **studies** , these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely. Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the EU GDPR, the United Kingdom' s GDPR ~~(" UK GDPR ")~~ , and the Personal Information Protection Act in South Korea, impose strict requirements for processing personal data. Under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros **under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR** or **, in each case,** 4 % of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. ~~104In~~ **In** the ordinary course of business, we ~~may~~ transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the European Economic Area (" EEA ") and United Kingdom (" UK ") to the United States in compliance with law, such as the EEA and UK' s standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. ~~Recently, however, the UK has implemented an International Data Transfer Agreement / Addendum and the EU- U. S. Data Privacy Framework has been introduced, (the latter of which allows for transfers of personal data for relevant U. S.- based organizations who self- certify compliance and participate in the Framework), but these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.~~ If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations ~~. The EU has also proposed a Regulation on Privacy and Electronic Communications (" ePrivacy Regulation ") which, if adopted, would impose new obligations on the use of personal data in the context of electronic communications, particularly with respect to online tracking technologies and direct marketing. Additionally, the EU adopted the EU Clinical Trials Regulation, which came into effect on January 31, 2022. This regulation imposes new obligations on the use of data generated from clinical trials and enables European patients to have the opportunity to access information about clinical trials~~ . The Cayman Islands Data Protection Act imposes obligations on data controllers in relation to the processing of personal data, and also introduced rights for data subjects (which may be subject to various exemptions), ~~including~~ **98including** , among others: (a) personal data must be processed fairly and on the basis of one of the grounds for processing as set out in the Data Protection Act; (b) personal data must be obtained for a specified lawful purpose; (c) personal data must be adequate, relevant and not excessive in relation to the purpose for which it was processed; (d) personal data must be accurate and, where necessary, kept up to date; (e) personal data must not be kept for longer than is necessary; (f) personal data must be processed in accordance with the rights of the data subject; (g) appropriate technical and organizational security measures must be taken to prevent unauthorized or unlawful processing, accidental loss or destruction of personal data; and (h) the personal data may not be transferred to a country unless that country ensures an adequate level of protection for the rights and freedoms of data subjects. In recent years, authorities of the PRC have promulgated certain laws and regulations in respect of information security, data collection and privacy protection regulations in the PRC, including the Cybersecurity Law of the PRC, the Provisions on Protection of Personal Information of Telecommunication and Internet Users, the Data Security Law of the PRC which became effective from September 1, 2021, and the Personal Information Protection Law of the PRC **(" PIPL ")** which became effective from November 1, 2021. **The PIPL imposes a set of specific obligations on covered businesses in connection with their processing and transfer of personal data and imposes fines of up to RMB 50 million or 5 % of the prior year' s total annual revenue of the violator.** Under the **PIPL** ~~Personal Information Protection Law of the PRC~~ , in case of any personal information processing, such individual prior consent shall be obtained, unless other circumstances clearly mentioned therein to the contrary. Further, any data processing activities in relation to the sensitive personal information such as biometrics, medical health and personal information of teenagers under fourteen years old are not

allowed unless such activities have a specific purpose, are highly necessary and have taken strictly protective measures. ~~105In~~ **Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. In** addition to data privacy and security laws, we contractually **are** ~~may be~~ subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. In particular, compliance with U. S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, increase our costs of legal compliance, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' suppliers' ability to operate in certain jurisdictions. Our or our service providers' and vendors' actual or perceived failure to comply with U. S. and foreign data protection laws and regulations could result in threatened or actual government investigations and / or enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and / or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we or our third- party service providers have violated individuals' privacy rights, failed to comply with data protection laws, 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. We publish privacy policies, self- certifications, and other documentation regarding our collection, use and disclosure of personal information and / or other confidential information. Although we endeavor to comply with our published policies, certifications, and documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our published policies, certifications, and documentation. Such failures can subject us to potential international, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. ~~There~~ **99There** is tax risk associated with the reporting of cross- border arrangements and activities between us and our subsidiaries. We are incorporated under the laws of the Cayman Islands and currently have subsidiaries in Mainland China, Hong Kong, Australia, the Cayman Islands and the United States. If we succeed in growing our business, we expect to conduct increased operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our 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. A tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a " permanent establishment " under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable. ~~106Tax~~ **Tax** authorities may disagree with our positions and conclusions regarding certain tax positions, resulting in unanticipated costs, taxes or non- realization of expected benefits. A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, the U. S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a " permanent establishment " under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, in which case, we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly, and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable. Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition, or results of operations. New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect. For instance, the recently enacted ~~Inflation Reduction Act (" IRA ")~~ imposes, among other rules, a 15 % minimum tax on the book income of certain large corporations and a 1 % excise tax on certain corporate stock repurchases. The Tax Cuts and Jobs Act of 2017 (" TCJA "), as amended by the Coronavirus Aid, Relief, and Economic Security Act significantly reformed the United States Internal Revenue Code of ~~1986~~

1001986 , as amended (the " Code "), by lowering U. S. federal corporate income tax rates, changing the utilization of future net operating loss carryforwards, permitting for the expensing of certain capital expenditures, eliminating the option to currently deduct research and development expenditures and requiring taxpayers to capitalize and amortize U. S.- based and non- U. S.- based research and development expenditures over five and fifteen years, respectively. and putting into effect significant changes to U. S. taxation of international business activities. Outside the U. S., various governments and organizations are increasingly focused on tax reform and other legislative or regulatory action to increase tax revenue, including the Organisation for Economic Co- operation and Development' s Base Erosion and Profit Shifting Project (" BEPS 2. 0 "). The IRA, TCJA, BEPS 2. 0 or any future tax reform legislation could have a material impact on the value of our deferred tax assets, result in significant one- time charges, and increase our future tax expenses. Risks Related to Doing Business in China and Our International OperationsChanges in the political and economic policies or in relations between China and the United States may affect our business, financial condition, results of operations and the market price of our ADSs. Due to our operations in China, our business, results of operations, financial condition and prospects may be influenced to a certain degree by economic, political, legal and social conditions in China or changes in government relations between China and the United States or other governments. The Chinese government may intervene in or influence our operations, which could result in a change in our operations and impact the value of our ADSs. Any economic downturn, whether actual or perceived, further decrease in economic growth rates or an otherwise uncertain economic outlook could affect our business, financial condition and results of operations, as well as the market price of our ADSs. In addition, the global macroeconomic environment is facing challenges. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions, and our business operations in the long term. There is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. The Chinese government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy, but may have a ~~107negative~~ **negative** effect on us. Due to our operations in China, any future Chinese, U. S. or other rules and regulations that place restrictions on capital raising or other activities by companies with operations in China could affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the United States or other governments deteriorate and geopolitical tensions between China and the United States increase, our business in China and United States, as well as the market price of our ADSs, may also be affected. Changes in U. S. and Chinese regulations may impact our business, our operating results, our ability to raise capital and the market price of our ADSs. The U. S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with certain operations based in China. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the United States or to China, our industry or on us. We conduct research activities and have business operations both in the United States and China. Any unfavorable government policies on cross- border relations and / or international trade, including increased scrutiny on companies with certain operations based in China, capital controls or tariffs, may affect the competitive position of our drug products, the hiring of scientists and other research and development personnel, the demand for our drug products, the import or export of raw materials in relation to drug development, our ability to raise capital, the market price of our ADSs or prevent us from selling our drug products in certain countries. Furthermore, the SEC has issued statements primarily focused on companies with certain operations based in China, such as us. For example, on July 30, 2021, Gary Gensler, Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in China, pursuant to ~~which~~ **101which** Chairman Gensler stated that he has asked the SEC staff to engage in targeted additional reviews of filings for companies with certain operations based in China. The statement also addressed risks inherent in companies with variable interest entity (" VIE ") structures. We do not have a VIE structure and are not in an industry that is subject to foreign ownership limitations by China. However, it is possible that our periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and this additional scrutiny could affect our ability to effectively raise capital in the United States. In response to the SEC' s July 30, 2021 statement, the China Securities Regulatory Commission (" CSRC ") announced on August 1, 2021, that " [i] t is our belief that Chinese and U. S. regulators shall continue to enhance communication with the principle of mutual respect and cooperation, and properly address the issues related to the supervision of China- based companies listed in the U. S. so as to form stable policy expectations and create benign rules framework for the market. " While the CSRC will continue to collaborate " closely with different stakeholders including investors, companies, and relevant authorities to further promote transparency and certainty of policies and implementing measures, " it emphasized that it " has always been open to companies' choices to list their securities on international or domestic markets in compliance with relevant laws and regulations. " If any new legislation, executive orders, tariffs, laws and / or regulations are implemented, if existing trade agreements are renegotiated or if the U. S. or Chinese governments take retaliatory actions due to the recent U. S.- China tension, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our ADSs. Compliance with China' s ~~new~~ **current** Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, regulations and guidelines relating to the multi- level protection scheme on cyber security and any other future laws and regulations may entail significant expenses and could affect our business. China has implemented or will implement rules and is considering a number of additional proposals relating to data protection. China' s ~~new~~ **current** Data Security Law took effect in September 2021. The Data Security Law ~~108provides~~ **provides** that the data processing activities must be conducted based on " data classification and hierarchical protection system " for the purpose of data protection and

prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the Chinese government. Additionally, China' s Cyber Security Law, promulgated by the Standing Committee of the National People' s Congress **(" SCNPC ")** in November 2016 and came into effect in June 2017, and the Administrative Measures for the Hierarchical Protection of Information Security promulgated by the Ministry of Public Security, National Administration of State Secrets Protection, State Cryptography Administration and other government authority in June 2007, requires companies to take certain organizational, technical and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that China adopt a multi- level protection scheme (" MLPS "), under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. Under the MLPS, entities operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level of the entity' s information and network systems. These levels range from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and implementation of the classified protection of cyber security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval. On July 10, 2021, the Cyberspace Administration of China (" CAC ") published a draft revision to the existing Cybersecurity Review Measures for public comment (the " Revised Draft CAC Measures "). On January 4, 2022, together with 12 other Chinese regulatory authorities, the CAC released the final version of the Revised Draft CAC Measures (the " Revised CAC Measures "), which came into effect on February 15, 2022. Pursuant ~~to~~ **102to** the Revised CAC Measures, critical information infrastructure operators procuring network products and services, and online platform operators (as opposed to " data processors " in the Revised Draft CAC Measures) carrying out data processing activities which affect or may affect national security, shall conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review. On November 14, 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment) (the " Draft Management Regulations ") **for public comment. On September 24** , ~~under~~ **2024, the State Council released the final version of the Draft Management Regulations (the " Management Regulations "),** which **came into effect on January 1, 2025. Under the Management Regulations, online** data processors refer to individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion. The ~~Draft~~ Management Regulations reiterate that **online** data processors shall be subject to **national** ~~cybersecurity~~ ----- **security** review **pursuant to relevant provisions** if ~~(i)~~ they **carry out** ~~process personal information of more than one million persons and they are aiming to list on foreign stock markets, or (ii) their~~ data processing activities **which** affect or may affect ~~Chinese~~ national security ~~. The Draft Management Regulations also request data processors seeking to list on foreign stock markets to annually assess their data security by themselves or through data security service organizations, and submit the assessment reports to relevant competent authorities. As the Draft Management Regulations are released only for public comment, the final version and the effective date thereof is subject to change~~ . As of the date of this Annual Report, we have not received any notice from any Chinese regulatory authority identifying us as a " critical information infrastructure operator, " " online platform operator " ~~or ,~~ " **online platform service provider " or " online** data processor, " or requiring us to go through the cybersecurity review procedures pursuant to the Revised CAC Measures and the ~~Draft~~ Management Regulations. Based on our understanding of the Revised CAC Measures ~~,~~ and the ~~Draft~~ Management Regulations ~~if enacted as currently proposed~~ , we do not expect to become subject to cybersecurity review by the CAC for issuing securities to foreign investors because: (i) the clinical and preclinical data we handle in our business operations, either by its nature or in scale, do not normally trigger significant concerns over PRC national security; and (ii) we have not processed, and do not anticipate to process in the foreseeable future, personal information for more than one million users or persons. However, there remains uncertainty as to how the Revised CAC Measures, and the ~~Draft~~ Management Regulations ~~if enacted as currently proposed~~ **when it comes into effect in January 2025** , will be interpreted or implemented; for example, neither the Revised CAC Measures nor the ~~Draft~~ Management Regulations provides further clarification or interpretation on the criteria ~~109for~~ **for** determining those activities that " affect or may affect national security " and relevant Chinese regulatory authorities may interpret it broadly. Furthermore, there remains uncertainty as to whether the Chinese regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Revised CAC Measures and the ~~Draft~~ Management Regulations. While we intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Revised CAC Measures, the ~~Draft~~ Management Regulations or other laws and regulations related to privacy, data protection and information security. Also, the National People' s Congress released the Personal Information Protection Law, which became effective on November 1, 2021. The Personal Information Protection Law provides a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The Personal Information Protection Law also provides that critical information infrastructure operators and personal information processing entities who process personal information meeting a volume threshold set by Chinese cyberspace regulators are also required to store in China personal information generated or collected in China, and to pass a security assessment administered by Chinese cyberspace regulators for any export of such personal information. Lastly, the Personal Information Protection Law contains proposals for significant fines for serious violations of up to RMB 50 million or 5 % of annual revenues from the prior year and may also be ordered to suspend any related activity by

competent authorities. We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China. In addition, certain industry- specific laws and regulations affect the collection and transfer of data in the PRC. The Regulations on the Administration of Human Genetic Resources of the PRC (the " HGR Regulation ") was promulgated by the State Council in May 2019 and came into effect in July 2019 **, and was further revised in May 2024** . It stipulates that foreign organizations, individuals, and the entities established or actually ~~controlled~~ **103controlled** by foreign organizations or individuals are forbidden to collect, preserve and export China' s human genetic resources. Foreign organizations and the entities established or actually controlled by foreign organizations or individuals may only utilize and be provided with China' s human genetic resources after satisfaction of all requirements under the HGR Regulation and other applicable laws, such as (i) China' s human genetic resources being utilized only in international cooperation with Chinese scientific research institutions, universities, medical institutions, and enterprises for scientific research and clinical ~~trials~~ **studies** after completion of requisite approval or filing formalities with competent governmental authorities, and (ii) China' s human genetic resources information being provided after required filing and information backup procedures have been gone through. In October 2020, the SCNPC promulgated the Biosecurity Law of the PRC, which **came into effect in April 2021 and was further revised in April 2024. The Biosecurity Law of the PRC** reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China' s human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. In May 2023, the Ministry of Science and Technology published the Implementing Rules for the Regulations on the Administration of Human Genetic Resources (the " HGR Implementing Rules ") which came into effect in July 2023. The HGR Implementing Rules have, among other things, further clarified the scope of China' s human genetic resources information, improved the procedure rules for applicable approval, filing and security review, and refined the provisions with respect to the forbiddance on the collection, preservation and export of China' s human genetic resources by foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals. There remain significant uncertainties as to how various provisions of the HGR Regulation and the related laws and regulations may be interpreted and implemented. Given such uncertainty, although we have made great efforts to comply with mandatory requirements of laws and government authorities in this regard, we cannot assure you that we will be deemed at all times in full compliance with the HGR Regulation, the Biosecurity Law of the PRC, the HGR Implementing Rules and other applicable laws in our utilizing of and dealing with China' s human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation, the Biosecurity Law of the PRC and the HGR Implementing Rules. ~~110Interpretation~~ --- **Interpretation** , application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation or changes in enforcement. Compliance with China' s ~~new~~ **current** Cyber Security Law and Data Security Law could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, offerings or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law and / or related implementing regulations. Any failure on our part to comply with such law or regulations or any other obligations relating to privacy, data protection or information security, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could adversely affect our business, financial condition and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law, the Revised CAC Measures and the recent Chinese government actions could adversely affect our ability, on favorable terms, to raise capital, including engaging in follow- on offerings of our securities in the U. S. market. The approval of, filing or other procedures with the CSRC or other Chinese regulatory authorities may be required in connection with issuing securities to foreign investors under Chinese law, and, if ~~required~~ **104required** , we cannot predict whether we will be able, or how long it will take us, to obtain such approval or complete such filing or other procedures. The Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors ~~(the " M & A Rules ")~~ purport to require offshore special purpose vehicles that are controlled by Chinese companies or individuals and that have been formed for the purpose of seeking a public listing on an overseas stock exchange through acquisitions of Chinese domestic companies or assets in exchange for the shares of the offshore special purpose vehicles shall obtain CSRC approval prior to publicly listing their securities on an overseas stock exchange. On July 6, 2021, the relevant Chinese government authorities published the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law. These opinions call for strengthened regulation over illegal securities activities and increased supervision of overseas listings by China- based companies, and propose to take effective measures, such as promoting the construction of relevant regulatory systems to regulate the risks and incidents faced by China- based overseas- listed companies. Furthermore, on February 17, 2023, the CSRC promulgated a new set of regulations that consists of the Trial **Administrative** Measures **of Overseas Securities Offering and Listing by Domestic Companies (the " Trial Measures ")** and five supporting guidelines which came into effect on March 31, 2023 to regulate overseas securities offering and listing activities by domestic companies either in direct or indirect form. According to the Trial Measures, we may be required to submit filings to the CSRC in connection with future issuances of our equity securities to foreign investors. For more details, see the Part I. Item 1. " Business — Regulation — Other Significant Chinese Regulation Affecting Our Business Activities in China ~~.~~ " **of this Annual Report.** As of the date of this Annual Report, we have not received any inquiry, notice, warning or sanction regarding obtaining

approval, completing filings or other procedures in connection with our previous issuances of securities to foreign investors from the CSRC or any other Chinese regulatory authorities that have jurisdiction over our operations. Based on the above and our understanding of the newly issued Trial Measures and the supporting guidelines, after they came into effect on March 31, 2023, we would not at once be required to submit an application to the CSRC for our previous issuances of securities to foreign investors, but if we intend to make any subsequent securities offering in the same overseas market which are determined as indirect overseas offering and listing by a domestic company under the Trial Measures, we ~~111may~~ **may** be required to submit filing with the CSRC within three working days after such subsequent securities offering is completed. However, there remains uncertainty as to the interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities, and we cannot assure you that the relevant Chinese regulatory authorities, including the CSRC, would reach the same conclusion as us. If it is determined in the future that the approval of, filing or other procedure is required with the CSRC or any other regulatory authority for our previous issuances of securities to foreign investors, or if we are required to complete relevant procedures for our subsequent securities offering in the same overseas market, it is uncertain whether we will be able and how long it will take for us to obtain the approval or complete the filing or other procedure or obtain a waiver for such procedures, despite our best efforts. If we, for any reason, are unable to obtain or complete, or experience significant delays in obtaining or completing, the requisite relevant approval (s), filing (s) or other procedure (s), the regulatory authorities may impose fines and penalties on our operations in China, limit our operating privileges in China, revoke our business licenses, delay or restrict the repatriation of the proceeds from securities offerings into China or take other actions that could have an adverse effect on our business, financial condition, results of operations and prospects, as well as the trading price of the ADSs. Any uncertainties and / or negative publicity regarding the aforementioned approval (s), filing or other procedure (s), the interpretation and implementation of existing laws and regulations, or any further laws, regulations or interpretations that may be released and enacted in the future could have a material adverse effect on the trading price of the ADSs. Pharmaceutical companies operating in China are required to comply with extensive regulations and hold a number of permits and licenses to carry on their business. Our ability to obtain and maintain ~~these~~ **105these** regulatory approvals is uncertain, and future government regulation may place additional burdens on our current and planned operations in China. The pharmaceutical industry in China is subject to extensive government regulation and supervision. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including product development activities, clinical ~~trials~~ **studies** , registration, production, distribution, packaging, labeling, storage and shipment, advertising, licensing and post- approval pharmacovigilance certification requirements and procedures, periodic renewal and reassessment processes, data security and data privacy protection requirements and compliance and environmental protection. In particular, we are subject to many of these laws and regulations because our wholly- owned subsidiary, Basecamp Bio, through which we conduct our technology development and early discovery activities, operates primarily in China. Violation of applicable laws and regulations may materially and adversely affect our business. The regulatory framework governing the pharmaceutical industry in China is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. The Chinese government has introduced various reforms to the Chinese healthcare system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the various reform initiatives remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the extent we expect, if at all. Moreover, the various reform initiatives could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business and prospects. As a company with operations and business relationships outside of the United States, our business is subject to economic, political, regulatory and other risks associated with international operations. As a company with operations in China, our business is subject to risks associated with conducting business outside the United States. In addition to our technology development and early discovery activities through Basecamp Bio in China, substantially all of our suppliers and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including: ● economic weakness, including inflation, or political instability in particular non- U. S. economies and markets; ~~112~~ ● differing and changing regulatory requirements for product approvals; ● differing jurisdictions could present different issues for securing, maintaining or obtaining freedom to operate in such jurisdictions; ● potentially reduced protection for intellectual property rights; ● difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations; ● changes in non- U. S. regulations and customs, tariffs and trade barriers; ● changes in non- U. S. currency exchange rates of the RMB; ● increasing geopolitical tensions between the U. S. and China and changes in a specific country' s or region' s political or economic environment especially with respect to a particular country' s treatment of or stance towards other countries; ● trade protection measures, import or export licensing requirements or other restrictive actions by governments; ● differing reimbursement regimes and price controls in certain non- U. S. markets; ● negative consequences from changes in tax laws; **106** ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ● variable tax treatment in different jurisdictions of options granted under our equity incentive plans; ● workforce uncertainty in countries where labor unrest is more common than in the United States; and ● business interruptions resulting from geo- political actions, including war and terrorism, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires. If we fail to comply with Chinese environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, fire safety and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our technology development and early discovery operations primarily occur in China and involve the use of hazardous materials, including chemical materials. Our operations also produce

hazardous waste products. We are therefore subject to Chinese laws and regulations concerning the discharge of wastewater, gaseous waste and solid waste during our processes, including those relating to product development. We engage competent third- party contractors for the transfer and disposal of these materials and wastes. Despite our efforts to comply fully with environmental and safety regulations, any violation of these regulations may result in substantial fines, criminal sanctions, revocations of operating permits, the shutdown of our facilities and the incurrence of obligations to take corrective measures. We cannot completely eliminate the risk of contamination or injury from these materials and wastes. In the event of contamination or injury resulting from the use or discharge of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil, administrative or criminal fines and penalties. Although we maintain workers' compensation insurance to cover costs and expenses incurred due to on- the- job injuries to our employees and public liability insurance to cover costs and expenses that may be incurred if third parties are injured on our property, such insurance may not provide adequate coverage against potential liabilities. Furthermore, the Chinese government may take steps towards the adoption of more stringent environmental regulations, and, due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any unanticipated change in the environmental regulations, our third- party ~~113manufacturers~~ --- **manufacturers** and other service providers may incur substantial capital expenditures to install, replace, upgrade or supplement their manufacturing facilities and equipment or make operational changes to limit any adverse impact or potential adverse impact on the environment in order to comply with new environmental protection laws and regulations. If such costs become prohibitively expensive, we may be forced to cease certain aspects of our business operations and our business ~~may~~ **could** be materially adversely affected. Development in the Chinese legal system could materially and adversely affect us. Chinese laws and regulations govern our operations in China and the PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value. As the laws and regulations are relatively new and the PRC legal system continues to evolve, there may be room for discretion in the implementation of these laws and regulations. And as these laws and regulations are evolving in response to changing economic and other conditions, factors related to the application and implementation of these laws and regulations may affect our business and results of operations. We may be exposed to liabilities under the U. S. Foreign Corrupt Practices Act (the " FCPA "), **U. S. domestic bribery laws,** and similar anti- corruption and anti- bribery laws of China and other countries in which we operate, as well as U. S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in ~~foreign~~ **107foreign** markets and any determination that we have violated these laws could have a material adverse effect on our business or our reputation. Our operations are subject to the FCPA **, U. S. domestic bribery laws,** and similar anti- bribery or anti- corruption laws, regulations or rules of China and other countries in which we operate. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from, directly or indirectly, offering, authorizing or making improper payments to **U. S. and** non- U. S. government officials for the purpose of obtaining or retaining business or other advantage. We may engage third parties for clinical ~~trials~~ **studies** outside of the United States, to sell our products abroad once we enter a commercialization phase, and / or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. As our business expands, the applicability of the FCPA and other anti- bribery laws to our operations will increase. If our procedures and controls to monitor anti- bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, fail to comply with applicable anti- bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and / or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects. In addition, our products may be subject to U. S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U. S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U. S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and / or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business. ~~114Regulatory~~ --- **Regulatory** Requirements on currency exchange may limit our ability to receive and use effectively financing in foreign currencies. Our Chinese subsidiaries' ability to obtain currency exchange is subject to certain foreign exchange regulations and, in the case of transactions under the capital account, requires the approval of and / or registration with Chinese government authorities, including the State Administration of Foreign Exchange (" SAFE "). In particular, if we finance our Chinese subsidiaries by means of foreign debt from us or other foreign lenders, the amount is not allowed to, among other things, exceed the statutory limits and such loans must be registered with the local branch of SAFE. If we finance our Chinese subsidiaries by means of additional capital contributions, these capital contributions are subject to registration with the State Administration for Market Regulation or its local branch, reporting of foreign investment information with the Ministry of Commerce of the People' s Republic of China ~~(" MOFCOM ")~~, or its local branch or registration with other governmental authorities in China. In light of the various requirements imposed by Chinese

regulations on loans to, and direct investment in, China- based entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government requirements or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our Chinese subsidiaries. If we fail to adhere to such requirements or obtain such approval, our ability to use the proceeds we received from the IPO and to capitalize or otherwise fund our Chinese operations, including our technology development and ~~early~~ **108early** discovery activities through Basecamp Bio, may be negatively affected, which could materially and adversely affect our ability to fund and expand our business. Chinese regulations relating to the establishment of offshore special purpose companies by residents in China may subject our China resident beneficial owners or our wholly foreign- owned subsidiaries in China to liability or penalties, limit our ability to inject capital into these subsidiaries, limit these subsidiaries' ability to increase their registered capital or distribute profits to us, or may otherwise adversely affect us. In 2014, SAFE promulgated the SAFE Circular 37, which requires residents of China to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a " special purpose vehicle. " The term " control " under SAFE Circular 37 is broadly defined as the operation rights, beneficiary rights or decision- making rights acquired by residents of China in the offshore special purpose vehicles or Chinese companies by such means as acquisition, trust, proxy, voting rights, repurchase, convertible bonds or other arrangements. SAFE Circular 37 further requires amendment to the registration in the event of any changes with respect to the basic information of or any significant changes with respect to the special purpose vehicle, such as an increase or decrease of capital contributed by China residents, share transfer or exchange, merger, division or other material events. If the shareholders of the offshore holding company who are residents of China do not complete their registration with the local SAFE branches, the Chinese subsidiaries may be prohibited from making distributions of profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore parent company and from carrying out subsequent cross- border foreign exchange activities, and the offshore parent company may be restricted in its ability to contribute additional capital into its Chinese subsidiaries. Moreover, failure to comply with the SAFE registration and amendment requirements described above could result in liability under Chinese law for evasion of applicable foreign exchange restrictions. Certain residents of China may hold direct or indirect interests in our company, and we will request residents of China who we know hold direct or indirect interests in our company, if any, to make the necessary applications, filings and amendments as required under SAFE Circular 37 and other related rules. However, we may not at all times be fully aware or informed of the identities of our shareholders or beneficial owners that are required to make such registrations, and we cannot provide any assurance that these residents will comply with our requests to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. The failure or inability of our China resident shareholders to ~~115comply~~ --- **comply** with the registration procedures set forth in these regulations may subject us to fines or legal sanctions, restrictions on our cross- border investment activities or those of our China subsidiaries and limitations on the ability of our wholly foreign- owned subsidiaries in China to distribute dividends or the proceeds from any reduction in capital, share transfer or liquidation to us, and we may also be prohibited from injecting additional capital into these subsidiaries. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under Chinese law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to make distributions to you could be materially and adversely affected. If we are classified as a China resident enterprise for China income tax purposes, such classification could result in unfavorable tax consequences to us and our non- Chinese shareholders or ADS holders. The Enterprise Income Tax Law of the People' s Republic of China (the " EIT Law "), which was promulgated in March 2007, became effective in January 2008 and was amended in February 2017 and December 2018, and the Regulation on the Implementation of the EIT Law, effective as of January 1, 2008 and as amended in April 2019, define the term " de facto management bodies " as " bodies that substantially carry out comprehensive management and control on the business operation, personnel, accounts and assets of enterprises. " Under the EIT Law, an enterprise incorporated outside of China whose " de facto management bodies " are located in China may be considered a " resident enterprise " and will be subject to a uniform 25 % ~~enterprise~~ **109enterprise** income tax (" EIT "), rate on its global income. The Notice Regarding the Determination of Chinese- Controlled Offshore- Incorporated Enterprises as Chinese Tax Resident Enterprises on the Basis of De Facto Management Bodies (" SAT Circular 82 "), issued by the State Taxation Administration of the People' s Republic of China (" SAT ") on April 22, 2009 and as amended in November 2013 and December 2017 further specifies certain criteria for the determination of what constitutes " de facto management bodies. " If all of these criteria are met, the relevant foreign enterprise may be regarded to have its " de facto management bodies " located in China and therefore be considered a Chinese resident enterprise. These criteria include: (i) the enterprise' s day- to- day operational management is primarily exercised in China; (ii) decisions relating to the enterprise' s financial and human resource matters are made or subject to approval by organizations or personnel in China; (iii) the enterprise' s primary assets, accounting books and records, company seals, and board and shareholders' meeting minutes are located or maintained in China; and (iv) 50 % or more of voting board members or senior executives of the enterprise habitually reside in China. Although SAT Circular 82 only applies to foreign enterprises that are majority- owned and controlled by Chinese enterprises, not those owned and controlled by foreign enterprises or individuals, the determining criteria set forth in SAT Circular 82 may be adopted by the Chinese tax authorities as the reference for determining whether the enterprises are Chinese tax residents, regardless of whether they are majority- owned and controlled by Chinese enterprises. We believe that neither we nor any of our subsidiaries outside of China is a China resident enterprise for Chinese tax purposes. However, the tax resident status of an enterprise is subject to determination by the Chinese tax authorities, and uncertainties remain with respect to the interpretation of the term " de facto management body. " If the Chinese tax authorities determine that we or any of our subsidiaries outside of China is a Chinese resident enterprise for EIT purposes, that entity would be subject to a 25 % EIT on its global income. If such entity derives income other than dividends from its

wholly- owned subsidiaries in China, a 25 % EIT on its global income may increase our tax burden. In addition, if we are classified as a China resident enterprise for Chinese tax purposes, we may be required to withhold tax at a rate of 10 % from dividends we pay to our shareholders, including the holders of our ADSs, that are non- resident enterprises. Further, non- resident enterprise shareholders (including our ADS holders) may be subject to a 10 % Chinese withholding tax on gains realized on the sale or other disposition of our ADSs or ordinary shares if such income is treated as sourced from within China. Furthermore, gains derived by our non- Chinese individual shareholders from the sale of our ordinary shares and ADSs may be subject to a 20 % Chinese withholding tax. It is unclear whether our non- China- based individual shareholders (including our ADS holders) would be subject to any Chinese tax (including withholding tax) on dividends received by such non- Chinese individual shareholders in the event we are determined to be a China resident enterprise. If any Chinese tax were to apply to such dividends, it would generally apply at a rate of 20 %. Chinese tax ~~116liability~~ --- **liability** may vary under applicable tax treaties. However, it is unclear whether our non- China shareholders would be able to claim the benefits of any tax treaties between their country of tax residence and China in the event that we are treated as a China resident enterprise. We and our shareholders face uncertainties in China with respect to indirect transfers of equity interests in China resident enterprises. The indirect transfer of equity interests in China resident enterprises by a non- China resident enterprise (" Indirect Transfer "), is potentially subject to income tax in China at a rate of 10 % on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. The SAT has issued several rules and notices to tighten the scrutiny over acquisition transactions in recent years. The Announcement of the State Administration of Taxation on Several Issues Concerning the Enterprise Income Tax on Indirect Property Transfer by Non- Resident Enterprises (" SAT Circular 7 "), sets out the scope of Indirect Transfers, which includes any changes in the shareholder' s ownership of a foreign enterprise holding Chinese assets directly or indirectly in the course of a group' s overseas restructuring, and the factors to be considered in determining whether an Indirect Transfer has a commercial purpose. An Indirect Transfer satisfying all the following criteria will be deemed to lack a bona fide commercial purpose and be taxable under Chinese laws: (i) 75 % or more of the equity value of the intermediary enterprise being transferred is derived directly or indirectly from the Chinese taxable assets; (ii) at any time during the one- year period before the indirect transfer, 90 % or more of the asset value of the intermediary enterprise (excluding cash) is ~~comprised~~ **110comprised** directly or indirectly of investments in China, or 90 % or more of its income is derived directly or indirectly from China; (iii) the functions performed and risks assumed by the intermediary enterprise and any of its subsidiaries that directly or indirectly hold the Chinese taxable assets are limited and are insufficient to prove their economic substance; and (iv) the non- Chinese tax payable on the gain derived from the indirect transfer of the Chinese taxable assets is lower than the potential Chinese income tax on the direct transfer of such assets. A transaction that does not satisfy all four tests in the immediately preceding sentence may nevertheless be deemed to lack a bona fide commercial purpose if the taxpayer cannot justify such purpose from a totality approach, taking into account the transferred group' s value, income, asset composition, the history and substance in the structure, the non- Chinese tax implications, any tax treaty benefit and the availability of alternative transactions. Nevertheless, a non- resident enterprise' s buying and selling shares or ADSs of the same listed foreign enterprise on the public market will fall under the safe harbor available under SAT Circular 7 if the shares and ADSs were purchased on the public market as well and will not be subject to Chinese tax pursuant to SAT Circular 7. We face uncertainties regarding the reporting required for and impact on future private equity financing transactions, share exchanges or other transactions involving the transfer of shares in our company by investors that are non- Chinese resident enterprises, or the sale or purchase of shares in other non- Chinese resident companies or other taxable assets by us. For example, the Chinese tax authorities may consider that a future securities offering involves an indirect change of shareholding in our Chinese subsidiaries and therefore it may be regarded as an Indirect Transfer under SAT Circular 7. Even if we believe no SAT Circular 7 reporting is required on the basis that such an offering has commercial purposes and is not conducted for tax avoidance, Chinese tax authorities may pursue us to report under SAT Circular 7 and request that we and our Chinese subsidiaries assist in the filing. As a result, we and our subsidiaries may be required to expend significant resources to provide assistance and comply with SAT Circular 7, or establish that we or our non- resident enterprises should not be subject to tax under SAT Circular 7, for such an offering or other transactions, which may have an adverse effect on our and their financial condition and day- to- day operations. Any failure to comply with Chinese regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations. In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the " Stock Option Rules "). In accordance with the Stock Option Rules and other relevant ~~117rules~~ --- **rules** and regulations, Chinese citizens or non- Chinese citizens residing in China for a continuous period of not less than one year who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a Chinese subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are Chinese citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plans are subject to such regulation. We plan to assist our employees to register their equity awards. However, any failure of our Chinese individual beneficial owners and holders of equity awards to comply with the SAFE registration requirements may subject them to fines and legal sanctions and may limit the ability of our Chinese subsidiaries to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors and employees under Chinese law. ~~Risks~~ **111Risks** Related to Our Intellectual PropertyIf we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected. We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect

the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our markets. Our success depends in large part on our ability to obtain and maintain patent protection for our product candidates and their intended uses, maintain trade secret protection of our platform technologies, as well as our ability to operate without infringing the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued, or may not result in issued patents that will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies or products. Obtaining and enforcing patents is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and / or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including due to delays as a result of global pandemics impacting our or our licensors' operations. Further, we may decide to not pursue or seek patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights. Or we may not be able to obtain a patent on such technology at all. Even if we can patent the technology, we may be able to patent only a limited scope of the technology, and the limited scope may be inadequate to protect our product candidates, or to block competitor products or product candidates that are similar to ours. Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. The claims in our pending patent applications directed to composition of matter of our product candidates may not be considered patentable by the United States Patent and Trademark Office (" USPTO ") or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents ~~118protect~~ --- **protect** the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products " off- label. " Although off- label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions for which many legal principles continue to change. In recent years, patent rights have been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent ~~protection~~ **112protection** . In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and / or unenforceable. The patent application process is subject to numerous risks and uncertainties, and we or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third- party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third- party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third- party intellectual property upon our freedom to operate, is highly uncertain. Patent applications in the United States and other foreign 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 were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. We or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and defending patents. We have pending U. S. and foreign patent applications in our portfolio; however, we cannot predict: ● if and when patents may issue based on our patent applications; ● the scope of protection of any patent issuing based on our patent applications; ● whether the claims of any patent issuing based on our patent applications will provide protection against competitors; ● whether or not third parties will find ways to invalidate or circumvent our patent rights; ● whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; ● whether we will need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose; ● whether the patent applications that we own or in- license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; and / or ● whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates. The claims in our pending patent applications directed to our product candidates and / or technologies may not be considered patentable by the USPTO or by patent offices in foreign countries. Any such patent applications may not be issued as granted patents. One aspect of the determination of patentability of our inventions depends on the scope and content of the " prior art, " information that was or is deemed available to ~~119a~~ **a** person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims

or, if issued, affect the validity or enforceability of a patent claim. There may be double patenting among our own patents, which the patent examiner (s) fail to raise during prosecution. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. ~~Our~~ **113Our** pending patent applications may be challenged in the USPTO or in patent offices in foreign countries. Also, because the issuance of a patent is not conclusive as to its scope, validity or enforceability, even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third- party pre- issuance submissions of prior art to the USPTO or patent offices in foreign countries or our issued patents may be subject to post- grant review (" PGR ") proceedings, oppositions, derivations, reexaminations, or inter partes review (" IPR ") proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in our patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technologies and product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, only limited protection may be available and our patent portfolio may not provide us with sufficient rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could have a material adverse effect on our business, financial condition, results of operations and prospects. We rely on trade secret and proprietary know- how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent protection for our product candidates and technologies, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know- how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know- how to be our primary intellectual property. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. We expect to rely on CROs and third parties to generate chemical molecules and important research data. Any disclosure, either intentional or unintentional, by our employees or third- party consultants and vendors or CROs that we engage to perform research, clinical ~~trials~~ **studies** or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. 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. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know- how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know- how, and if the ~~120license~~ --- **license** is not available on commercially- viable terms, then we may not be able to complete development of, or commercialize, our products. Although we require all of our employees, consultants, collaborators, CROs, contract manufacturers, advisors and any third parties who have access to our proprietary know- how, information or technologies to enter into confidentiality agreements, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We cannot be certain that our trade secrets and other confidential proprietary information may not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the ~~outcome~~ **114outcome** is unpredictable. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. We also seek to preserve the integrity and confidentiality of our data and trade secrets 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, and we may not have adequate remedies for any breach. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations. We may rely on one or more in- licenses from third parties. If we lose these rights, our business may be materially adversely affected, and if disputes arise with one or more licensors, we may be subjected to future litigation as well as the potential loss of or limitations on our ability to develop

and commercialize products and technologies covered by these license agreements. The growth of our business may depend in part on our ability to acquire or in- license additional proprietary rights. We may be unable to acquire or in- license any relevant third- party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would adversely affect our business. We may need to cease use of the technology covered by such third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non- exclusive, and may allow our competitors access to the same technologies licensed to us. The licensing and acquisition of third- party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive for commercializing our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates and technology that we may seek to acquire. We may in the future enter into license agreements with third parties under which we receive rights to intellectual property that are important to our business. Our rights to use the technology we license are subject to the continuation of and compliance with the terms of those agreements. These intellectual property license agreements may require of us various development, regulatory and / or commercial diligence obligations, payment of milestones and / or royalties and other obligations. If we fail to comply with our obligations under these agreements, we use the licensed intellectual property in an unauthorized manner or we are subject to bankruptcy- related proceedings, the terms of the license agreements may be materially ~~121modified~~ **modified** , such as by rendering currently exclusive licenses non- exclusive, or it may give our licensors the right to terminate their respective agreement with us, which could limit our ability to implement our current business plan and materially adversely affect our business, financial condition, results of operations and prospects. We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on ~~reasonable~~ **115reasonable** terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property. In some cases, we may not control the prosecution, maintenance or filing of the patents to which we hold licenses, or the enforcement of those patents against third parties. Hence, our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed in a manner consistent with the best interests of our business. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Further, we may have limited control over these activities or any other intellectual property that may be in- licensed. For example, we cannot be certain that such activities by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third- party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves. In the event our licensors fail to adequately pursue and maintain patent protection for patents and applications they control, and to timely cede control of such prosecution to us, our competitors might be able to enter the market, which would have a material adverse effect on our business. Moreover, disputes may arise with respect to our licensing or other upstream agreements, including: ● the scope of rights granted under the agreements and other interpretation- related issues; ● whether and the extent to which our systems and consumables, technologies and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; ● the sublicensing of patent and other rights under our collaborative development relationships; ● our diligence obligations under the license agreements and what activities satisfy those diligence obligations; ● the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and ● the priority of invention of patented technology. In spite of our efforts to comply with our obligations under our in- license agreements, our licensors might conclude that we have materially breached our obligations under our license agreements and might therefore, including in connection with any aforementioned disputes, terminate the relevant license agreement, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If any such in- license is terminated, or if the licensed patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to market or develop products similar to ~~122ours~~ **ours** . In addition, absent the rights granted to us under such license agreements, we may infringe the intellectual property rights that are the subject of those agreements, we may be subject to litigation by the licensor, and if such litigation by the licensor is successful we may be required to pay damages to such licensor, or we may be required to cease our development and commercialization activities which are deemed infringing, and in such event we may ultimately need to modify our activities or products to design around such infringement, which may be time- and resource- consuming, and which may not be ultimately successful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. ~~In~~

116In addition, certain of our future agreements with third parties 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, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor' s express consent in order for an assignment or transfer to take place. Our intellectual property licensed from third parties may be subject to retained rights. Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property. The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the " Bayh- Dole Act "); these include the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products. While it is our policy to avoid engaging our university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co- developed intellectual property will be free from government rights pursuant to the Bayh- Dole Act. If, in the future, we co- own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh- Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and / or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and / or applications and any patent rights we may own or license in the future. We rely on our outside counsel, patent annuity service providers, or our licensing partners to pay these fees due to non- U. S. patent agencies. If these fees are not paid to the USPTO or the non- U. S. patent agencies when due, our rights to such patents or patent applications may be abandoned or otherwise materially impaired. The USPTO and various non- U. S. government patent agencies require compliance with several procedural, documentary, and other similar provisions during the patent application process. For example, many ~~123countries~~ **countries** , including the U. S. and China, require a foreign filing license to seek patent protection in a country outside of the inventor' s or invention' s country. Each country' s laws regarding foreign filing licenses vary and may even conflict. We employ reputable law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance 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~~ **117prescribed** time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years from the earliest filing date of a non- provisional patent application. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. For instance, a patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not necessarily extend to all patent claims, but instead only to patent claims that read on the product as approved. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of our new product candidates such as ~~GSBR~~ **aleniglipron, ACCG** - ~~1290~~ **2671** , ANPA- 0073 **, LTSE- 2578** and any of our future product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension) as compensation for effective patent term lost during product development and FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Further, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to

our patents, or may grant more limited extensions than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may be able to take advantage of our investment in development and clinical ~~trials~~ **studies** by referencing our clinical and preclinical data and launch their product candidates earlier than might otherwise be the case. ~~124Intellectual~~ --- **Intellectual** property rights do not necessarily address all potential threats to our business. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative: ● others may be able to make compounds or formulations that are similar to our product candidates but that are not covered by the claims of any patents that we own or control; ● we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control; ● we might not have been the first to file patent applications covering certain of the inventions we own or control; **118** ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; ● it is possible that noncompliance with the USPTO and foreign governmental agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process or technology export can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction; ● pending patent applications that we own or control may not lead to issued patents; ● issued patents that we own or control may be held invalid or unenforceable as a result of legal challenges; ● our competitors might conduct research and development activities in the United States and other foreign countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive product candidates for sale in our major commercial markets; ● we may not develop additional proprietary technologies that are patentable; ● we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in- license will result in issued patents with claims that directed to our product candidates or uses thereof in the United States or in other foreign countries; ● there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; ● countries other than the United States may have patent laws that are less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates; ● the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; ● if enforced, a court may not hold that our patents are valid, enforceable and infringed; ● we may not develop additional proprietary technologies that are patentable; and ● the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications. ~~125Third~~ --- **Third** parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business. Our commercial success depends, in part, upon our ability and the ability of our current or future collaborators to develop, manufacture, market and sell our current and any future product candidates 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 complex litigation regarding patents and other intellectual property rights. Because the intellectual property landscape in the industry in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our freedom to operate without infringing on third- party rights. U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our ~~fields~~ **119fields**, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods. Our product candidates and other proprietary technologies we may develop may infringe existing or future patents owned by third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future product candidates and technologies, including interference or derivation, PGR and IPR proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize our current and any future product candidates. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, a court of competent jurisdiction may not invalidate the claims of any such U. S. patent. If we are found to infringe a third party' s valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our product candidate (s) and technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and

commercializing the infringing technologies or product candidate, or redesign our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our current or any future product candidates or force us to cease some or all of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects. Third parties asserting their patent or other intellectual property rights against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays, and may impact our reputation. ~~126In~~ **In** addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Additionally, during the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings in ~~the~~ **120the** litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, programs or intellectual property could be diminished. Accordingly, the market price of our ADSs may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. Competitors or other third parties may infringe or otherwise violate our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technologies claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. 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 insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or patent offices in foreign countries or made a misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post- grant proceedings such as ex parte reexaminations, IPR, or PGR, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. There may be invalidating prior art, of which we and the patent examiner were unaware during prosecution. There may be double patenting among our own patents, which the patent examiner (s) fail to raise during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party' s use of our patented technologies falls under the safe harbor to patent infringement under 35 U. S. C. § 271 (e) (1). An adverse outcome in a litigation or other proceeding involving our patents could limit our ~~127ability~~ --- **ability** to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our future licensors is threatened, it could dissuade other companies from collaborating with us to license, develop or commercialize current or future product candidates. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such case, we could ultimately be forced to cease use of such trademarks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation,

there is a risk that some of our confidential information could be compromised by disclosure during ~~litigation~~ **121litigation** . There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ADSs. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Further, interference or derivation proceedings provoked by third parties or brought by the USPTO or patent offices in foreign countries may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technologies or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, derivation or other proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees. Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties. Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk- adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non- litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical ~~trials~~ **studies** , continue our internal research programs, in- license needed technologies or other product candidates, or enter into development partnerships that would help us bring our product candidates to market. ~~128Changes~~ --- **Changes** in U. S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other foreign countries could increase uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our patents or narrow the scope of our patent protection. On September 16, 2011, the Leahy- Smith America Invents Act (the " Leahy- Smith Act ") was signed into law. When implemented, the Leahy- Smith Act included several significant changes to U. S. patent law that impacted how patent rights could be prosecuted, enforced and defended. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost- effective avenues for competitors to challenge the validity of patents. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including PGR, IPR, and derivation proceedings. Further, because of a lower evidentiary standard in these USPTO post- grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO ~~proceeding~~ **122proceeding** sufficient for the USPTO to hold a patent claim invalid even though the same evidence would be insufficient to invalidate the patent claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our 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 could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, under the Leahy- Smith Act, the United States transitioned from a " first- to- invent " system to a " first- to- file " system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, 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 will require us to be cognizant going forward of the time from invention to filing of a patent application. 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 or our licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensor' s patents or patent applications. Even where we have a valid and enforceable patent, we 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. The USPTO developed new regulations and procedures governing the administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. It remains unclear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a negative

effect on our business. In addition, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or ~~129changes~~ --- **changes** in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business. Filing, prosecuting and defending patents covering our current and any future product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and, further, may export otherwise infringing product candidates to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These product candidates may compete with our product candidates in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. ~~Many~~ **123Many** companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed trade secrets or other confidential information of their current or former employers or claims asserting inventorship or ownership of what we regard as our own intellectual property. Many of our employees, consultants, and advisors are currently or were previously employed at universities or other healthcare, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer or client. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, ~~130we~~ **we** may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being invalid or unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co- ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. ~~Our~~ **124Our** licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U. S. government, such that our licensors are not the sole and exclusive owners of the patents we in- licensed. If other third parties have ownership rights or other rights to our in-

licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing product candidates and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market our products. Any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, may not be complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. For example, we may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Also, our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. One aspect of the determination of patentability of our inventions depends on the scope and content of the " prior art, " information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the ~~131patentability~~ --- **patentability** of the claims of our patent applications or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third- party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third- party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third- party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we may not be the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U. S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U. S. applications containing a patent claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the Leahy- Smith Act, which brought into effect significant changes to the U. S. patent laws, including new procedures for challenging pending patent applications and issued patents. ~~If~~ **125If** our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our current or future trademarks or trade names may be challenged, opposed, infringed, circumvented, invalidated, cancelled, declared generic, determined to be not entitled to registration, or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in foreign jurisdictions. Although we would be 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 foreign jurisdictions, 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. Any trademark litigation could be expensive. In addition, we could be found liable for significant monetary damages, including treble damages, disgorgement of profits and attorneys' fees, if we are found to have willfully infringed a trademark. We may not be able to protect our exclusive right to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential collaborators or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Moreover, any name we have proposed 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. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it 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. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. Risks Related to Our ADSsThe price of our ADSs may be volatile, and you could lose all or part of your investment. The trading price of our ADSs is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In

~~132addition~~ --- **addition** to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report, these factors include: ● the commencement, enrollment or results of our ongoing and planned preclinical studies and clinical ~~trials~~ **studies**, or any future preclinical studies or clinical ~~trials~~ **studies**, we may conduct of our current and any future product candidates, or changes in the development status of our current and any future product candidates; ● any delay in preparing regulatory submissions to support development or commercialization of our current and any future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such submissions, including without limitation the FDA' s issuance of a " refusal to file " letter or a request for additional information; ● adverse results or delays in our preclinical studies and clinical ~~trials~~ **studies**; **126** ● our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial; ● adverse regulatory decisions, including failure to receive marketing approval for our current and any future product candidates; ● changes in laws or regulations applicable to our current and any future product candidates, including but not limited to clinical trial requirements for approvals; ● the failure to obtain coverage and adequate reimbursement of our current and any future product candidates, if approved; ● changes on the structure of healthcare payment systems; ● any changes to our relationship with any manufacturers, suppliers, licensors, future collaborators or other strategic partners; ● our inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices; ● our inability to establish collaborations if needed; ● our failure to commercialize our current and any future product candidates; ● additions or departures of key scientific or management personnel; ● unanticipated serious safety concerns related to the use of our current and any future product candidates; ● introduction of new products or services offered by us or our competitors, or the release or publication of clinical trial results from competing product candidates; ● announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors; ● our ability to effectively manage our growth; ● actual or anticipated variations in quarterly operating results; ● our cash position; ● our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; ● publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts; ● changes in the market valuations of similar companies; ~~133~~ ● overall performance of the equity markets; ● issuances of debt or equity securities; ● sales of our ADSs by us or our shareholders in the future, or the perception that such sales may occur; ● trading volume of our ADSs; ● changes in accounting practices; ● ineffectiveness of our internal controls; ● disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; ● significant lawsuits, including patent or shareholder litigation; **127** ● general geopolitical and macroeconomic conditions, including as a result of bank failures **, tariffs**, global pandemics, the Russia / Ukraine conflict or the Israel- Hamas war; and ● other events or factors, many of which are beyond our control. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ADSs regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, operating results or financial condition. Although our annual financial statements were audited and reported upon by auditors who are currently subject to inspection by the Public Company Accounting Oversight Board (" PCAOB "), there is no guarantee that future audit reports will be prepared by auditors that are subject to inspection by the PCAOB and, as such, future investors may be deprived of such inspections, which could result in limitations or restrictions to our access of the U. S. capital markets. Furthermore, trading in our securities may be prohibited under the Holding Foreign Companies Accountable Act (" HFCA Act ") or the Accelerating Holding Foreign Companies Accountable Act (" AHFCA Act ") if the SEC subsequently identifies that our audit work is performed by an auditor that the PCAOB is unable to inspect or investigate completely, and as a result, U. S. national securities exchanges, such as the Nasdaq, may delist our securities. As part of a continued regulatory focus in the United States on access to audit and other information, the United States passed the HFCA Act in December 2020. The HFCA Act requires the SEC to identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by a non- U. S. authority in the auditor' s local jurisdiction. The HFCA Act also requires public companies identified by the SEC to certify that they are neither owned nor controlled by a foreign government, and make certain additional disclosures in their SEC filings. The HFCA Act also provides that if an auditor of a U. S. listed company' s financial statements is not subject for three consecutive " non- inspection years " after the HFCA Act becomes effective, the SEC must prohibit the securities of such issuer from being traded on a U. S. national securities exchange. However, in June 2021, the U. S. Senate passed the AHFCA Act which amends the HFCA Act and ~~require~~ **requires** the SEC to prohibit an issuer' s securities from trading on any U. S. stock exchanges if its auditor is subject to two " non- inspection years " instead of three. On February 4, 2022, the U. S. House of Representatives passed the America Creating Opportunities for Manufacturing, Pre- Eminence in Technology, and Economic Strength Act of 2022, which contained, among other things, an identical provision. In December 2021, the PCAOB issued a report on its determination that it is unable to inspect or investigate completely PCAOB- registered ~~134accounting~~ --- **accounting** firms headquartered in Mainland China and in Hong Kong. Also, in December 2021, the SEC adopted final amendments to its rules implementing the HFCA Act and established procedures to identify issuers and prohibit the trading of the securities of certain registrants as required by the HFCA Act. This rule stated that only the principal accountant, as defined by Rule 2- 05 of Regulation S- X and PCAOB AS 1205, is " deemed ' retained' for purposes of Section 104 (i) of the Sarbanes- Oxley Act and the Commission' s determination of whether the registrant should be a Commission Identified Issuer. " In December 2022, the PCAOB vacated its determination that it was unable to inspect and investigate PCAOB- registered public accounting firms in Mainland China and Hong Kong. As a result, until such time as the PCAOB issues a new determination, the SEC has determined that there are no issuers currently at risk of having their securities

subject to a trading prohibition under the HFCA Act. However, while vacating those determinations, the PCAOB noted that, should it encounter any impediment to conducting an inspection or investigation of auditors in Mainland China or Hong Kong as a result of a position taken by any authority there, the PCAOB would act to immediately issue a new determination. ~~In May 2023, we dismissed PricewaterhouseCoopers LLP and engaged Ernst~~ **128Ernst** & Young LLP ~~as~~**,** our independent registered public accounting firm ~~. Each of PricewaterhouseCoopers LLP and Ernst & Young LLP,~~ is headquartered in the United States, is registered with the PCAOB and is an auditor of companies that are both registered with the SEC and publicly traded in the United States. As a result, the HFCA Act ~~did not previously and~~ does not currently apply to us. However, if our operations fundamentally change in a way that requires our independent registered public accounting firm to be located in China in order to comply with the standards of the PCAOB regarding auditors then the HFCA Act would apply to us. Such a restriction would negatively impact our ability to raise capital. We view the likelihood to be remote that our operations will fundamentally change, as to require our auditor to be located in China. Additionally, it is possible that in the future Congress could amend the HFCA Act or the SEC could modify its regulations to apply the restrictions, including trading prohibitions and delisting, under the HFCA Act in situations in which an independent registered public accounting firm in China performs part of the audit such as in our current situation. There are currently no such proposals. Further, while we understand that there has been dialogue among the CSRC, the SEC and the PCAOB regarding the inspection of PCAOB- registered accounting firms in China, there can be no assurance that, in the future, we will be able to comply with requirements imposed by U. S. regulators. The market price of our ADSs could be adversely affected as a result of anticipated negative impacts of these executive or legislative actions upon, as well as negative investor sentiment towards, companies with operations in China that are listed in the United States, regardless of whether these executive or legislative actions are implemented and regardless of our actual operating performance. We have identified material weaknesses in our internal control over financial reporting **in the past** and may identify additional material weaknesses in the future or fail to maintain effective internal control over financial reporting, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations. We have **previously** identified material weaknesses in our internal control over financial reporting ~~in the past, one of which has not been remediated and continues to exist as of December 31, 2023~~ . A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. ~~The~~ **We previously reported a** material weakness **in** ~~which continues to exist as of December 31, 2023 is~~ that we did not design and maintain an effective control environment commensurate with our financial reporting requirements as we lacked a sufficient complement of professionals commensurate with our financial reporting requirements. Additionally, the lack of a sufficient number of professionals resulted in an inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives. This material weakness did not result in any material misstatements to the consolidated financial statements. This material weakness could result in a misstatement of substantially all of our accounts or disclosures that ~~135would~~ ~~---~~ **would** result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected. The material weakness **was** ~~will not be considered~~ remediated ~~until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. We are working to remediate the material weakness~~ as ~~efficiently and effectively as possible. At this time, we cannot provide an estimate~~ of **June 30** ~~costs expected to be incurred in connection with implementing this remediation plan; however~~ , **2024** ~~these remediation measures will be time consuming, will result in us incurring significant costs, and will place significant demands on our financial and operational resources~~ . **In** ~~Although we have begun to implement measures to address the material weakness, the implementation of these measures may not fully address the material weakness and deficiency in our internal control over financial reporting. Further, in~~ the future we may determine that we have additional material weaknesses. Our failure to ~~remediate the material weakness or failure to~~ identify and address any other material weaknesses that may be identified in the future could result in material misstatements to our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which may result in volatility in and a decline in the market price of our securities. ~~See Part II. Item 9A. " Controls and Procedures — Management' s Plan to Remediate the Material Weakness ".~~ Our principal shareholders and management own a significant percentage of our voting securities and will be able to exert significant control over matters subject to shareholder approval. As of December 31, ~~2023~~ **2024** , our executive officers, directors, five percent shareholders and their affiliates beneficially owned approximately ~~34~~ **48** % of the voting power of our outstanding share capital **(excluding the 18, 000, 000 ordinary shares issued to our depositary bank for bulk issances of ADSs reserved for future issuances upon the exercise or vesting of awards granted under our equity incentive plans)** . Therefore, these ~~shareholders~~ **129shareholders** will have the ability to influence us through their ownership positions. These shareholders may be able to determine all matters requiring shareholder approval. For example, these shareholders, acting together, may be able to control elections of directors, issuances of equity, including to our employees under equity incentive plans, amendments of our organizational documents, or approval of any merger, amalgamation, sale of assets or other major corporate transaction. These shareholders' interests may not always coincide with our corporate interests or the interests of other shareholders, and these shareholders may exercise their voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other shareholders. This may prevent or discourage unsolicited acquisition proposals or offers for our ADSs that you may believe are in your best interest as a holder of our ADSs. **Substantial** ~~A significant portion of our total outstanding shares are restricted from immediate resale, but may be sold into the market in the near~~ future ~~. This~~ **sales of our ADSs** could cause the market price of our ADSs to drop significantly, even if our business is doing well. Sales of a substantial number of our ADSs in the public market could occur at any time. If our shareholders sell, or the market perceives that our shareholders intend to sell, substantial amounts of our ADSs

in the public market, the market price of our ADSs could decline significantly. **In** ~~On August 2, 2023, 77, 752, 483 ordinary shares (excluding~~ the **future we may** ~~18, 000, 000 ordinary shares issued~~ **issue** ~~to our depositary bank for bulk issuance of~~ ADSs ~~reserved for~~ **or** ~~future issuances upon the~~ **other** ~~exercise or vesting~~ **securities if we need to raise additional capital and, in the event a large number** of **ADSs are sold** ~~awards granted under our equity incentive plans) became available for sale~~ in the public market, ~~following the expiration of lock- up agreements entered into by substantially all of our shareholders in connection with the IPO. Sales of a substantial number of such shares, or the perception that~~ such sales ~~may occur,~~ could ~~cause~~ **reduce** the ~~market~~ **trading** price of our ADSs ~~to fall or make it more difficult for our securityholders to sell their ADSs at a time and price that they deem appropriate. In October 2023, we completed our Private Placement for aggregate gross proceeds of approximately $ 300 million before deducting placement agent fees and other private placement expenses. An aggregate of 13621, 617, 295 ordinary shares and 2, 401, 920 newly designated non- voting ordinary shares were issued pursuant to the Purchase Agreement. Each holder of the non- voting ordinary shares had the right to convert each non- voting ordinary share held by such holder into one ordinary share, subject to certain beneficial ownership limitations, as described further in the description of the rights of the non- voting ordinary shares included as Exhibit 4. 5 to this Annual Report. The purchase price was $ 12. 49 per share (or the equivalent of $ 37. 47 per ADS), which represents the ADS closing price on the Nasdaq Global Market immediately preceding the signing of the Purchase Agreement on September 29, 2023. As of December 31, 2023, all outstanding non- voting ordinary shares had been converted into ordinary shares~~. In addition, promptly following the completion of our IPO, we filed a registration statement registering the issuance of approximately 22, 099, 376 ordinary shares (which may be in the form of ADSs) subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. **We also intend to file future registration statements on Form S- 8 under the Securities Act registering the issuance of additional ordinary shares (or ADSs), including because the number of shares that may be issued under certain employee equity benefit plans automatically increase as a result of the operation of certain " evergreen " provisions in our equity plans.** Shares (or ADSs) registered under ~~this~~ **these** registration ~~statement~~ **statements** are available for sale in the public market subject to vesting arrangements and exercise of options and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act. If these additional shares or ADSs are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs could decline. Holders of our ADSs have fewer rights than our shareholders and must act through the depositary to exercise their rights. Holders of our ADSs do not have the same rights as our shareholders and may only exercise their voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Holders of the ADSs will appoint the depositary or its nominee as their representative to exercise the voting rights attaching to the ordinary shares represented by the ADSs. When a general meeting is convened, if you hold ADSs, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. We will take all commercially reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you that you will receive voting materials in time to instruct the depositary to vote, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting. ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff (s) in any such action. The deposit agreement governing the ADSs representing our ordinary shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement, our ordinary shares or the ADSs or the transactions contemplated thereby, ~~including~~ **130including** claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court in New York, which have non- exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement, our ordinary shares and the ADSs and the transactions contemplated thereby. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based on a creditor' s negligence in failing to liquidate collateral upon a guarantor' s demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of ~~137which~~ --- **which** we believe are applicable in the case of the deposit agreement, our ordinary shares or the ADSs or the transactions contemplated thereby. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of the federal securities laws. If you or any other holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement, our ordinary shares or the ADSs or the transactions contemplated thereby, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and / or the depositary. If a lawsuit is brought against us and / or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may augur different results than a trial by jury would have had, including results that could be less favorable to the plaintiff (s) in any such action, depending on, among other things,

the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing. You may not receive distributions on our ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs. Although we do not have any present plans to declare or pay any dividends on our ordinary shares, in the event we declare and pay any dividends, the depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to register under U. S. securities laws any offering of ADSs, ordinary shares or other securities received through such distributions. We also have no obligation to take any other action to permit distribution on the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have an adverse effect on the value of your ADSs. Your right to participate in any future rights offerings may be limited, which may cause dilution to your holdings. We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to you in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary bank will not make rights available to you unless the rights and any related securities are registered under the Securities Act or are otherwise exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration ~~under~~ **131under** the Securities Act. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings. Because we do not anticipate paying any cash dividends on our ADSs in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment. We have never declared or paid a dividend on our ordinary shares in the past, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in our ADSs to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law, including that our company may only pay dividends out of profits or out of the credit standing in our share premium account, and provided always that in no circumstances may a dividend be paid if it would result in ~~138our~~ **our** inability to pay our debts as they fall due in the ordinary course of business. In addition, our shareholders may, subject to our **amended and restated** memorandum and articles of association, by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. As a result, capital appreciation, if any, on our ADSs will be your sole source of gains for the foreseeable future. We are subject to tax in the Cayman Islands and the United States. We are a Cayman Islands corporation as of the date of this Annual Report. We are treated as an exempted company for Cayman Islands tax purposes. We are also treated as a U. S. corporation subject to U. S. federal income tax pursuant to Section 7874 of the Code, and are subject to U. S. federal income tax on our worldwide income. As a result, we are subject to tax both in the Cayman Islands and the United States, which could have a material adverse effect on our financial condition and results of operations. It is unlikely that we will pay any dividends on our ordinary shares or ADSs in the foreseeable future. However, dividends received by " non- U. S. holders " will be subject to U. S. withholding tax. In addition, because the ordinary shares or ADSs are treated as shares of a U. S. domestic corporation, the U. S. gift, estate and generation- skipping transfer tax rules generally apply to a non- U. S. holder of ordinary shares or ADSs. Each holder or prospective holder of our ordinary shares or ADSs should seek tax advice from an independent tax advisor based on such holder' s particular circumstances. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. As of December 31, ~~2023~~ **2024**, we had $ ~~84~~ **99. 2 million and $ 147**. 8 ~~million and $ 146. 5~~ million of U. S. federal and state net operating loss (" NOL ") carryforwards, respectively, available to offset future taxable income. Under U. S. federal income tax law, federal NOLs incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80 % of taxable income for taxable years beginning after December 31, 2020. Any NOLs incurred in tax years beginning before December 31, 2017, may be used to offset up to 100 % of future taxable income, but will begin to expire in varying amounts in ~~2037~~ **2036**, unless previously utilized. Similar rules may apply under state tax laws. As of December 31, ~~2023~~ **2024**, we also had aggregate U. S. federal and state R & D credits of approximately $ ~~2~~ **5**. ~~2~~ **7** million and $ ~~0~~ **1**. ~~5~~ **3** million, respectively. U. S. federal R & D credits carryforwards begin to expire in 2039 unless previously utilized. The state R & D credit carryforwards do not expire. Our NOL carryforwards and R & D credits are subject to review and possible adjustment by the U. S. and state tax authorities. ~~In~~ **132In** addition, under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards, R & D credits and certain other tax attributes to offset its post- change income or taxes may be limited. This could limit the amount of NOLs, R & D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Subsequent ownership changes and changes to the U. S. tax rules in respect of the utilization of NOLs, R & D credits and other applicable tax attributes carried forward may further affect the limitation in future years. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently

increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows. We have not undertaken a study under Section 382 of the Code, and it is possible that we have previously undergone one or more ownership changes so that our use of NOLs is subject to limitation. We may experience ownership changes in the future as a result of subsequent shifts in our share ownership, including as a result of our IPO. As a result, if we earn net taxable income, our ability to use our pre- change ~~139NOLs~~ **NOLs** to offset U. S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. **At** ~~In addition, at~~ the state level, **California has suspended** ~~there may be periods during which~~ the use of NOLs ~~is~~ **by certain taxpayers for tax years beginning on or after January 1, 2024, and before January 1, 2027. Other states may also** ~~suspended~~ -- **suspend** or otherwise ~~limited~~ **place limitations on the use of NOLs** , which could accelerate or permanently increase state taxes owed. We will incur significantly increased costs as a result of operating as a company whose ADSs are publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives. As a public company in the United States, we will incur significant legal, accounting and other expenses that we did not incur ~~previously~~ **prior to our IPO** . These expenses will likely be even more significant ~~after~~ **in the future since** we no longer qualify as an emerging growth company ~~and / or a smaller~~ **as of December 31, 2024. We are subject to the** reporting ~~company~~ **requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition** . ~~The~~ **In addition, the** Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act (the " Dodd- Frank Act "), the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Pursuant to Section 404 of the Sarbanes- Oxley Act, ~~beginning with our Annual Report on Form 10- K for the year ended December 31, 2023,~~ we **are** ~~will be~~ required to furnish a report by our senior management on our internal control over financial reporting. ~~However~~ **As of June 30** , ~~while~~ **2024, the end of our second fiscal quarter and the date of assessment for our filer status, the market value of our ordinary shares held by non- affiliates exceeded $ 700. 0 million. As a result,** we ~~remain~~ **are a large accelerated filer and ceased to be** an emerging growth company ~~or~~ **effective December 31, 2024. Additionally, we will no longer qualify as** a smaller reporting company ~~as discussed below~~ **beginning with our first Quarterly Report on Form 10- Q for the quarterly period ending March 31, 2025. As a result of this transition** , we **are** ~~will not be~~ required to include an attestation report on internal ~~controls~~ - **control** over financial reporting issued by our independent registered public accounting firm **with this Annual Report on Form 10- K for the fiscal year ended December 31, 2024** . To prepare for ~~eventual~~ compliance with Section 404, we ~~will be engaged~~ **133engaged** in a process to document and evaluate ~~our internal controls over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal controls over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal controls over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed time frame or at all, that our internal controls over financial reporting is effective as required by Section 404. We are an emerging growth company and a smaller reporting company, and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our ADSs less attractive to investors. We are an " emerging growth company, " as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from various public company reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to have~~ our internal control over financial reporting ~~audited by our independent registered public accounting firm under~~ **, which is both costly and challenging. In this regard, we have dedicated internal resources, engaged outside consultants and adopted a detailed work plan to assess and document the adequacy of internal control over financial reporting. We will continue to incur increasing costs with regards to compliance with** Section 404 ~~of the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation~~ in ~~our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We may take advantage of these~~ -- **the future** ~~exemptions until December 31, 2028, the last day of the fiscal year ending after the fifth anniversary of our IPO or until we are no longer an emerging growth company, whichever is earlier. We will cease to be an 140emerging growth company prior to the end of such five- year period if certain earlier events occur, including if we become a " large accelerated filer " as defined in Rule 12b- 2 under the Exchange Act, our annual gross revenues equal or exceed $ 1. 235 billion or we issue more than $ 1. 0 billion of non- convertible debt in any three- year period prior to such time. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with certain new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and~~

~~therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies. We are also a " smaller reporting company " as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our ADSs held by non- affiliates is less than $ 250. 0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and our ADSs held by non- affiliates is less than $ 700. 0 million measured on the last business day of our second fiscal quarter~~ . Since shareholder rights under Cayman Islands law differ from those under U. S. law, you may have difficulty protecting your shareholder rights. We are an exempted company limited by shares incorporated under the laws of the Cayman Islands. Our corporate affairs are governed by our **amended and restated** memorandum and articles of association, the Companies Act (as amended) of the Cayman Islands and the common law of the Cayman Islands. The rights of shareholders to take action against our directors, actions by our minority shareholders and the fiduciary responsibilities of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from the common law of England, the decisions of whose courts are of persuasive authority, but are not binding, on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities laws than the United States. Some U. S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. In addition, Cayman Islands companies may not have standing to initiate a shareholder derivative action in a federal court of the United States. Shareholders of Cayman Islands exempted companies like us have no general rights under Cayman Islands law to inspect corporate records, other than the **amended and restated** memorandum and articles of association and any special resolutions passed by such companies, and the registers of mortgages and charges of such companies. The Registrar of Companies of the Cayman Islands shall make available the list of the names of the current directors of the Company (and where applicable the current alternate directors of the Company) for inspection by any person upon payment of a fee by such person. Our directors have discretion under our **amended and restated** memorandum and articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest. Certain corporate governance practices in the Cayman Islands, which is our home country, differ significantly from requirements for companies incorporated in other jurisdictions such as the United States. Currently, we do not plan to rely on home country practice with respect to any corporate governance matter. However, if we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U. S. domestic issuers. ~~141As~~ **As** a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by our management, members of our board of directors or our controlling shareholders than they would as public shareholders of a company incorporated in the United States. Provisions in our amended and restated memorandum and articles of association may prevent or frustrate attempts by our shareholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our ADSs may be lower as a result. There are provisions in our amended and restated memorandum and articles of association that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other shareholders. For example, as of the date of this Annual Report, our board of directors will have the authority to issue up to ~~90~~ **100** , ~~187~~ **000** , ~~562~~ **000** shares of an additional class or classes of shares, which could include preference shares. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the other classes of shares without any further vote or action by ~~our~~ **134our** shareholders. The issuance of such shares may delay or prevent a change of control transaction. As a result, the market price of our ADSs and the voting and other rights of our shareholders may be adversely affected. An issuance of other classes of shares may result in the loss of voting control to other shareholders. Our charter documents will also contain other provisions that could have an anti- takeover effect, including: ● only one of our three classes of directors will be elected each year; ● shareholders will be entitled to remove directors only for cause; ● shareholders will not be permitted to take actions by written consent; and ● shareholders must give advance notice to nominate directors or submit proposals for consideration at annual general meetings. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our ADSs. You may be subject to limitations on transfers of your ADSs. Your ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when deemed necessary or advisable by it in good faith in connection with the performance of its duties or at our reasonable written request, subject in all cases to compliance with applicable U. S. securities laws. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason. General Risk **FactorsFailure** ~~FactorsWe will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In~~

addition, the Sarbanes- Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes- Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd- Frank Act was enacted and 142included significant corporate governance and executive compensation related provisions that require the SEC to adopt additional rules and regulations in these areas, such as " say on pay " and proxy access. Emerging growth companies and smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Shareholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time- consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies. As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes- Oxley Act, the regulations of Nasdaq, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes- Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. We must perform system and process evaluation and testing of our internal ~~controls~~ **control** over financial reporting to allow management to report on the effectiveness of our internal ~~controls~~ **control** over financial reporting in our annual report, as required by Section 404 of the Sarbanes- Oxley Act. Prior to our IPO, we ~~have~~ **had** never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. In addition, our independent registered public accounting firm **is** ~~will be~~ required to attest to the effectiveness of our internal control over financial reporting **beginning** ~~in our first annual report required to be filed~~ with **this Annual Report on Form 10- K for** the **year ended December 31, 2024** ~~SEC following the date we are no longer an emerging growth company~~. We anticipate that the process of building our accounting and financial functions and infrastructure will require significant additional professional fees, internal costs and management efforts. We expect that we will need to implement a new internal system to combine and streamline the management of our financial, accounting, human resources and other functions. However, such a system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Any disruptions or difficulties in implementing or using such a system could ~~adversely~~ **135adversely** affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. **If** ~~143If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if~~ we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information, the market price of our ADSs could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. If we are unable to maintain effective internal controls, our business, financial position and results of operations could be adversely affected. As a public company, we are subject to the requirements of Section 404 of the Sarbanes- Oxley Act, which require annual management assessments of the effectiveness of our internal control over financial reporting **. In addition, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting beginning with this Annual Report on Form 10- K for the year ended December 31, 2024** . The rules governing the standards that must be met for management to determine that our internal control over financial reporting is effective are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management has in the past and may in the future identify material weaknesses or deficiencies ~~which may not be remedied in time to meet the deadline imposed by the Sarbanes- Oxley Act~~ . For example, we have **previously** identified material weaknesses in our internal control over financial reporting in the past, one of which ~~has not~~ **we reported to have** been remediated ~~and continues to exist~~ as of ~~December 31~~ **June 30** , ~~2023~~ **2024** . These reporting and other obligations place significant demands on our management and administrative and operational

resources, including accounting resources. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. If we **identify any future material weaknesses and** are unable to remediate ~~our~~ **such** material weakness and conclude that our internal control over financial reporting is effective, or if in the future our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, this could have an adverse effect on our business, financial position and results of operations. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably ensure that information we must disclose in reports we file or submit pursuant to the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. ~~These~~ **136These** inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. ~~144Future~~ --- **Future** changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations. Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. ~~See Part II. Item 7. " Management' s Discussion and Analysis of Financial Condition and Results of Operations — Recent Accounting Pronouncements. "~~ If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the price and trading volume of our ADSs could decline. The trading market for our ADSs will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our ADSs, and such lack of research coverage may adversely affect the market price of our ADSs. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our ADSs could decline if one or more equity research analysts downgrade our ADSs or issue other unfavorable commentary or research about us. If one or more equity research analysts cease coverage of us or fail to publish reports on us regularly, demand for our ADSs could decrease, which in turn could cause the trading price or trading volume of our ADSs to decline. We could be subject to securities class action litigation or material legal proceedings which could have a negative impact on our reputation or business. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. In addition, from time to time, we **are** ~~have been~~ and may in the future be involved in legal and regulatory proceedings or investigations concerning matters that arise in the ordinary course of our business. Such proceedings could result in significant fines or penalties, have an adverse impact on our reputation, business and financial condition or results or operations and divert the attention of our management from the operation of our business. We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Our headquarters and main research facility are located near San Francisco, California, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our ~~headquarters~~ **137headquarters** or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third- party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect ~~145our~~ **our** supply chain, it could have a material adverse effect on our ability to conduct our clinical ~~trials~~ **studies**, our development plans and business. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations also produce hazardous waste products. We generally contract with

third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Our failure to meet Nasdaq' s continued listing requirements could result in a delisting of our ADSs. If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our ADSs. Such a delisting would likely have a negative effect on the price of our ADSs and would impair your ability to sell or purchase our ADSs when you wish to do so. In the event of a delisting, any action taken by us to restore compliance with listing requirements may not allow our ADSs to become listed again, stabilize the market price or improve the liquidity of our ADSs, prevent our ADSs from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with the listing requirements of Nasdaq. ~~146~~ **138**