Risk Factors Comparison 2025-03-03 to 2024-03-28 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, the section of this Annual Report titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our financial statements and related notes appearing elsewhere in this Annual Report, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment. This Annual Report also contains forward- looking statements that involve risks and uncertainties. See " Special Note Regarding Forward- Looking Statements. " Our actual results could differ materially and adversely from those anticipated in these forward- looking statements as a result of certain factors, including those set forth below. Summary of Risk Factors Our business is subject to numerous risks and uncertainties, including those highlighted in this section below, that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in more detail in the risk factors below, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition, and results of operations. Such risks include, but are not limited to: ● We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We are not currently profitable, and may never achieve or sustain profitability. If we are unable to achieve or sustain profitability, the market value of our common stock will likely decline. ● We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability. ● Operating our business requires substantial additional capital to finance our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations. ● We currently depend significantly on the success of ~~furmonertinib~~ **firmonertinib** , which is our only product candidate in clinical development. If we are unable to advance ~~furmonertinib~~ **firmonertinib** in clinical development, obtain regulatory approval and ultimately commercialize ~~furmonertinib~~ **firmonertinib** , or experience significant delays in doing so, our business will be materially harmed. ● Clinical and preclinical development of new biopharmaceutical products involves a lengthy and expensive process with uncertain timelines and outcomes, and results of prior clinical trials and studies of ~~furmonertinib~~ **firmonertinib and our other product candidates** are not necessarily predictive of future results. ~~Furmonertinib~~ **Firmonertinib and our other product candidates** may not achieve favorable results in our clinical trials or receive regulatory approval on a timely basis, if at all. ● Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials or nonclinical studies could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects. ● Enrollment and retention of patients in clinical trials 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. ● Use of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates could be associated with adverse side effects, adverse events or other safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved drug label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition. ● Several of the ongoing clinical trials for our lead product candidate, ~~furmonertinib~~ **firmonertinib** , are being conducted outside the United States, including in China. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business. ● Interim, topline and preliminary data from our clinical trials and nonclinical 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. ● The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. ● ~~A~~ **Firmonertinib has been granted** Breakthrough Therapy Designation ~~by~~ **for the treatment of first- line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations from the FDA and we may seek Breakthrough Therapy Designation for** ~~the~~ **other product candidates in the future. Even if we apply for Breakthrough Therapy Designation in the future, we might not receive such designation, and even if received, such designation** FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval. ● Furmonertinib has been granted Fast Track Designation by the FDA for the treatment of patients with NSCLC harboring activating EGFR or HER2 kinase domain mutations, including exon 20 insertion mutations and we may seek Fast Track Designation for other product candidates in the future. Even if we apply for Fast Track Designation in the future, we might not receive such designation, and even if received, such designation may not actually lead to a faster development or regulatory review or approval process. Further, such designation could be withdrawn by the FDA. ● We heavily rely on our exclusive license with Allist to provide us with intellectual property rights to develop and commercialize ~~furmonertinib~~ **firmonertinib** . Any termination or loss of significant rights under our agreements with Allist would adversely affect our development or commercialization of ~~furmonertinib~~ **firmonertinib** . ~~● We rely on, and intend to continue to rely on third parties to conduct,~~

~~supervise and monitor our clinical trials and nonclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize furmonertinib and any future product candidates may 55be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects~~ . ● We currently rely on a Chinese third party for the manufacture of ~~furmonertinib~~ **firmonertinib and other product candidates** for clinical development **, and potential future commercial supply of firmonertinib,** and expect to continue to rely on third parties for the foreseeable future **. We expect to rely on a Chinese third party for the manufacture of ARR- 217 for clinical development** . This reliance on third parties increases the risk that we will not have sufficient quantities of ~~furmonertinib~~ **firmonertinib or ARR- 217** or such quantities at an acceptable cost, which could delay, prevent or impair our development or potential commercialization efforts. ● Even if we receive regulatory approval for ~~furmonertinib~~ **firmonertinib** or **any other current or future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, firmonertinib and** any future product candidates, ~~we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, furmonertinib and any future 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, if any of them are approved. **61** ● We face significant competition, and if our competitors develop and commercialize technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective, safer, or less expensive than ~~furmonertinib~~ **firmonertinib** and any future product candidates we develop, our business and our ability to develop and successfully commercialize products will be adversely affected ~~. ● Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide. ● We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer~~ . ● We are subject to various U. S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could expose us to criminal sanctions, civil and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings, among other penalties, any of which could harm our results of operations and financial condition. ● If our internal information technology systems, or those used by our CROs, clinical sites, or other contractors or consultants upon which we rely, are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, litigation, fines, penalties and liability, compromise of sensitive information related our business, and other adverse consequences. ● ~~If we are unable to obtain and maintain, sufficient intellectual property protection for furmonertinib or future product candidates or technology, or if the scope of our intellectual property rights is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize furmonertinib or any future product candidates may be adversely affected. ●~~ We depend heavily on intellectual property licensed from ~~a~~ third ~~party~~ **parties** , and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business. ~~● We may not be able to protect our intellectual property and proprietary rights throughout the world. ● The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses. ● Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. ● We have identified material weaknesses in our internal control over financial reporting related to our control environment. If we do not remediate the material weaknesses in our internal control over financial reporting, or if we fail to establish and maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock. 56Risks~~ -- **Risks** Related to Our Limited Operating History, Financial Position and Capital ~~RequirementsWe~~ -- **Requirements We** have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We are not currently profitable, and may never achieve or sustain profitability. If we are unable to achieve or sustain profitability, the market value of our common stock will likely decline. We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We do not have any products approved for sale and have not generated any revenue since our inception. If ~~furmonertinib~~ **firmonertinib** is not successfully developed, approved and commercialized, we may never generate significant revenue, if we generate any revenue at all. Our net losses were $ **80. 5 million and $** 69. 3 ~~million and $ 36. 9~~ 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 $ ~~157~~ **238** . ~~8~~ **3** million. Substantially all of our losses have resulted from expenses incurred in connection with in- licensing intellectual property related to, and developing, ~~furmonertinib~~ **firmonertinib** and from general and administrative costs associated with our operations. ~~Furmonertinib~~ **Firmonertinib , our other product candidates,** and any future product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize ~~furmonertinib~~ **firmonertinib and our other product candidates** , seek to identify, assess, acquire, in- license intellectual property related to or develop additional product candidates and operate as a public company. In addition **, we are obligated to make milestone payments and royalty payments under certain license agreements and collaboration agreements. For example** , we are obligated to pay Allist milestone payments up to an aggregate of $ 765. 0 million upon the achievement of certain development, regulatory and sales

milestone events as set forth in the Allist License Agreement, as defined herein. We are also obligated under the Allist License Agreement to pay Allist tiered royalties based on net sales of Licensed Products, as defined herein. **Furthermore, we are obligated to pay Lepu Biopharma milestone payments up to an aggregate of $ 1. 17 billion upon the achievement of certain development, regulatory and sales milestone events as set forth in the Lepu Biopharma Agreement, as defined herein. We are also obligated under the Lepu Biopharma Agreement to pay Lepu Biopharma tiered royalties based on net sales of Licensed Products, as defined herein.** See " Business — Licenses, Partnerships and Collaborations — ~~Allist Agreements "~~. If these payments become due, we may not have sufficient funds available to meet our obligations and our development efforts may be harmed. To become and remain profitable, we must succeed in developing, obtaining regulatory approvals for, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials of ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future ~~product~~ **62product** candidates, acquiring additional product candidates, obtaining regulatory approval for ~~furmonertinib~~ **firmonertinib** and any future product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, achieve our strategic objectives or even continue our operations. A decline in the value of our company could also cause stockholders to lose all or part of their investment. We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability. 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 upon which you can evaluate our business and prospects. We commenced operations in April 2021 and, to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, in- licensing our product ~~candidate~~ **candidates** , ~~furmonertinib~~ **firmonertinib , and our other product candidates** , establishing our intellectual property portfolio and conducting research, preclinical studies, and clinical trials. We have not yet completed any pivotal clinical trials, obtained regulatory approvals, manufactured products at commercial scale, or arranged for a third party to do so on our behalf, or conducted 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~~. ~~57Operating~~ -- **Operating** our business requires substantial additional capital to finance our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations. The development of biopharmaceutical product candidates is capital- intensive. We expect our expenses to substantially increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials for ~~furmonertinib~~ **firmonertinib , our other product candidates,** and potentially seek regulatory approval for ~~furmonertinib~~ **firmonertinib and our other current** and any future product candidates we may develop, acquire or in- license additional product candidates and operate as a public company. In addition, if we are able to progress ~~furmonertinib~~ **firmonertinib and our other product candidates** through development and commercialization, we will be required to make milestone and royalty payments to ~~Allist~~ **our licensors** from whom we have in- licensed intellectual property related to ~~furmonertinib~~ **our product candidates** . If we obtain regulatory approval for ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reliably estimate the actual amount of financing necessary to successfully complete the development and commercialization of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company. 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 existing cash and cash equivalents, including the proceeds from our recently completed initial public offering, will enable us to fund our operations ~~into 2026~~ **through at least twelve months from the issuance date of these financial statements** . 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 plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Our existing cash and cash equivalents, ~~including the net proceeds from our recently completed initial public offering,~~ may not be sufficient to complete development of ~~furmonertinib~~ **firmonertinib , our other product candidates** , or any future product candidate, and we will require substantial capital in order to advance ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates ~~through~~ **63through** clinical trials, regulatory approval and commercialization. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from factors that include but are not limited to, **change in** inflation **rates** , **trade sanctions, tariffs** the conflicts in the Middle East and between Russia and Ukraine and other factors, 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, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. 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, or even cease operations. We expect to finance our cash needs through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. In order to obtain financing, we may be required to relinquish rights to some of our technologies or drug candidates or otherwise agree to terms unfavorable to us. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop ~~furmonertinib~~ **firmonertinib , our other product candidates** and any future product candidates. Our future capital requirements, both near and long- term, will depend on many factors, including, but not limited to: ● the initiation, type, number, scope, progress, expansions, results, costs and timing of clinical trials and studies of ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates we may choose to pursue, including any modifications to clinical development plans based on feedback that we may receive from regulatory authorities; ~~58~~ ● the costs and timing of manufacturing for ~~furmonertinib~~ **firmonertinib , our other product candidates** , or any future product candidate, including commercial manufacture at sufficient scale, if any product candidate is approved, including as a result of inflation, any supply chain issues or component shortages; ● requirements of regulatory authorities in any jurisdictions in which we may seek approval for ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates and our anticipated timing for seeking approval in such jurisdictions; ● the costs, timing and outcome of regulatory meetings and reviews of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates; ● any delays and cost increases that may result from any health epidemics and outbreaks, including COVID- 19; ● the costs of obtaining, maintaining, enforcing and protecting our patents and other intellectual property and proprietary rights; ● our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal control over financial reporting; ● the costs associated with hiring additional personnel and consultants as our business grows, including additional executive officers and clinical development, regulatory, Chemistry, Manufacturing, and Controls (CMC) quality and commercial personnel; ● the timing and amount of the milestone, royalty or other payments we must make to ~~Allist~~ **our licensors** , from whom we have in- licensed ~~furmonertinib~~ **our current product candidates** , or any future licensors; ● the costs and timing of establishing or securing sales and marketing capabilities if ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidate is approved; **64** ● our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third- party payors and adequate market share and revenue for any approved products; ● our ability and strategic decision to acquire or develop future product candidates other than ~~furmonertinib~~ **firmonertinib** , and the timing of such development, if any; ● patients' willingness to pay out- of- pocket for any approved products in the absence of coverage and / or adequate reimbursement from third- party payors; ● the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and ● costs associated with any products or technologies that we may in- license or acquire. Conducting clinical trials and nonclinical studies and potentially identifying future product candidates is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and commercialize ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates. If approved, ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates may not achieve commercial success. Our commercial revenue, if any, will initially be derived from sales of ~~furmonertinib~~ **firmonertinib** , which we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. Raising additional capital may cause dilution to our stockholders, 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 cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. We do not have any committed external source of funds. **On February 3, 2025, we filed an automatic universal shelf registration on Form S- 3 with the SEC, which became effective upon filing, on which we registered for sale any combination of our common stock, preferred stock, debt securities, warrants, rights and / or units from time to time and at prices and on terms that we may determine (2025 Form S- 3), including up to $ 250 million of common stock which we may offer and sell, from time to time at our sole discretion, under our at- the- market program sales agreement that we entered into with Jefferies LLC (Jefferies) in February 2025 (2025 Sales Agreement).** In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include ~~59liquidation~~ **liquidation** or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. If we raise additional funds through ~~future~~ collaborations, licenses and other similar arrangements, we may be required to relinquish valuable rights to our future revenue streams, product candidates, research programs, intellectual property or proprietary technology, or grant licenses on terms that may not be

favorable to us and / or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would 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 might otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose. ~~Risks~~ **65Risks** Related to the Development and Regulatory Approval of Our Product CandidatesWe currently depend significantly on the success of ~~furmonertinib~~ **firmonertinib** , which is our only product candidate in clinical development. If we are unable to advance ~~furmonertinib~~ **firmonertinib** in clinical development, obtain regulatory approval and ultimately commercialize ~~furmonertinib~~ **firmonertinib** , or experience significant delays in doing so, our business will be materially harmed. We currently only have one product candidate in clinical development, ~~furmonertinib~~ **firmonertinib** , the intellectual property for which we have in- licensed and which is in Phase 3 clinical development. Our business presently depends significantly on our ability to successfully develop, obtain regulatory approval for, and commercialize ~~furmonertinib~~ **firmonertinib** in a timely manner. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and may be able to better sustain the delay or failure of a lead product candidate. In addition, our assumptions about ~~furmonertinib~~ **firmonertinib** ' s development potential are partially based on the data generated from preclinical studies and clinical trials conducted by our licensor and we may observe materially and adversely different results as we continue to conduct our clinical trials. The success of ~~furmonertinib~~ **firmonertinib** will depend on several factors, including the following: ● successful initiation, enrollment and completion of ongoing and future clinical trials with favorable results in accordance with good clinical practice (GCP) requirements and other applicable rules and regulations; ● acceptance of regulatory submissions by the FDA or comparable foreign regulatory authorities for the conduct of nonclinical studies and clinical trials of ~~furmonertinib~~ **firmonertinib** , including clinical trials conducted outside the United States, including China, and our proposed design of planned nonclinical studies and clinical trials of ~~furmonertinib~~ **firmonertinib** ; ● the frequency, severity, and types of adverse events observed, or that we may observe, in nonclinical studies and clinical trials; ● maintaining relationships with contract research organizations (CROs) and clinical sites for the clinical development of ~~furmonertinib~~ **firmonertinib** , and ability of such CROs and clinical sites to comply with clinical trial protocols, current GCP and other applicable requirements; ● demonstrating the safety and efficacy of ~~furmonertinib~~ **firmonertinib** to the satisfaction of applicable regulatory authorities, including by establishing a safety database of a size satisfactory to regulatory authorities; ● receipt and maintenance of marketing approvals from applicable regulatory authorities for the initial indication for use and any additional indications, including approvals of NDAs from the FDA, and maintaining any such approvals; ● maintain relationships with our third- party manufacturers and their ability to comply with current Good Manufacturing Practice (cGMP) requirements as well as making arrangements with our third- party manufacturers for, or establishing our own, clinical or commercial manufacturing capabilities at a cost and scale sufficient to support commercialization; ~~60~~ ● establishing sales, marketing and distribution capabilities and launching commercial sales of ~~furmonertinib~~ **firmonertinib** , if and when approved, whether alone or in collaboration with others; ● obtaining, establishing, maintaining and enforcing patent and any potential trade secret protection or regulatory exclusivity for ~~furmonertinib~~ **firmonertinib** ; ● maintaining an acceptable safety profile of ~~furmonertinib~~ **firmonertinib** following regulatory approval, if any; ● maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell ~~furmonertinib~~ **firmonertinib** , if approved; and ● acceptance of ~~furmonertinib~~ **firmonertinib** , if approved, by patients, the medical community and third- party payors. If we are unable to develop, receive marketing approval for and successfully commercialize ~~furmonertinib~~ **firmonertinib** , or if we experience delays as a result of any of the above factors or otherwise, our business would be significantly harmed. ~~Clinical~~ **66Clinical** and preclinical development of new biopharmaceutical products involves a lengthy and expensive process with uncertain timelines and outcomes, and results of prior clinical trials and studies of ~~furmonertinib~~ **firmonertinib and our other product candidates** are not necessarily predictive of future results. ~~Furmonertinib~~ **Firmonertinib and our other product candidates** may not achieve favorable results in our clinical trials or receive regulatory approval on a timely basis, if at all. Clinical and preclinical development of new biopharmaceutical candidates is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or nonclinical studies will be conducted as planned or completed on schedule, if at all, and failure or delays can occur at any time during the trial or study process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of development. The historical failure rate for product candidates in our industry is high, particularly in the earlier stages of development. The results from preclinical studies or clinical trials of ~~a~~ product ~~candidate~~ **candidates** or a competitor' s product candidate in the same class may not predict the results of later clinical trials of our product candidate, and interim, topline, or preliminary results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. We do not know how ~~furmonertinib~~ **firmonertinib or our other product candidates, including ARR- 217,** will perform in on- going and future clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on earlier clinical trials and preclinical studies, and many product candidates fail in clinical trials despite very promising early results. Furthermore, although ~~furmonertinib~~ **firmonertinib** is currently approved and commercially distributed by Allist in China as a first- line therapy to treat classical EGFRm NSCLC based on successful clinical trials conducted within China, there is no guarantee that we will be able to replicate all the results of any prior trials in the indications and doses we are exploring in our on- going and future clinical trials or even if we do, whether such results would lead to approval of the product candidate by the FDA or other health authorities. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Based upon negative or inconclusive results, we or any future collaborator may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials or delay our on-

going or future clinical trials, which would cause us to incur additional operating expenses and delays and may not be sufficient to support regulatory approval on a timely basis or at all. As a result, we cannot be certain that our ongoing and planned clinical trials will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of ~~furmonertinib~~ **firmonertinib or our other product candidates** in those and other indications, which could have a material adverse effect on our business, financial condition, results of operations and prospects. ~~61Any~~ -- **Any** difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials or nonclinical studies could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects. Before obtaining marketing approval from regulatory authorities for the sale of ~~furmonertinib~~ **firmonertinib** or any **of our other or** future product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates for their intended use (s) in humans. Before we can initiate clinical trials for any future product candidates, 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 trial protocol, as part of an IND or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our nonclinical development programs. For example, we have not yet sought alignment **with the FDA** on the **ex- China** design of **the** ~~our planned~~ adjuvant study of ~~furmonertinib~~ **firmonertinib** ~~with the FDA or comparable foreign regulatory authorities~~ **initiated by Allist, which we may participate in** . Such authorities may ask us to collect more clinical data prior to permitting us to ~~initiate~~ **participate in** the ~~planned~~ global registrational Phase 3 clinical trial to investigate the potential benefit of ~~furmonertinib~~ **firmonertinib** in the adjuvant setting. Moreover, even if we commence clinical trials, issues relating to the safety and efficacy of current or future drug candidates may arise that could cause regulatory authorities to suspend, delay, or terminate such clinical trials. Any such delays in the commencement or completion, or ~~the~~ **67the** termination or suspension, of our ongoing and planned clinical trials or nonclinical studies for ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product ~~candidate~~ **candidates** could significantly affect our product development timelines and product development costs and harm our financial position. We do not know whether our planned clinical trials and nonclinical studies will begin on time or be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials and nonclinical studies can be delayed for a number of reasons, including delays related to: ● inability to obtain animals or materials to initiate and generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials; ● obtaining allowance from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design; ● the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials; ● any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● delays in identifying, recruiting and training suitable clinical investigators; ● obtaining approval from one or more institutional review boards (IRBs) or ethics committees (EC) responsible for the oversight of human subjects research conducted at clinical trial sites; ● IRBs / ECs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial; ● changes or amendments to the clinical trial protocol; ● clinical sites deviating from the trial protocol or dropping out of a trial; ● failure by our CROs to perform in accordance with GCP requirements or applicable regulatory rules and guidelines in other countries; ● obtaining raw materials for manufacturing sufficient quantities of ~~furmonertinib~~ **firmonertinib , our other product candidates, including ARR- 002, and ARR- 217,** or obtaining sufficient quantities of combination therapies or other materials needed for use in clinical trials and nonclinical studies; ● obtaining adequate materials for packaging clinical trial material; ~~62~~ ● expiration of the shelf life of clinical material for use in clinical trials prior to the enrollment of any of our clinical trials; ● subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post- treatment follow- up, including subjects failing to remain in our trials due to movement restrictions, ~~heath~~ **health** reasons or otherwise resulting from any public health concerns, such as COVID- 19; ● individuals choosing an alternative product for the indications for which we are developing ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, or participating in competing clinical trials; ● lack of adequate funding to continue the clinical trials, nonclinical studies, manufacturing or incurring greater costs than we anticipate; ● research subjects experiencing severe or serious unexpected ~~drug~~ **treatment** - related adverse effects; ● occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates; ● selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data; **68** ● transfer of manufacturing processes to larger- scale facilities operated by a contract manufacturing organization (CMO), as a result of changes in U. S. legislation or otherwise, delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with cGMP regulations or other applicable requirements; and ● third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner. In addition, disruptions caused by COVID- 19 or future public health concerns may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Ethics Committees or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated in whole or in part by us, by the IRBs of the institutions in which such trials are being conducted, by a data safety monitoring board for such trial or by the FDA or comparable foreign regulatory 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 GCP, other regulatory requirements or our

clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold or other adverse findings, 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 regulators or IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Further, conducting clinical trials in foreign countries, as has been done for ~~furmonertinib~~ **firmonertinib** and intended to be done in the future for ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects 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 schemes, and political and economic risks, including war, relevant to such foreign countries. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study results. The FDA or ~~63comparable~~ **comparable** foreign regulatory authority 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 comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates. In addition, many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials, whether in whole or in part, may also ultimately lead to the denial of regulatory approval of a product candidate. We may make formulation or manufacturing changes to ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates as a result of changes in U. S. legislation or otherwise, in which case we may need to conduct additional nonclinical studies or clinical trials to bridge our modified product candidates to earlier versions. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects. ~~Enrollment~~ **69Enrollment** and retention of patients in clinical trials 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, along with treatment duration and completion of required follow- up periods. Clinical trials may be prolonged, or we may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate as required by the FDA or applicable foreign authorities. For certain of our product candidates, including ~~furmonertinib~~ **firmonertinib**, the conditions which we may evaluate include limited patient pools from which to draw. In some cases, patient populations are located at specific academic sites focused on such indications, which often host multiple competing clinical trials. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases that we are targeting or may not meet the entry criteria for such trials. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical trials or in 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. In addition, the process of finding and diagnosing patients may prove costly. The eligibility criteria of our clinical trials, 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, thereby delaying or preventing further development and potential marketing 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. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment or retention in our clinical trials for a variety of reasons. Patient enrollment and retention in clinical trials depends on many factors, including: ● the size and nature of the targeted patient population; ● the severity of the disease or condition under investigation; ● the availability and efficacy of approved therapies for the disease or condition under investigation; ● perceived risks and benefits of the product candidate under study; ● efforts to facilitate timely enrollment in clinical trials; ● patient referral practices of physicians; ~~64~~ ● 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 of competing therapies for the same indication; ● the proximity of patients to clinical sites; ● continued enrollment of prospective patients by clinical trial 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 and after treatment; ● the risk that patients will drop out of a trial before completing all site visits; **70** ● delays or difficulties in enrollment and completion of studies due to travel or quarantine policies, or other factors, including those related to COVID- 19 or future pandemics; and ● clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available approved or investigational therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating. Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of our product candidate or any negative results a competitor may report in

clinical trials of the competitor' s product candidate in the same class, may make it difficult or impossible to recruit and retain patients in other clinical trials of our 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, such as COVID- 19, 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, or prevent us or our partners from completing our clinical trials at all, and harm our ability to obtain approval for such product candidate. Further, if patients drop out of our clinical trials, miss scheduled doses or follow- up visits, or otherwise fail to follow clinical trial protocols for any reason, the integrity of data from our clinical trials 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 rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and future clinical trials 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. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials. Use of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates could be associated with adverse side effects, adverse events or other safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved drug label or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition. As is the case with biopharmaceuticals generally, adverse side effects associated with the use of ~~furmonertinib~~ **firmonertinib** have been observed and it is likely there may be adverse side effects with **our other product candidates and** any future product candidates we may develop. Results of our ongoing and future clinical trials of ~~furmonertinib~~ **firmonertinib** or other product candidates could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects or unexpected characteristics. Undesirable ~~65side~~ **side** effects caused by our product candidates when used alone or in combination with approved or investigational drugs could cause us or regulatory authorities to interrupt, delay or partially or completely halt clinical trials and could result in a restrictive prescription drug label, post- approval requirements, or lead to the delay of the planned clinical development, or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Drug- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences could severely harm our business, prospects, operating results and financial condition. The severity of adverse events (AEs) is described by grade on a scale of increasing severity from Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), Grade 4 (life- threatening) and Grade 5 (death). Serious adverse events (SAEs) are adverse events that are life threatening, require or prolong hospitalization, result in persistent or significant disability / incapacity, result in congenital anomalies or birth defects, or any other medical event which investigators judge to represent significant hazards. It should be noted that " Severe " and " Serious " are not synonymous as not all AEs that are severe (Grade 3) meet the criteria for SAE while Grade 4 (life- threatening) and Grade 5 (death) AEs are SAEs. AEs and SAEs that are determined to be related to the drug (s) being tested are reported as TRAEs and TRSAEs. TRAEs leading to discontinuation of study drug (s) are commonly reported to indicate the manageability of treatment- related toxicities. In the FURLONG trial, TRSAEs were observed in ten out of ~~178~~ **71178** treated patients and six out of 178 patients discontinued participation in the trial as a result of TRAEs. In the FAVOUR trial, as of the June 15, 2023 interim data cut- off date, TRSAEs were observed in six out of 86 of the treated patients and two out of 86 patients discontinued participation in the trial as a result of TRAEs. The most frequent TRAEs in the FAVOUR trial as of June 15, 2023 were diarrhea, anemia, aspartate aminotransferase increased, alanine aminotransferase increased, blood creatinine increased, mouth ulceration, rash, electrocardiogram QT prolonged, white blood cell count decreased, decreased appetite, weight decreased, skin fissures, and paronychia. Isolated cases of Grade ≥ 3 reversible hepatic transaminases accompanied with increased total bilirubin have been observed at ~~furmonertinib~~ **firmonertinib** dose levels higher than 80 mg daily. In the FURTHER trial, based on data as of ~~June 15~~ **July 5** , ~~2023~~ **2024** , TRSAEs were observed in ~~four~~ **eleven** out of ~~54~~ **116** of the treated patients and ~~three~~ **six** out of ~~54~~ **116** patients discontinued participation in the trial as a result of TRAEs. The most common TRSAEs (defined as ≥ 1 %), across the FURLONG, FAVOUR and FURTHER trials were diarrhea, 1. ~~9~~ **1** % (~~six~~ **4** out of ~~318~~ **380**), ~~and~~ liver enzyme elevation, 1. ~~9~~ **1** % (~~six~~ **4** out of ~~318~~ **380), and pneumonitis / ILD, 1. 1 % (4 out of 380**). The discontinuation rate due to TRAEs across the FURLONG, FAVOUR and FURTHER trials was 3. ~~5~~ **7** % (~~eleven~~ **14** out of 318) ~~, including one patient who discontinued due to diarrhea and one patient who discontinued due to liver enzyme elevation~~ . See " Business — ~~Furmonertinib~~ **Firmonertinib** : Our Lead Development Candidate " for additional information. Moreover, if ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may elect to interrupt, delay, or abandon their development in whole or in part or limit their development to more narrow uses, lower doses, 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 potential approval and commercial expectations for the product candidate if approved. We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials or based on the findings of our competitors' ongoing clinical trials of molecules in the same class. Many compounds that showed promise initially have later been found to cause side effects that prevented further development of the compounds. If ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates receives marketing approval, and we or others

later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw, suspend or limit approvals of such product, or seek an injunction against its manufacture or distribution; ● we may be required to recall a product or change the way such product is administered to patients; ● regulatory authorities may require additional warnings on the label, such as a " black box " warning or a contraindication; ● we may be required to change the way a product is distributed or administered, conduct additional clinical trials or conduct post- marketing studies or surveillance studies; ~~66~~ ● we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; ● sales of the product may decrease significantly or the product could become less competitive; and ● our reputation may suffer. Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects. ~~We~~ **72We** may not be successful in our efforts to investigate ~~furmonertinib~~ **firmonertinib** in additional indications. We may expend our limited resources to pursue, acquire or license a new product candidate or a particular indication for ~~furmonertinib~~ **firmonertinib** 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 indications for ~~furmonertinib~~ **firmonertinib** to treat NSCLC. We may fail to generate additional clinical development opportunities for ~~furmonertinib~~ **firmonertinib** for a number of reasons, including that ~~furmonertinib~~ **firmonertinib** may, in indications we are seeking or may seek in the future, on further study, be shown to have harmful side effects, limited to no efficacy, or other characteristics that suggest it is unlikely to receive marketing approval and achieve market acceptance in such additional potential indications. Our resource allocation and other decisions may cause us to fail to identify and capitalize on viable potential product candidates or additional indications for ~~furmonertinib~~ **firmonertinib** . Our spending on current and future research and development programs for new product candidates or additional indications for existing product candidates may not yield any commercially viable product candidates or indications. If we do not accurately evaluate the commercial potential or target market for a particular indication or product candidate, we may fail to develop such product candidate or indication, we may relinquish valuable rights to that product candidate through collaborations, license agreements and other similar arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such indication or product candidate, or we may negotiate less advantageous terms for any such arrangements than is optimal. Additionally, we may pursue additional in- licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management' s time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment. We are currently developing and may in the future develop our product candidates in combination with other therapies, and safety or supply issues with combination- use products may delay or prevent development and approval of our product candidates. We are currently developing and may in the future develop our product candidates in combination with one or more cancer therapies. For example, we are evaluating use of ~~furmonertinib~~ **firmonertinib** in combination with ICP- 189, a SHP2 inhibitor, in collaboration with InnoCare. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidates or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. Similarly, if the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. ~~67We~~ **We** may also evaluate our product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or a similar regulatory authority outside of the United States. We may be unable to effectively identify and collaborate with third parties for the evaluation of our product candidates in combination with their therapies. We will not be able to market and sell any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval. The regulations prohibiting the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. In addition, there are additional risks similar to the ones described for our products currently in development and clinical trials that result from the fact that such cancer therapies are unapproved, such as the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval. ~~If~~ **73If** the FDA or a similar regulatory authority outside of the United States does not approve these other drugs or revokes approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market such product. Several of the ongoing clinical trials for our lead product candidate, ~~furmonertinib~~ **firmonertinib** , are being conducted **outside the United States, including in China, and we expect to conduct future clinical trials of firmonertinib and our other product candidates** outside the United States, including in China. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business. Several of the ongoing clinical trials for our lead product candidate, ~~furmonertinib~~ **firmonertinib** , are being conducted both inside and outside of the United States, including in China. Specifically, we are enrolling patients globally in our FURVENT and FURTHER trials. Furthermore, our

partner Allist is conducting the FAVOUR trial in China and our partner InnoCare is conducting the SHP2i combination trial in **China. We expect the initial clinical study of ARR- 217 to be conducted outside the United States, including** China. The acceptance of study data from clinical trials conducted outside the U. S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U. S., 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 were performed by clinical investigators of recognized competence and pursuant to 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. **Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met.** In February 2022, the FDA publicly rebuked an oncology product sponsor for submitting a marketing application with Phase III clinical data solely from China. ~~Additionally~~ **More recently** , ~~the FDA' s~~ **members of Congress have raised national security concerns related to U. S.** clinical trial **sponsors utilizing study sites in China that may** ~~requirements, including sufficient size of patient populations and statistical powering, must~~ be ~~met~~ **owned or operated by the Chinese military. It remains to be seen whether the current administration and / or the 119th Congress (2025- 26) take steps to restrict or limit the conduct of clinical research activities in China or other jurisdictions, or to otherwise require additional due diligence checks or oversight by sponsors** . Many foreign regulatory authorities have similar approval requirements. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U. S. or the applicable jurisdiction, including any trials conducted in China. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, 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. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted, which may increase costs or time required to complete the clinical trial. Conducting clinical trials outside the United States, particularly in China, also exposes us to additional risks, including risks associated with: ● additional foreign regulatory requirements; ● foreign exchange fluctuations; ● compliance with foreign manufacturing, customs, shipment and storage requirements; ● inconsistent standards for reporting and evaluating clinical data and adverse events; ● ~~COVID- 19~~ **infectious disease pandemics or epidemics** or any other **form of** ~~pandemic or epidemic or any~~ future public health ~~emergencies~~ **emergency** ; ~~68~~ ● diminished protection of intellectual property in some countries; ~~and~~ **and74** ● political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data. Interim, topline and preliminary data from our clinical trials and nonclinical 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, topline or preliminary data from our clinical trials and preclinical studies, which is 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 **. For example, in September 2024, we announced positive interim proof- of- concept data from the FURTHER trial of firmonertinib in first- line patients with locally advanced or metastatic EGFRm NSCLC with PACC mutations. In this interim readout, 64 % of patients (n = 14 out of 22 patients) were observed to experience a reduction in tumor size of at least 30 % from the baseline in a patient without evidence of progression as measured by RECIST 1. 1 criteria. Median DOR had not yet been reached, with 90. 9 % (n = 20 / 22) of patients with confirmed responses remaining on study** . 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 interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, 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 published. As a result, topline and preliminary data should be viewed with caution until the final data are available. Interim data from clinical trials that we may complete are further 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 interim, topline, or preliminary data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. In addition, others, including regulatory authorities, 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. Moreover, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, 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 candidate or our business. If the interim, 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, ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. The regulatory approval

processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. The clinical development, manufacturing, labeling, storage, record- keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. We are not permitted to market our product candidates in the United States until we receive regulatory approval of an NDA from the FDA. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable ~~regulatory~~ **75regulatory** authorities have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in ~~69development~~ -- **development**, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from adequate and well- controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe available nonclinical or clinical data support the safety or efficacy of our product candidates, such data may not be sufficient to obtain approval from the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional ~~preclinical~~ **nonclinical** studies or clinical trials for our product candidates either prior to or post- approval, or may object to elements of our clinical development program. The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including: ● such authorities may disagree with the design or execution of our clinical trials; ● negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval; ● serious and unexpected drug- related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates; ● the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; ● such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country; ● we may be unable to demonstrate to such authorities that a product candidate' s clinical and other benefits outweigh its safety risks; ● such authorities may disagree with our interpretation of data from preclinical studies or clinical trials; ● such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials; ● such authorities may disagree with us regarding the formulation, labeling and / or the product specifications of our product candidates; ● approval may be granted only for indications that are significantly more limited than those sought by us, and / or may include significant restrictions on distribution and use; ● such authorities may find deficiencies in the manufacturing processes or facilities of the third- party manufacturers with which we contract for clinical and commercial supplies; or ● such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission. With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. ~~Even~~ **76Even** if we eventually complete clinical trials and receive approval of an NDA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and / or the implementation of a Risk Evaluation and Mitigation Strategy (REMS), which may be required because the FDA believes it is necessary to ensure safe use of the ~~70product~~ -- **product** after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects. Obtaining 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, ~~Furmonertinib~~ **firmonertinib** has been approved by the National Medical Products Administration (NMPA) of China and is currently commercially distributed in China by Allist as a first- line treatment of locally advanced or metastatic NSCLC patients with classical EGFRm as well as pre- treated patients with T790M mutations. Even if the NMPA or a foreign regulatory authority grants marketing approval of one of our product candidates, it does not mean that the FDA or comparable regulatory authorities in other jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in such countries, including the United States. 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 nonclinical studies or clinical trials because clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate also must be approved for reimbursement before it can be offered for sale in that jurisdiction. In some cases, the price that we intend to charge for our future commercial 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. ~~A~~ **Firmonertinib has been granted** Breakthrough Therapy Designation ~~by~~ **for the treatment of first- line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations from** the FDA **and we may seek Breakthrough Therapy Designation for other product candidates in the future. Even if we apply for Breakthrough Therapy Designation in the future, we might not receive such designation, and even if received, such designation** may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval. We received Breakthrough Therapy Designation for ~~furmonertinib~~ **firmonertinib** for the treatment of first- line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations from the FDA in October 2023, and we may seek such designation in the future for other product candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development. Drugs designated as Breakthrough Therapies are also eligible for accelerated approval. The FDA has discretion to determine whether the criteria for a Breakthrough Therapy has been met and whether to grant a Breakthrough Therapy Designation to an investigational product. Accordingly, even if we believe, after completing early clinical trials, that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or ~~approval~~ **77approval** compared to product candidates considered for approval under conventional FDA procedures and does not change the standard for approval by the FDA. In addition, even after granting Breakthrough Therapy Designation to our product candidates, the FDA may later decide that such product candidates no longer meet the conditions for qualification and withdraw such designation. ~~71Furmonertinib~~ **Firmonertinib** has been granted Fast Track Designation by the FDA for the treatment of patients with NSCLC harboring activating EGFR or HER2 kinase domain mutations, including exon 20 insertion mutations and we may seek Fast Track Designation for other product candidates in the future. Even if we apply for Fast Track Designation in the future, we might not receive such designation, and even if received, such designation may not actually lead to a faster development or regulatory review or approval process. Further, such designation could be withdrawn by the FDA. If a drug candidate is intended or the treatment of a serious or life- threatening disease or condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this disease or condition, a product sponsor may request a Fast Track designation from the FDA. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track designated product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA **/ BLA** is submitted, the application may be eligible for priority review. An NDA **/ BLA** submitted for a Fast Track designated product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA **/ BLA** on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA **/ BLA** , the FDA agrees to accept sections of the ~~NDA~~ **application** and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. If we seek Fast Track designation from the FDA, we may not receive it and even if we receive such designation, it does not ensure that we will receive marketing approval or that approval will be granted in any particular time frame. Many product candidates that have received Fast Track designation have ultimately failed to obtain approval. We also may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if it is no longer supported by data from our clinical development program. Fast Track designation alone also does not guarantee qualification for the FDA' s priority review procedures for marketing applications. In January 2022, the FDA granted Fast Track designation to ~~furmonertinib~~ **firmonertinib** for the treatment of patients with NSCLC harboring activating EGFR or HER2 kinase domain mutations, including exon 20 insertion mutations. We may seek to utilize the FDA' s accelerated approval pathway for certain ~~furmonertinib~~ **firmonertinib** indications and may pursue this pathway for future therapeutic candidates. There is no assurance that, upon receipt of such future marketing application, if any, the FDA will agree to file it and conduct a substantive review of the data or that FDA will agree that we have met the substantial evidence of effectiveness **and safety** standard necessary to support marketing approval. If unable to obtain approval under the accelerated approval pathway, we may be required to conduct additional nonclinical studies or clinical trials beyond those that we currently contemplate for certain ~~furmonertinib~~ **firmonertinib** indications, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA for certain ~~furmonertinib~~ **firmonertinib** indications, or for other future therapeutic candidates for which the accelerated approval pathway may be appropriate, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA may seek to withdraw accelerated approval. We previously announced that, based on discussions with the FDA, there is potential to pursue an accelerated approval for ~~furmonertinib~~ **firmonertinib** for the treatment of NSCLC patients diagnosed with PACC mutations using ORR as the surrogate endpoint. Under the accelerated approval provisions in the FDC Act and the FDA' s implementing regulations, the FDA may grant accelerated approval to a therapeutic product candidate designed to treat a serious or life- threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint, or intermediate clinical endpoint, that is reasonably likely to predict clinical benefit or on ~~a~~ **78a** clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of

alternative treatments. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible ~~72morbidity~~ -- **morbidity** or mortality that is reasonably likely to predict an effect on irreversible morbidity, mortality, or other clinical benefit. The FDA may not accept any future application for accelerated approval for ~~furmonertinib~~ **firmonertinib** in NSCLC patients diagnosed with PACC mutations, may not grant marketing approval on a timely basis, or may not grant approval at all. The FDA or foreign regulatory authorities could require us to conduct further studies prior to considering our application or granting approval of any type. We might not be able to fulfill the FDA' s requirements in a timely manner or at all, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA. A failure to obtain accelerated approval or any other form of expedited development, review, or approval for ~~furmonertinib~~ **firmonertinib** would result in a longer time period to commercialization of ~~furmonertinib~~ **firmonertinib** , would increase the cost of development of ~~furmonertinib~~ **firmonertinib** and could harm our competitive position in the marketplace. Following high- profile voluntary withdrawals of accelerated approval indications by several oncology sponsors as a result of post- approval trials failing to verify their drug products' clinical benefit for those indications, which resulted in December 2022 amendments by Congress to the FDA' s authorities related to accelerated approval, public scrutiny of the accelerated approval pathway is likely to continue and may lead to further legislative and / or administrative changes in the future. Moreover, even if we receive accelerated approval from the FDA for certain ~~furmonertinib~~ **firmonertinib** indications, we will be subject to rigorous post- marketing requirements, including the completion of one or more confirmatory post- approval clinical trials to verify the clinical benefit of the product in that patient population, and submission to the FDA of all promotional materials for review prior to their dissemination. The FDA could also seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post- approval study, a post- approval study does not confirm the predicted clinical benefit, other evidence shows that the product is not safe or effective under the conditions of use, or we disseminate promotional materials that are found by the FDA to be false and misleading. Products that receive accelerated approval may be subject to expedited withdrawal procedures if post- approval studies fail to verify the predicted clinical benefit. In addition, as **noted above** ~~part of the Consolidated Appropriations Act for 2023~~ , Congress **recently** provided **the** FDA **with** new statutory authorities to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these amendments to the FDC Act, the agency may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted. At this time, it has not been fully determined how a future confirmatory post- approval clinical trial for ~~furmonertinib~~ **firmonertinib** in NSCLC patients diagnosed with PACC mutations would be designed or implemented, whether more than one trial will become necessary, or what the FDA would expect with respect to the timing of initiating such a confirmatory clinical trial for ~~furmonertinib~~ **firmonertinib** , should it be granted accelerated approval. If we fail to receive accelerated approval for ~~furmonertinib~~ **firmonertinib** in this patient population or fail to comply with the post- marketing requirements, our business, results of operations, prospects and the price of our common stock may be materially and adversely affected. Disruptions at the FDA and other government agencies caused by funding shortages **, mass layoffs,** 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, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA and other government agencies to review and approve new medical products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency' s ability to perform routine functions. Average review times at the FDA and other government agencies 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 or modifications to approved drugs to be reviewed and / or approved by necessary government agencies, which would ~~adversely~~ **79adversely** affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities during that period. **In early 2025, following the inauguration of President Trump, the Trump Administration began terminating federal government employees, including at the FDA. The impact of mass layoffs at the agency and other governmental offices with which we interact is unclear at this time. However, it is expected that with a reduction in staff of up to 50 %, the FDA in the future may be unlikely to meet its application review goals or to continue to be available for timely interactions with medical product developers. It is currently unclear how the U. S. biopharmaceutical industry will be affected by the Trump Administration' s major changes to the FDA and the federal government as a whole.** ~~73Separately~~ -- **Separately** , in response to COVID- 19, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to COVID- 19, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar policy measures in response to COVID- 19 **or other emerging infectious disease outbreaks, epidemics or pandemics** . If a prolonged government shutdown or slowdown occurs, or if global health concerns similar to COVID- 19 prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business will be harmed. For

planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the regulatory submissions or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical trials, receipt of regulatory approval or the commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including: ● our available capital resources or capital constraints we experience; ● the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators; ● our ability to identify and enroll patients who meet clinical trial eligibility criteria; ● our receipt of authorizations by the FDA and comparable foreign regulatory authorities, and the timing thereof; ● other actions, decisions or rules issued by regulators; ● the efforts of our collaborators with respect to the commercialization of our products, if any; and ● the securing of, costs related to, and timing issues associated with, commercial product manufacturing as well as sales and marketing activities. If we fail to achieve announced milestones in the timeframes we expect, the commercialization of any of our product candidates may be delayed, and our business, results of operations, financial condition and prospects may be adversely affected. ~~Risks~~ **80Risks** Related to Our Reliance on Third PartiesWe heavily rely on our exclusive license with Allist to provide us with intellectual property rights to develop and commercialize ~~furmonertinib~~ **firmonertinib** . Any termination or loss of significant rights under our agreements with Allist would adversely affect our development or commercialization of ~~furmonertinib~~ **firmonertinib** . Under the Allist License Agreement we have, among other things, secured an exclusive, royalty- bearing, and sublicensable license under certain intellectual property (including patents and know- how) owned or controlled by Allist to develop and commercialize any product containing ~~furmonertinib~~ **firmonertinib** or any of its salts or derivatives (the Licensed Compound) as an active ingredient of a product (the Licensed Product), which is led by a joint collaboration committee (the Collaboration Committee), comprising of representatives from both Allist and us. We granted Allist a non- exclusive sublicensable license to certain information, data, results and improvements related to the Licensed Product. Either party has the right to terminate the Allist License Agreement, subject to specified cure periods, for the material breach by the ~~74other~~ -- **other** party or the bankruptcy or insolvency of the other party. If the Allist License Agreement is terminated for any reason, including as a result of our failure to meet our obligations under the Allist License Agreement to make any milestone payments or royalties to Allist, our business and operations would be materially harmed. We are obligated to pay Allist milestone payments up to an aggregate of $ 765 million upon the achievement of certain development, regulatory and sales milestone events. In addition, we are obligated to pay Allist tiered royalties based on net sales of Licensed Products. In addition, upon termination of the Allist License Agreement by either Allist or us, (i) if the termination is for any reason other than by us for the material breach by Allist, then we may at our discretion continue to distribute and sell Licensed Products for a reasonably sufficient wind- down period up to 24 months from the termination, in accordance with the Allist License Agreement, and are obligated to continue to make all applicable payments to Allist for the Licensed Products we sell, and (ii) if the termination is by us for the material breach by Allist, then we would have the right to continue under the Allist License Agreement in lieu of the termination but with our milestone and royalty payment obligations substantially reduced. If these payments become due, we may not have sufficient funds available to meet our obligations and our development efforts may be harmed. Furthermore, we entered into the Allist Collaboration Agreement with Allist to govern the conduct of Global Study. See “ Business — Licenses, Partnerships and Collaborations — Allist Agreements **.** ” ~~.~~Pursuant to the Allist Collaboration Agreement, if either party or both parties wish to jointly conduct a Global Study, one or both parties, as the case may be, will prepare and submit the proposed strategy, internal process timeline, along with other required documents for such proposed Global Study to the Collaboration Committee for its review and approval before the protocol filing with any regulatory authorities. If the Collaboration Committee cannot come to a mutual agreement on the proposed strategy or any other particular matter, this could delay our ability to develop or commercialize ~~furmonertinib~~ **firmonertinib** , which could have a material adverse effect on our business and operations. Additionally, if we do not receive all of the necessary products, information, reports and data from Allist to which we are entitled under the Allist Collaboration Agreement in a timely manner, our business could be materially harmed. Reported data or other clinical development announcements by third parties, including Allist, may adversely affect our clinical development plan. Allist is currently conducting clinical studies in China, including a Phase 1b trial with ~~furmonertinib~~ **firmonertinib and a phase 2 trial in second line EGFRm NSCLC patients with exon 20 insertion mutations** , and previously completed a Phase 3 clinical trial in China. Allist is also commercializing ~~furmonertinib~~ **firmonertinib** in China. If announcements by Allist or other third parties with whom we collaborate **, or by third parties with whom Allist collaborates** , now or in the future, are unfavorable with respect to their clinical trials, or with respect to post- approval monitoring, our clinical development plans may be adversely affected. Further, even if announcements by such third parties are favorable with respect to their clinical trials, our planned clinical trials for ~~furmonertinib~~ **firmonertinib** , and any future clinical trials we may conduct, differ from their clinical trials and investors should not place undue reliance upon any of such third parties’ reported data or other clinical development announcements. ~~We~~ **81We** rely on, and intend to continue to rely on, third parties to conduct, supervise and monitor our clinical trials and nonclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We are dependent on third parties to conduct our clinical trials and preclinical and nonclinical studies. Specifically, we rely on, and intend to continue to rely on, medical institutions, clinical investigators, CROs and consultants to conduct nonclinical studies and clinical trials, in each case in accordance with our study protocols and applicable regulatory requirements. These CROs,

investigators and other third parties play a significant role in the conduct and timing of these studies or trials and the subsequent collection and analysis of data. Though we expect to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, while we have and will have agreements governing the activities of our third- party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our ~~75regulatory~~ -- **regulatory** responsibilities. In addition, we and our CROs are required to comply with GLP and GCP requirements, as applicable, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities related to the conduct of nonclinical studies and clinical trials, respectively. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GLP or GCP or other requirements, the collected nonclinical data or the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical studies or clinical trials before approving our marketing applications, if ever. Furthermore, our clinical trials must be conducted with materials manufactured in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position. In addition, principal investigators for our clinical trials are expected to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any NDA we submit. Any such delay or rejection could prevent us from receiving regulatory approval for, or commercializing, ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner or at all. Switching or adding CROs, investigators and other third parties involves additional cost and requires our management' s time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. ~~We~~ **82We** currently rely on a Chinese third party for the manufacture of ~~furmonertinib~~ **firmonertinib and other product candidates, including ARR- 217,** for clinical development **and potential future commercial supply of firmonertinib,** and expect to continue to rely on third parties for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of ~~furmonertinib~~ **firmonertinib or ARR- 217,** or such quantities at an acceptable cost, which could delay, prevent or impair our development or potential commercialization efforts. We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial- scale manufacturing capabilities. We rely on a third party, and expect to continue to rely, on third parties for the manufacture of ~~furmonertinib~~ **firmonertinib , other product candidates, including ARR- 217,** and related raw materials for clinical development, as well as for commercial manufacture ~~if~~ **of** ~~furmonertinib~~ **firmonertinib and our other product candidates, including ARR- 217,** receives marketing approval. The facilities used by third- party manufacturers to manufacture ~~furmonertinib~~ **firmonertinib** must be approved by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit an NDA to the FDA or make any comparable submission to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third- party manufacturers for compliance with cGMP requirements for manufacture of products. If these third- party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third- party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve ~~76these~~ -- **these** facilities for the manufacture of ~~furmonertinib~~ **firmonertinib , or our other product candidates, including ARR- 217** or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market ~~furmonertinib~~ **firmonertinib , and our other product candidates, including ARR- 217** , if approved. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations also could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of ~~furmonertinib~~ **firmonertinib or** ~~or~~ **our** other **product candidates, including ARR- 217,** future products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and our financial position. Our or a third party' s failure to execute on our manufacturing requirements on commercially reasonable terms, in a timely manner and in

compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including: ● an inability to initiate or complete clinical trials of ~~furmonertinib~~ **firmonertinib , our other product candidates, including ARR- 217** or any **other** future product candidates in a timely manner; ● delay in submitting regulatory applications, or receiving marketing approvals, for ~~furmonertinib~~ **firmonertinib , our other product candidates, including ARR- 217,** or any **other** future product candidates; ● subjecting third- party manufacturing facilities or our potential future manufacturing facilities to additional inspections by regulatory authorities; ● requirements to cease development or to recall batches of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates; and ● in the event of approval to market and commercialize ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, an inability to meet commercial demands for ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates. In addition, we do not have any long- term commitments or supply agreements with any third- party manufacturers. We may be unable to establish any long- term supply agreements with third- party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of ~~furmonertinib~~ **firmonertinib , other potential 83product candidates, including ARR- 217,** or such quantities at an acceptable cost. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: ● failure of third- party manufacturers to comply with regulatory requirements and maintain quality assurance; ● breach of the manufacturing agreement by the third party; ● failure to manufacture our product candidates according to our specifications; ● failure to obtain adequate raw materials and other materials required for manufacturing; ● failure to manufacture our product according to our schedule or at all; ● failure to successfully scale up manufacturing capacity, if required; ● misappropriation of our proprietary information, including any potential trade secrets and know- how; and ● termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval or jeopardize our ability to commence or continue commercialization of ~~furmonertinib~~ **firmonertinib , our other product candidates, including ARR- 217, or** or any future product candidates, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our existing or future third- party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Without additional suppliers of required raw materials, we may also be unable to meet the commercial needs of a commercial launch of any future product candidates. ~~77In~~ **In** addition, our current and anticipated future dependence upon others for the manufacture of ~~furmonertinib~~ **firmonertinib , other product candidates, including ARR- 217,** and any future product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. A portion of our product development and manufacturing for our product candidate ~~furmonertinib~~ **firmonertinib and other product candidates, including ARR- 217,** takes place in China through third- party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China, or a change in the regulatory framework in the United States or China, could materially adversely affect our business, financial condition and results of operations. Currently, we rely on and have agreements with two third- party contract manufacturers, Raybow and WuXi STA to supply the drug substance for ~~furmonertinib~~ **firmonertinib** to be used in planned clinical trials and with WuXi STA, with whom we have executed technology transfer related to the manufacture of drug product, to manufacture the clinical trial supplies of ~~furmonertinib~~ **firmonertinib** drug product. Both of third- party contract manufacturers are located in China, and we expect to continue to use such third- party manufacturers for such product candidates. **We expect to rely on manufacturers in China for ARR- 217 drug substance and drug product for use in initial clinical studies and also expect to rely on WuXi XDC for the manufacture of ARR- 002 for initial clinical studies.** Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster, or other causes could impair our ability to operate our business on a day- to- day basis and to continue our development of our product candidates. Furthermore, since these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U. S. or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs ~~on the chemical intermediates we use~~ that ~~are~~ **ultimately result in increased** ~~manufactured~~ **manufacturing costs** ~~in China~~ . The ~~recently proposed~~ BIOSECURE Act ~~is~~ **considered by the U. S. Congress 2024 was** aimed at discouraging federal contracting with certain Chinese biotechnology companies for biotechnology equipment or services, including WuXi AppTec Co., Ltd. (WuXi AppTec) and its subsidiaries, parent affiliates, or successors on the development or manufacturing of pharmaceutical products. **In** ~~Finally, in~~ February 2024, certain U. S. Senators and Representatives sent a letter to the Biden administration requesting that both WuXi AppTec, WuXi STA' s parent company, and the affiliated WuXi Biologics be ~~added~~ **84added** to the Department of Defense' s Chinese Military Companies List (1260H list), the Department of Commerce' s Bureau of Industry and Security Entity List, and the Department of Treasury' s Non- SDN Chinese Military- Industrial Complex Companies List. ~~While~~ **The companies were also named in** the ~~Biden administration~~ **initial version of the BIOSECURE Act, which** has yet to ~~take action on this letter,~~ **be reintroduced in the current Congress and the bill' s prospects under the Trump Administration are currently uncertain.** ~~adding~~ **Adding** WuXi STA **or related entities** on any or all of the aforementioned lists could materially impact supply of ~~furmonertinib~~ **firmonertinib or ARR- 002** from WuXi STA **and related entities** . The **re- introduction,** enactment and implementation of the **original** BIOSECURE Act **, or similar legislation that could develop in the 119th Congress** , may similarly impact supply of ~~furmonertinib~~ **firmonertinib or ARR- 002** from WuXi STA **or related entities** . If we are required to 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. For example, in the event that we need to switch our third- party manufacturer of ~~furmonertinib~~ **firmonertinib or ARR- 002** from WuXi STA **or related entities** , we anticipate that the complexity of the manufacturing

process may impact the amount of time it may take to secure a replacement manufacturer. The delays associated with the verification of a new manufacturer, once we are able to identify an alternative source, could negatively affect our ability to develop product candidates in a timely manner or within budget, which could materially adversely affect our business, financial condition and results of operations. We have entered into and in the future may seek to enter into collaborations, license agreements and other similar arrangements and may not be successful in doing so, and even if we are, we may relinquish valuable rights and may not realize the benefits of such relationships, and our collaborations would be subject to other risks attendant to third party relationships, including inability to prevent or control actions taken or not taken by such third parties which may adversely impact us. We are currently collaborating with third parties to develop certain of our potential drug candidates. For example, we are collaborating with Allist with respect to certain aspects of ~~furmonertinib~~ **firmonertinib and are collaborating with Lepu Biopharma with respect to ARR- 217** . In the future, we may seek to enter into collaborations, joint ventures, license agreements and other similar arrangements for the development or commercialization of ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. For example, certain of the cancer disease areas that we believe our product candidates address require large, costly and later- stage clinical trials, which a collaboration partner may be better positioned to finance and / or conduct. In addition, a component of our strategy is to maximize the commercial value of our current and future product candidates, which may also strategically align with partnering commercial rights with partners that have large and established sales organizations. To the extent that we decide to enter ~~78into~~ -- **into** collaborations, joint ventures, license agreements and other similar arrangements, we may not be successful in our efforts to establish or maintain such collaborations because our research and development pipeline may be insufficient, any future product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time- consuming and complex. Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us. For example, we may need to relinquish valuable rights to our future revenue streams, research programs, intellectual property or product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. In addition, if we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license or strategic transaction, we will achieve an economic benefit that justifies such transaction. Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of a product candidate is delayed, the safety of a product candidate is questioned or the sales of an approved product candidate are unsatisfactory. ~~Collaborations~~ **85Collaborations** involving ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates would pose significant risks to us, including the following: ● collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; ● collaborators may not perform their obligations as expected or at all; ● we could grant exclusive rights to our collaborators that would prevent us from collaborating with others; ● collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; ● collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; ● collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; ● product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; ● a collaborator with marketing and distribution rights to any product candidate that achieves regulatory approval may not commit sufficient resources to the marketing and distribution of such products; ● a collaborator' s sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings; ● disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays in or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; ~~79~~ ● collaborators may not properly enforce, maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation; ● collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability; ● collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding our out- licensed product candidates; ● we may be required to invest resources and attention into such collaboration, which could distract from other business objectives; ● disputes may arise between the collaborators and us regarding ownership of or other rights in the intellectual property generated in the course of the collaborations; ● collaboration agreements may not lead to development or commercialization of product candidates in the most

efficient manner or at all; **86** ● if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated; and ● collaborations may be terminated, including for the convenience of the collaborator, prior to or upon the expiration of the agreed upon terms and, if terminated, we may find it more difficult to enter into future collaborations or be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. Any termination of collaborations we currently depend on or may enter into in the future, or any delay in entering into collaborations related to ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Risks Related to Commercialization of ~~Furmonertinib~~ **Firmonertinib , Our Other Product Candidates,** and any Future Product CandidatesEven if we receive regulatory approval for ~~furmonertinib~~ **firmonertinib or any other current or future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, firmonertinib, ~~or~~ our other product candidates, and** any future product candidates, ~~we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, furmonertinib and any future 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, if any of them are approved. Any regulatory approvals that we may receive for ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates will require the submission of various post- marketing reports to regulatory authorities, will subject us to surveillance requirements to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications and may include burdensome post- approval study or risk management requirements. For example, the FDA may require REMS as a condition of approval of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, which could include requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for such products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, facility registration, and continued compliance with cGMPs for product manufacturing and GCP requirements for any clinical trials that we conduct post- approval. Manufacturers of approved products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other ~~80regulatory --~~ **regulatory** authorities for compliance with cGMP regulations and standards **. In addition, should accelerated approval be granted to any of our product candidates, we will be required to complete confirmatory clinical trials to verify the drug' s clinical benefit (s) and to make certain mandatory submissions to the FDA that are not applicable to drug products with " full " or traditional FDA marketing approvals (i. e., those not subject to accelerated approval requirements)** . Failure to comply with regulatory requirements or later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, may result in a regulatory agency imposing restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including: ● restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; ● restrictions on product distribution or use, or requirements to conduct post- marketing studies or clinical trials; **87** ● restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; ● fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters, or adverse publicity; ● refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals; ● product seizure or detention, or refusal to permit the import or export of our products; and ● injunctions and the imposition of civil or criminal penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates and to generate revenue, could require us to expend significant time and resources in response and could generate negative publicity. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also 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. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. The FDA and other regulatory agencies strictly regulate the marketing, labeling, advertising, and promotional claims that may be made about prescription drug products, such as ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, if approved. These regulations include standards and restrictions for direct- to- consumer advertising, industry- sponsored scientific and educational activities, promotional activities involving the internet and off- label promotion. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. **However, companies may share truthful and not misleading information that is not inconsistent with the labeling, and the FDA has recently published guidance for industry outlining modernized recommendations for how drug**

manufacturers can share scientifically sound and clinically relevant information on unapproved uses with health care providers so long as such presentations are not promotional. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product' s labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote **or advertise** any **future commercial** products will be narrowly limited to those indications that are specifically approved by the FDA. If we are found to have promoted ~~such~~ off- label uses **for an FDA- approved drug product** , ~~however~~ **or to have promoted an investigational drug before it has been granted some form of marketing approval** , we may become subject to significant liability. The U. S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. ~~81If~~ **If** we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates, and we do not obtain, or face delays in obtaining, FDA approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or ~~new~~ **88new** therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. We are working with a diagnostics company to develop a **companion** diagnostic for **firmonertinib** ~~FDA approval~~ to identify patients with EGFR ~~Exon~~ **exon** 20 insertion mutations and we may be required to pursue a similar approach for EGFR PACC mutations. The process of obtaining or creating such diagnostic is time consuming and costly. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and the FDA has generally required premarket approval of companion diagnostics for cancer therapies. The approval or clearance of a companion diagnostic as part of the therapeutic product' s further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect. If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains marketing approval, we and / or third- party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third- party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. For example, our EGFR exon 20 insertion mutations clinical trials may generate insufficient data to enable the approval by the FDA of the **companion** diagnostic that we are working with a diagnostics company to develop. We or our collaborators may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all. The commercial success of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates will depend upon the degree of market acceptance of such product candidates by healthcare providers, product recipients, healthcare payors and others in the medical community. If ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates fail to achieve the broad degree of adoption by the medical community necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business. Even if ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates receive regulatory approval, they may not be commercially successful and may not gain market acceptance among healthcare providers, individuals within our target population, healthcare payors or the medical community. The commercial success of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. The degree of market acceptance of our products will depend on a number of factors, including: ● demonstration of clinical efficacy and safety, including as compared to any more- established products; ● the indications for which our product candidates are approved; ● the limitation of our targeted patient population and other limitations or warnings contained in any FDA- approved labeling; ● acceptance of a new drug for the relevant indication by healthcare providers and their patients; ● the **establishment of compliant, timely and secure product distribution networks; ● the** pricing and cost- effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies; ~~82~~ ● our ability to obtain and maintain sufficient third- party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third- party payors; ● the willingness of patients to pay all, or a portion of, out- of- pocket costs associated with our products in the absence of sufficient third- party coverage and adequate reimbursement; **89** ● any restrictions on the use of our products, and the prevalence and severity of any adverse effects; ● potential product liability claims; ● the timing of market introduction of our products as well as availability, safety and efficacy of competitive drugs; ● the effectiveness of our or any potential future collaborators' sales and marketing strategies; and ● unfavorable publicity relating to the product. If ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidate is approved for marketing but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third- party payors regarding the benefits of our products may require significant resources and may never be successful. The successful commercialization of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels

and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue. The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third- party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations thereunder. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available, or at an acceptable level, for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third- party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our future products, pricing of existing drugs may limit the amount we will be able to charge for our products. Increasingly, other third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If ~~83reimbursement~~ -- **reimbursement** is not available or is available only at limited levels, we may not be able to successfully commercialize our future products and may not be able to obtain a satisfactory financial return on products that we may develop. There is significant uncertainty related to third- party payor coverage and reimbursement of newly approved products. In the United States, third- party payors, including private and governmental payors, such as the Medicare and ~~Medicaid~~ **90Medicaid** programs, play an important role in determining the extent to which new drugs will be covered. Some third- party payors may require pre- approval of coverage for new or innovative drugs before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for ~~furmonertinib~~ **firmonertinib , our other product candidates** and any future product candidates, if approved. Obtaining and maintaining reimbursement status is time- consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third- party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely. Additionally, the IRA authorized the ~~Centers for Medicare & Medicaid Services (~~ CMS ~~)~~ to negotiate drug prices annually for a select number of single source Medicare Part D drugs without generic competition starting in payment year 2026, and to negotiate drug prices for a select number of Medicare Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new ~~regulations~~ **statutory requirements** but their impact on the biopharmaceutical industry in the United States remains uncertain, in part due to several pending federal lawsuits challenging the constitutionality of the program **. The outcome of such ongoing lawsuits, as well as potential legislative changes enacted by Congress or programmatic changes implemented at CMS by the Trump Administration, may impact the IRA drug price negotiation program in the future** . We cannot be sure that coverage and reimbursement will be available for any product that we commercialize in the future and, if reimbursement is available, what the level of reimbursement will be. Outside **of** the United States, international ~~operations~~ **biopharmaceutical sales** are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our ~~products~~ **product** candidates, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, if any, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Moreover, increasing efforts by governmental and third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our ~~products~~ **product candidates, if approved,** due to the trend toward

managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs, surgical procedures and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. ~~84We~~ **We** face significant competition, and if our competitors develop and commercialize technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective, safer, or less expensive than ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates we develop, our business and our ability to develop and successfully commercialize products will be adversely affected. The biopharmaceutical industry is characterized by rapid advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or ~~may~~ **91may** develop products, product candidates and processes competitive with ~~furmonertinib~~ **firmonertinib** . ~~Furmonertinib~~ **Firmonertinib , our other product candidates,** and any future product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Our competitors include larger and better- funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in research in our target indications and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, and our inability to compete successfully could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in- licensing intellectual property related to new product candidates, as well as entering into collaborations, joint ventures, license agreements and other similar arrangements. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We believe that our current and future competition for resources and eventually for customers comes from companies that are commercializing or developing candidates targeting EGFRm- positive NSCLC, including, but not limited to, AstraZeneca, Johnson & Johnson, **Blossom Hill Therapeutics** ~~Takeda Pharmaceutical Company Limited, Blueprint Medicines Corp~~ , Dizal Pharmaceutical, Oric Pharmaceuticals, Black Diamond Therapeutics, Inc., **Cullinan Therapeutics, Inc.,** Taiho Pharmaceutical Co., Ltd., Boehringer Ingelheim and Bayer AG **. In March 2024 and October 2024, chemotherapy in combination with the anti- EGFR anti- MET bispecific antibody amivantamab was approved in the United States and Europe, respectively, for first line EGFRm NSCLC patients with exon 20 insertion mutations** . In October 2023, Johnson & Johnson presented the results of the Phase 3 PAPILLON study of chemotherapy in combination with the anti- EGFR anti- MET bispecific antibody amivantamab in first- line NSCLC patents with EGFR exon 20 insertion mutations, and announced in July 2023 that the PAPILLON study met its primary endpoint. In October 2023, Dizal Pharmaceutical and Oric Pharmaceuticals provided updates on their oral EGFR inhibitors sunvozertinib and ORIC- 114, respectively, each of which is being studied in Phase 1 trials in first- line NSCLC patients with EGFR exon 20 insertion mutations. **In January 2025, Taiho Therapeutics and Cullinan Therapeutics announced that their study of the oral EGFR inhibitor zipalertinib met the primary endpoint in a phase 2B clinical trial of patents in second or later line NSCLC patients with EGFR exon 20 insertion mutations.** Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered, the timing and scope of regulatory 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. Competing products may render ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates 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. See " Business — Competition. " We currently have **limited marketing and** no ~~marketing~~ --- **market** ~~and~~ **access or** sales ~~organization~~ **organizations** and have no experience as a company in commercializing products, and we may need to 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 **limited marketing and** no internal sales ~~, marketing~~ or distribution capabilities, nor have we commercialized a product. If ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidate ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, 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 with the marketing, sale or ~~85distribution~~ -- **distribution** of biopharmaceutical products and there are significant risks involved in the building and managing of 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, monitor compliance on an ongoing basis, and ~~effectively~~ **92effectively** 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 compete with many companies that currently have extensive, experienced and well- funded market access, marketing and sales operations to recruit, hire, train and retain marketing and sales personnel, and will have to compete with those companies to recruit, hire, train and retain any of our own market access, marketing and sales personnel. If we are unable to expand our sales and marketing team, we may be unable to compete successfully against these more established companies **.** 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 revenue 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. If the market opportunities for ~~furmonertinib~~ **firmonertinib** and any **other current or** future product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. The precise incidence and prevalence for the various mutations of NSCLC we aim to address with ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates are unknown. Our projections of both the number of people who have EGFRm NSCLC or other diseases we target, 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 a number of internal and third- party estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these indications. While we believe our assumptions and the data underlying our estimates are reasonable, we have not independently verified the accuracy of the third- party data on which we have based our assumptions and estimates, and these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. The total addressable market across all of the potential indications for ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each such product candidate which receives marketing approval for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of such 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 product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition and results of operations. Our future growth may depend, in part, on our ability to operate 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 ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates in foreign markets. We are not permitted to market or promote any product candidate before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for ~~furmonertinib~~ **firmonertinib** or any **other current or** future 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, commercial sales, pricing and distribution of ~~furmonertinib~~ **firmonertinib , our other product candidates** and any future product candidates. Approval procedures may be more onerous than those in the United States and may require that we conduct additional ~~preclinical~~ **nonclinical** studies or clinical trials. If we obtain regulatory approval of product candidates and ~~86ultimately~~ -- **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; **93** ● the existence of additional third- party patent rights of potential relevance to our business; ● unexpected changes in tariffs, trade barriers and regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with export control and import laws and regulations; ● 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 revenue, 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; ● differing regulatory requirements with respect to manufacturing **, packaging or distribution** of products; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; ● business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires; and ● disruptions resulting from the impact of public health pandemics or epidemics ~~(including, for example, COVID- 19)~~. We may not successfully identify, acquire, develop or commercialize new potential product candidates. Part of our business strategy is to expand our product candidate pipeline by identifying and validating new product candidates, which we may develop ourselves, in- license or otherwise acquire from others. In addition, in the event that our existing product candidates do not receive regulatory approval or are not successfully commercialized, then the success of our business will depend on our ability to expand our product pipeline through internal development, in- licensing or other acquisitions. We may be unable to identify relevant product candidates. If we do identify such product candidates, we may be unable to reach acceptable terms with any third party from which we desire to in- license or acquire them. Any product candidates we identify, acquire, in- license, develop, or manufacture may not be safe or effective for their targeted diseases, and may not receive marketing authorization in a timely manner, or at all. 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 and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to ~~furmonertinib~~ **firmonertinib or any other current or future product candidates, which may change from time to time; ● the timing and success or failure of preclinical studies or clinical trials for**

firmonertinib or other current or any future product candidates ~~, which may change from time to time; 87 ● the timing and success or failure of preclinical studies or clinical trials for furmonertinib or any future product candidates~~ or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; ● coverage and reimbursement policies with respect to ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates, if approved, and potential future drugs that compete with our products; ● expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies; **94** ● the level of demand for any approved products, which may vary significantly; ● future accounting pronouncements or changes in our accounting policies; ● the timing and amount of any milestone, royalty or other payments payable by us or due to us under any collaboration, licensing or other similar agreement; and ● changes in general market and economic conditions. 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 common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide. We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer. We are a clinical- stage company, and, as of December 31, ~~2023~~ **2024** , had ~~40~~ **52** full- time employees. We are highly dependent on the research and development, clinical and business development expertise of ~~Zhengbin (Bing) Yao, Ph. D.,~~ our ~~co- founder, Chief Executive~~ **executive** ~~Officer~~ **officers** ~~and Chairman, and Stuart Lutzker, M. D., Ph. D., our co- founder and President of Research and Development~~ , as well as the other principal members of our management, scientific and clinical team. Although we have entered into offer letters with our executive officers, each of them may terminate his or her employment with us at any time. We do not maintain " key person " insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock ~~, particularly after the expiration of the lock- up agreements described herein~~ . We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other ~~88businesses~~ -- **businesses** . Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. We will need to develop and expand our organization, and we may encounter difficulties in managing our growth and expanding our operations successfully, which could disrupt our operations. As of December 31, ~~2023~~ **2024** , we had ~~40~~ **52** full- time employees. As we continue development and pursue the potential commercialization of ~~furmonertinib~~ **firmonertinib , our other product candidates** and any future product candidates, as well as ~~transition to~~ **continue 95to** ~~functioning~~ --- **function** as a public company, we will need to expand our financial, accounting, development, regulatory, manufacturing, information technology, marketing and sales capabilities or contract with third parties to provide these capabilities for us. We may have difficulty identifying, hiring and integrating new personnel. The expansion of our operations may lead to significant costs and may divert the attention of our management and business development resources away from day- to- day activities and devote a substantial amount of time to managing internal or external growth. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties and we may not be successful in doing so. Our future financial performance and our ability to develop and commercialize ~~furmonertinib~~ **firmonertinib , our other product candidates** and any future product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We are subject to various U. S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could expose us to criminal sanctions, civil and administrative penalties, contractual damages, reputational harm and diminished profits and future earnings, among other penalties, any of which could harm our results of operations and financial condition. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include: ● the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the

referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation; ● the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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 civil False Claims Act; ● the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ~~89~~ ● 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 CMS information related to payments and other " transfers of value " made to physicians, defined to include doctors, dentists, optometrists, podiatrists and chiropractors, certain non- physician practitioners, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse- midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; ~~and~~ **96** ● analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers; **and** ● some state **or local** laws **that** require biotechnology companies to comply with the ~~biotechnology~~ **biopharmaceutical** industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government ~~and may require drug manufacturers~~ to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; ~~some state laws that require biotechnology companies~~ to report information on the pricing of certain drug products; and ~~some state and local laws that require~~ the registration ~~or~~ **of** pharmaceutical sales representatives **doing business within the jurisdiction, among other potentially applicable state and local laws and regulations** . Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government- funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government- funded healthcare programs. Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates and may affect the prices we may set. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost- containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the ACA was enacted in the United States. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. ~~90In~~ **In** addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on the Medicaid drug rebate, set at 100 % of a drug' s average manufacturing price, beginning January 1, 2024. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to

product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program ~~reimbursement~~ **97reimbursement** methodologies for products. Most recently, the IRA introduced a number of significant drug pricing reforms, including the establishment of a drug price negotiation program within the HHS (beginning in 2026) that requires manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation (first due in 2023), and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs (beginning in 2025). The program being implemented by HHS is currently the subject of several federal lawsuits, and its ultimate form remains uncertain. Additional drug pricing proposals could also appear in future legislation **as the Trump Administration and the 119th Congress begin to develop and articulate policy proposals related to prescription drug pricing and the biopharmaceutical industry more broadly** . At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U. S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers (PBMs), and other members of the health care and pharmaceutical supply chain, an important decision that had led to further and more aggressive efforts by states in this area. The FTC in mid- 2022 also launched sweeping investigations into the practices of the PBM industry **, and published interim reports with its findings in mid- 2024 and January 2025,** that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements, ~~and Congress has been convening hearings to learn more about~~ **including in the current 2025- 2026 congressional session where** PBM ~~practices~~ **reform continues to be a bipartisan priority. During the previous congressional session, numerous PBM reforms were considered in both the Senate** and **the House of Representatives;** ~~the~~ **they** ~~pharmaceutical supply chain more broadly~~ **included diverse legislative proposals such as eliminating rebates; divorcing service fees from the price of a drug, discount, or rebate; prohibiting spread pricing; limiting administrative fees; requiring PBMs to report formulary placement rationale; promoting transparency** . Significant efforts to change the PBM industry as it currently exists in the U. S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including innovative drug product developers like us. Legally mandated price controls on payment amounts by third- party payors or other restrictions, if enacted and applicable to any of our future commercial products, could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. We expect that these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. 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 ~~furmonertinib~~ **firmonertinib , our other product candidates** and any future product candidates, if approved. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit, delay or cease commercialization of any products we may develop. We face an inherent risk of product liability as a result of the clinical trials of ~~furmonertinib~~ **firmonertinib , our other product candidates,** and any future product candidates and will face an even greater risk if we commercialize our product candidates, especially if our products are prescribed for off- label uses, even if we do not promote such uses. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, ~~administering~~ **98administering** or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts. ~~91If~~ **If** we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit, delay or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for our future products; ● injury to our reputation and significant negative media attention; ● withdrawal of clinical trial participants; ● costs to defend the related litigation; ● a diversion of our management' s time and our resources; ● substantial monetary awards to any injured patients; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● significant negative financial impact; ● the inability to commercialize ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates; and ● a decline in our stock 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 or if we commence commercialization of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates. 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. Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employment benefits liability ~~, business automobile~~ , workers' compensation, products liability, malicious invasion of our electronic systems, and directors' and officers', and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. ~~We~~ **99We** are subject to ~~stringent~~ **complex** and evolving U. S. and foreign laws, regulations, **and** rules, **as well as** contractual obligations, and policies related to data privacy and ~~security~~ **data protection** . Our **, or those of collaborators or other third parties on which we rely,** actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. In the ordinary course of business, we collect **and** ~~, receive, store,~~ process ~~, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process or processing)~~ personal data and other sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third- party data ~~(collectively, sensitive data)~~ . Our data processing activities may subject us to numerous **privacy and** data **protection** ~~privacy and security 92obligations --~~ **obligations** , such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to **privacy and** data **protection** ~~privacy and security~~ . Various federal, state, local and foreign legislative and regulatory bodies, or self- regulatory organizations, may expand **or amend** current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding **privacy and** data **protection** ~~privacy and security~~ . In the United States, federal, state, and local governments have enacted numerous **privacy and** data **protection** ~~privacy and security~~ laws, including data breach notification laws, personal data privacy laws, consumer protection laws, e. g., Section 5 of the Federal Trade Commission Act, and other similar laws, e. g., wiretapping laws. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations (collectively, HIPAA), imposes certain privacy and security requirements for individually identifiable health information on certain entities, namely certain healthcare providers, health plans, and healthcare clearinghouses (covered entities) and their respective " business associates " who directly or as a subcontractor provide services involving the creation, use, maintenance or disclosure of individually identifiable health information on covered entities' behalf. As a clinical trial sponsor, we are not directly subject to HIPAA, but we do have relationships with providers and other entities subject to the law and thus must structure those relationships in a manner consistent with HIPAA requirements. If any of the physicians or other health care providers or entities with whom we expect to do business are found to be not in compliance with HIPAA or other applicable privacy laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs. If regulatory authorities challenge our activities, or those of a collaborator or other third party on which we rely, under HIPAA or other privacy laws applicable to the privacy and security of health information, any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any investigation of or enforcement against us or the third parties with whom we contract, including a research collaborator, regardless of the outcome, would be costly and time consuming, and may negatively affect our ability to conduct clinical trials, results of operations and financial condition. **Other federal and state laws establish additional requirements for protecting the privacy and security of health information that is not protected by HIPAA. For instance, Washington state recently passed the " My Health My Data " Act, which came into force in 2024 and regulates " consumer health data, " which is defined as " personal information that is linked or reasonably linkable to a consumer and that identifies a consumer' s past, present, or future physical or mental health. " The " My Health My Data " Act provides exemptions for personal data used or shared in connection with certain research activities, including data subject to 45 C. F. R. Parts 46, 50 and 56. Notably, the " My Health My Data " Act contains a private right of action. In addition, Nevada recently enacted a consumer health data privacy bill, SB 370, which also took effect in 2024, and regulates " consumer health data. " SB 370 shares many similarities with Washington' s " My Health My Data " Act, and Connecticut recently amended its comprehensive privacy law to include heighted regulation of " consumer health data. "** ~~Additionally --~~ **Additional states may adopt health- specific privacy laws that could impact our business activities and our collection and handling of health- related data. More broadly , various U. S. states now regulate the processing of personal data. For example, California was the first of an ever- increasing number of states to enact comprehensive state privacy legislation with** the California Consumer Privacy Act (CCPA) ~~applies to personal information of consumers , business representatives, and employees, and among other things requires~~ **which went into effect in January of 2020. The CCPA established a privacy framework for** covered businesses ~~to provide specific disclosures in~~ **by creating an expanded definition of personal data, establishing data** privacy **rights for** ~~notices and honor requests of~~ California residents ~~to exercise certain privacy rights , including the right~~ **requiring covered businesses** to **provide** ~~opt out of certain~~ disclosures ~~of~~ **to California residents, and creating a statutory damages framework with** ~~their --~~ **the** ~~information. The~~ **potential for severe damages for violations of the** CCPA ~~provides~~ **and** for **businesses that fail** ~~civil penalties of up~~ to ~~$ 7~~ **implement reasonable security procedures and practices to prevent data breaches** , ~~500 per violation~~ as well as a private right of action ~~with statutory damages~~ for certain data breaches ~~, thereby potentially increasing risks associated with a data breach . Although the law includes limited exceptions, including for certain information collected as part of clinical trials, the CCPA may impact our processing of personal~~

~~information and increase our compliance costs. Additionally~~ **100Additionally** , **in 2020 California voters passed** the California Privacy Rights Act of 2020 (CPRA) **, which went into effect on January 1, 2023. The CPRA** significantly **amends and** expands the CCPA, such as granting additional rights to California residents, including the right to correct personal ~~information~~ **data** and additional opt- out rights. ~~The~~ **Among other things, the** CPRA also establishes a regulatory agency ~~dedicated to enforcing~~ **, the California Privacy Protection Agency, which enacts new regulations under** the CCPA and ~~the CPRA. Other states, such as~~ **has** ~~Connecticut~~ **expanded enforcement authority. In 2023** , ~~Colorado, Indiana, Iowa, Texas and Utah, have also passed~~ comprehensive privacy laws **in Virginia** , **Colorado, Connecticut,** and ~~similar~~ **Utah all took effect, and** laws **in Montana, Oregon, and Texas took effect during 2024. Laws in a number of other U. S. states took effect, or** are ~~being considered~~ **set to take effect,** in ~~several~~ **2025, in 2026, and beyond. Additional U. S. states have proposals under consideration, all of which are likely to increase our regulatory compliance costs and risks, exposure to regulatory enforcement action, and** other **liabilities** ~~states, as well as at the federal and local levels~~ . While these state privacy laws, ~~like~~ **such as** the CCPA, ~~also~~ **contain** ~~exempt~~ **exemptions** ~~some~~ **for certain types of personal data, such as personal** data processed in the context of clinical trials ~~(and most also exempt employee and business personal data)~~ , these ~~developments~~ **laws may** further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. The scope and enforcement of these laws is uncertain and **evolving** ~~subject to rapid change. For example, increasing concerns about health information privacy have recently prompted the federal government to take a newly expansive view of the scope of existing privacy laws and regulations. Congress and some states are considering (and in some cases have passed) new laws and regulations that further and more broadly protect the privacy and security of personal health information~~ . In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self- regulatory standards that may place additional burdens on us. **Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal data as well. For example, the European Parliament and the Council of the European Union adopted a comprehensive general data privacy framework called the General Data Protection Regulation (GDPR), which went into effect in 2018 and implemented a broad data protection framework that expanded the scope of EU data protection law, and applies to entities located inside and outside of the EU that process, or control the processing of, personal data relating to individuals located in the EU, including clinical trial data. The GDPR also imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification, and the use of third- party processors in connection with the processing of the personal data. In particular, medical or health data, and genetic and biometric data used to uniquely identify an individual, are all classified as " special category " data under the GDPR and are subject to heightened restrictions and compliance obligations. Further, EU member states have a broad right to impose additional conditions – including restrictions – on these data categories. This is because the GDPR allows EU member states to derogate from the requirements of the GDPR mainly in regard to specific processing situations (including special category data and processing for scientific or statistical purposes). As EU member states continue to reframe their national legislation to harmonize with the GDPR, we will need to monitor compliance with all relevant EU member states' laws and regulations, including** ~~There~~ **where permitted derogations from the GDPR are introduced, all of which could limit our ability to collect, use and share EU data, and could cause our compliance costs to increase, ultimately adversely affecting our business, financial condition, results of operations and prospects. Relatedly, following Brexit and the expiry of the Brexit transition period, which ended on December 31, 2020, the EU GDPR has been implemented in the United Kingdom (as the UK GDPR). The UK GDPR sits alongside the United Kingdom Data Protection Act 2018 which implements certain derogations in the EU GDPR into United Kingdom law. Under the UK GDPR, companies not established in the United Kingdom but who process personal data in relation to the offering of goods or services to individuals in the United Kingdom, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £ 17. 5 million or 4 % of global turnover. Transfers of personal data to certain countries outside of the EU and the UK** are also **highly regulated under** ~~various laws and regulations in other~~ -- **the GDPR** ~~jurisdictions outside the United States relating to data privacy~~ and **UK GDPR** ~~security, with which we may need to comply~~ . For example, the **GDPR only permits exports of personal data outside of the** EU ~~GDPR and~~ **to " non- adequate " countries where** ~~the~~ **there** ~~United Kingdom' s equivalent~~ **is a suitable data transfer mechanism in place to safeguard personal data** (~~UK GDPR~~ **e. g.** , ~~and together with~~ the EU ~~GDPR,~~ **Commission approved Standard Contractual Clauses or certification under** the ~~GDPR~~ **Data Privacy Framework**) **. On July 16** , ~~impose strict requirements~~ **2020, the Court of Justice of the EU, or the CJEU, issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C- 311 / 18) (Schrems II). This decision called into question certain data transfer mechanisms as between the EU member states and the U. S. The CJEU is the highest court in Europe and the Schrems II decision heightened the burden to assess U. S. national security laws on their business, and future actions of EU data protection authorities are difficult to predict at this time. While the Data Privacy Framework was meant to address the concerns raised by the CJEU in Schrems II, it will likely be subject to future legal challenges. Consequently, there is some risk of any data transfers from the EU being halted. If we have to rely on third parties to carry out services** for **us, including** processing personal data ~~. Notably~~ **on our behalf** , ~~the EU~~ **we are required under** GDPR **to enter into contractual arrangements to flow down or help 101ensure that these third parties only process such data according to our instructions** and ~~UK GDPR impose large~~ **have sufficient security measures in place. Any security breach or non-compliance with our contractual terms or breach of applicable law by such third parties could result in enforcement actions, litigation, fines and** penalties ~~for~~ - **or adverse publicity and could cause customers** ~~noncompliance, including the potential for fines of up~~ to **lose trust in us** ~~€ 20 million under the EU GDPR / £ 17. 5 million under the UK GDPR~~ , **which**

would have ~~or 4 % of the annual global revenue of the noncompliant entity, whichever is greater. The EU GDPR and~~ an ~~UK GDPR also provide for private litigation related to~~ adverse impact on our reputation and business. Any contractual arrangements requiring the processing of personal data from ~~brought by classes of data subjects or consumer protection organizations authorized at law to represent their~~ the ~~interests. Additionally,~~ EU ~~member states~~ to us in the U. S. will require greater scrutiny and assessments as required under Schrems II and may have ~~introduce further conditions, including limitations, and~~ an ~~93make their~~ adverse impact ~~own~~ on cross- border transfers ~~laws and regulations further limiting the processing of ' special categories~~ of personal data ~~, including personal data related to health, biometric data used for~~ or increase costs of ~~unique identification purposes and genetic information, which could limit our ability to collect, use and share EU data, and could cause our~~ compliance ~~costs to increase, ultimately adversely affecting our business, financial condition, results of operations and prospects~~. In addition to privacy ~~the GDPR~~ and data protection laws in the U. S ~~. data privacy laws~~, ~~virtually every~~ E. U, and U. K,, various other international ~~jurisdiction~~ jurisdictions in which we operate ~~has~~ have established ~~its own~~ legal ~~framework~~ frameworks relating to privacy, data protection, and information security matters to which we may also be subject. For example, we are also subject to laws in China. Under the Cybersecurity Law of the People' s Republic of China (China' s Cybersecurity Law), any collection, use, transfer and storage of personal information of a Chinese citizen through a network by the network operator should be based on the three principles of legitimacy, justification and necessity and requires the consent of the data subject. The rules, purposes, methods and ranges of such collection should also be disclosed to the data subject. China' s data localization requirements are becoming increasingly common in sector- specific regulations, and laws including data localization requirements exist in many of the other jurisdictions in which we operate. For example, China' s Cybersecurity Law requires operators of critical information infrastructure (CIIOs) to store personal information and important data collected and generated from the critical information infrastructure within China. Non- compliance with China' s Cybersecurity Law can result in fines for the relevant entity as well as for the personnel directly responsible. On September 14, 2022, the Cyberspace Administration of China (CAC), China' s top cybersecurity regulator, released new amendments to China' s Cybersecurity Law for public consultation and if the amendments are passed, the amended law will increase the penalties for violations of cybersecurity obligations under the Cybersecurity Law to up to RMB 50 million, in line with those under the Data Security Law and PIPL. Building on this, China' s Data Security Law (Data Security Law) became effective on September 1, 2021. The primary purpose of the Data Security Law is to regulate data activities, safeguard data security, promote data development and usage, protect individuals and entities' legitimate rights and interests, and safeguard state sovereignty, state security and development interests. The Data Security Law applies extraterritorially, and to a broad range of activities that involve " data " (not only personal or sensitive data). Under the Data Security Law, entities and individuals carrying out data activities must abide by various data security obligations. For example, the Data Security Law proposes to classify and protect data based on the importance of data to the state' s economic development, as well as the degree of harm it will cause to national security, public interests, or legitimate rights and interests of individuals or organizations when such data is tampered with, destroyed, leaked, or illegally acquired or used. The appropriate level of protective measures is required to be taken for each respective class of data. The Data Security Law also echoes the data localization requirement in the Cybersecurity Law and requires important data to be stored locally in China. Such important data may only be transferred outside of China subject to compliance with certain data transfer restrictions, such as passing a security assessment organized by the relevant authorities. The Cybersecurity Review Measures, which took effect on February 15, 2022 in China, clarify when entities must apply for a mandatory cybersecurity review from the Chinese government authorities. These circumstances include (i) when CIIOs purchase network products that may affect national security, (ii) when a network platform operator' s data processing activities may affect national security, or (iii) when a network platform operator holds personal information of more than one million individuals and plans on listing publicly outside China. Network platform operators are not defined under the Cybersecurity Review Measures ~~,~~ but are understood to be broadly interpreted to include all Internet platform operators or service providers, thus providing for a broad application. A mandatory cybersecurity review is likely to prolong the timeline of any contemplated listing timeline outside China and increase the regulatory compliance burden on entities that are subject to this requirement. At this time, the Company does not act as a network platform operator and does not hold the personal information of more than one million individuals in China, and as such, we do not believe the Company would be subject to the Cybersecurity Review Measures. However, the relevant Chinese authorities have great discretion , and it is generally uncertain as to how they may interpret and enforce the Cybersecurity Review Measures in practice. ~~Additionally~~ 102Additionally , on August 20, 2021, China announced the Personal Information Protection Law (PIPL), which took effect on November 1, 2021. The PIPL is intended to clarify the scope of application, the definitions of personal information and sensitive personal information, the legality of personal information processing and the basic requirements of notice and consent, among other things. The PIPL also sets out data localization requirements for CIIOs ~~94and~~ and personal information processors who process personal information above a certain threshold prescribed by the relevant authorities. The PIPL also includes a list of rules which must be complied with prior to the transfer of personal information outside of China, such as compliance with a security assessment or certification by an agency designated by the relevant authorities or entering into standard form model contracts approved by the relevant authorities with the overseas recipient. On July 7, 2022, the CAC issued Security Assessment Measures for Outbound Data Transfers, which became effective on September 1, 2022. The Security Assessment Measures for Outbound Data Transfers clarifies the security assessment requirement under the PIPL and requires a data processor to apply for the security assessment organized by the CAC under any of the following circumstances before the information is transferred outbound: (i) where a data processor provides key data overseas, (ii) critical information infrastructure operator and personal information processors who process more than one million individuals' personal information; (iii) where a data processor has cumulatively provided personal information of over 100, 000 individuals or sensitive personal information of over 10, 000 individuals in total abroad since January 1st of the previous year. Additionally, on November 18, 2022, the CAC and the State Administration of Market

Regulation issued the Implementation Rules for Personal Information Protection Certification which apply with immediate effect and which provide important guidance on obtaining a personal information certification for lawful cross- border transfer of personal information under the PIPL. Notably, the PIPL, similar to both the GDPR and certain U. S. privacy laws, applies extraterritorially. Failure to comply with PIPL can result in fines of up to RMB 50 million or 5 % of the prior year' s total annual revenue for the personal information processor and / or a suspension of services or data processing activities. Other potential penalties include a fine of up to RMB 1 million on the person in charge or directly responsible personnel and, in serious cases, individuals and entities may be exposed to criminal liabilities under other local Chinese law, such as the Criminal Law of the People' s Republic of China. The PIPL also prohibits responsible personnel for violations of the PIPL from holding high level management or data protection officer positions in relevant enterprises. In addition to China' s Cybersecurity Law, the Data Security Law and the PIPL, the government agencies of China promulgated several regulations or released a number of draft regulations for public comments which are designed to provide further implemental guidance in accordance with the laws mentioned above. We cannot predict what impact the new laws and regulations or the increased costs of compliance, if any, will have on our operations in China, in particular the Data Security Law or PIPL, or the increased costs of compliance, if any, will have on our operations in China due to their recent enactment and the limited guidance available on their scope and applicability, particularly on PIPL. It is also generally unclear how the laws will be interpreted and enforced in practice by the relevant government authorities as often the abovementioned laws are drafted broadly and thus leaves great discretion to the relevant government authorities to exercise. ~~The evolving~~ **We also publicly post privacy policies** and ~~overarching~~ **notices that describe our practices concerning our collection, use, disclosure and other processing of personal data. Although we endeavor to** ~~complexity ----~~ **comply with our public- facing privacy policies and notices, we may at times fail to do so or be perceived to have failed to do so, and we may be subject us to enforcement actions if our privacy policies and notices are found to be deceptive, unfair or misrepresentative** of **our actual practices, which could result in, regulatory inquiries and investigations or adverse publicity and could cause our customers and collaborators to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects. Applicable data** privacy and data protection laws **may conflict with each other,** and **by complying with the laws or** regulations ~~around the world may require us to design, implement and maintain different types~~ of **one** ~~state- or country- based, privacy- related compliance controls and programs simultaneously in multiple jurisdictions~~ **jurisdiction** , ~~thereby further increasing~~ the **Company may find that it is violating the laws** ~~complexity and cost of compliance. These costs, including others relating to increased regulatory oversight and compliance, could materially and adversely affect our~~ **or** ~~business or our growth plans and result~~ **regulations of another jurisdiction. Despite the Company' s efforts, the Company may not have fully complied** in ~~damages or liability~~ **the past and may not** in **the future. Evolving legal, contractual, and** other ~~forms as a result of failure to implement proper programmatic controls, failure to adhere to those controls, or the malicious or inadvertent breach of applicable~~ privacy and data protection ~~requirements by us, our employees, our business partners, or our customers. In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross- border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. 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 EEA and the UK to the United States in compliance with law, such as the EEA and UK' s standard contractual clauses, these 95mechanisms 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 the 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 EU GDPR' s cross- border data transfer limitations. In addition to data privacy and security laws, we are also bound by other contractual** obligations ~~related to data privacy and security~~ , ~~and our efforts to comply with such obligations may not be successful. Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations~~ could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of personal ~~information~~ **data** , which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such ~~changes~~ **103changes** could ~~compromise~~ **impact** our ability to develop an adequate marketing strategy and pursue our growth strategy effectively **,** or even prevent us from providing certain products in jurisdictions in which we currently operate **,** and in which we may operate in the future **,** or incur potential liability in an effort to comply ~~with such legislation~~ , which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often **evolving** ~~changing laws, regulations and contractual~~ requirements is expensive and difficult, and suspected and actual failure to comply ~~with any data privacy or security requirements~~ , whether by us, ~~one of~~ our **service providers,** CROs, business partners or ~~another~~ -- **other** third **parties, or any inadvertent or unauthorized access to or use or disclosure of data that we store or handle as** ~~party~~ **part of operating our business** , could adversely affect our business, financial condition, results of operations and prospects ~~, including~~

but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and / or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The recent implementation of the CCPA, EU GDPR and UK GDPR have increased our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the CCPA and other applicable state laws, EU GDPR and UK GDPR and other applicable laws and regulations, which could divert management' s attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EEA and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business. Any actual or perceived failure by us or our third- party service providers to comply with any federal, state or foreign laws, rules, regulations, industry self- regulatory principles, industry standards or codes of conduct, regulatory guidance, orders to which we may be subject or other legal obligations relating to privacy, data protection, data security or consumer protection could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non- compliance with any standards, laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of data that we store or handle as part of operating our business. Any of these events could adversely affect our reputation, business, or financial condition , including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited -- **limit our** ability to develop or commercialize our products; expenditure of time and resources to defend any claim **; investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding** or our inquiry **privacy and security practices; requirements that we provide notices, credit monitoring services and / or credit restoration services or other relevant services to impacted individuals** ; adverse publicity **actions against our licenses to do business** ; **reputational damage; and injunctive relief** or substantial changes to our business model or operations . We cannot assure you that our CROs, CMOs or other **may also be contractually required to indemnify and hold harmless** third - party service providers with access to our or our suppliers', manufacturers', collaborators', trial participants' and employees' sensitive information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security incidents, which could have a 96corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and / or which could in turn adversely affect our business, financial condition, results of operations and prospects. We cannot assure you that our contractual measures and our own privacy and security- related safeguards will protect us from the risks associated with the third- party processing of such information. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects. We also publicly post our privacy policies and practices --- **parties** concerning our collection, use, disclosure and other processing of the personal information provided to us by our website visitors and by our customers. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Our publication of our privacy policies and other statements we publish that provide promises and assurances about privacy and security can subject us to potential state and federal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause our customers and collaborators to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects . The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co- insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. If our internal information technology systems, or those used by our CROs, clinical sites, or other contractors or consultants upon which we rely, are or were compromised, become unavailable or suffer security **cybersecurity** breaches **incidents** , loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, litigation, fines, penalties and liability, compromise of sensitive information related our business, and other adverse consequences. In the ordinary course of our business, we, and the third parties upon which we rely, process sensitive data and as a result, we and the third parties upon which we rely face a variety of evolving threats which could cause **cybersecurity incidents. Despite our implementation of** security incidents. Our **measures, our** internal information technology systems and those of our CROs, clinical sites, and other contractors and consultants upon which we rely are vulnerable to cyberattacks, computer viruses, bugs, worms, or other malicious codes, malware, including as a result of advanced persistent threat intrusions, and other attacks by computer hackers, cracking, application security attacks, social engineering, including through phishing attacks, supply chain attacks and vulnerabilities through our third- party service providers, denial- of- service attacks, such as credential stuffing, credential harvesting, personnel misconduct or error, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats **. Finally, developments in artificial intelligence and machine learning provide threat actors with the capability to use more sophisticated means to**

attack our systems and may exacerbate cybersecurity risk. There can be no assurance that we will be successful in preventing cybersecurity incidents or successfully mitigating their effects . Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " organized criminal threat actors, personnel, such as through theft or misuse, sophisticated nation states, and nation- state- supported actors. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation- state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data, including sensitive customer information, loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make ~~extortion~~ payments **to the threat actors** , but we may be unwilling or unable to do so, including, for example, if applicable laws or regulations prohibit such payments. ~~97Some~~ **104Some threat** actors also now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain and ability to produce, sell and distribute our goods and services. In addition to experiencing a ~~security~~ **cybersecurity** incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Furthermore, future or past business transactions, such as acquisitions or integrations, could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Additionally, we may discover security ~~issues~~ **vulnerabilities or risks** that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. While we take steps to detect and remediate vulnerabilities, we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a ~~security~~ **cybersecurity** incident has occurred **, if at all** . Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. We rely on third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud- based infrastructure, encryption and authentication technology, employee email, and other functions. We also rely on third- party service providers to assist with our clinical trials, provide other products or services, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a ~~security~~ **cybersecurity** incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems, including our services, or the third- party information technology systems that support us and our services. Any of the previously identified or similar threats could cause a ~~security~~ **cybersecurity** incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A ~~security~~ **cybersecurity** incident or other interruption could disrupt our ability, and that of third parties upon whom we rely, to provide our products and services and conduct clinical trials. The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, clinical sites, and other contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. If any such incidents were to occur and cause interruptions in our operations, it could result in a disruption of our business and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to ~~98recover~~ **105recover** or reproduce the data ~~,~~ or may limit our ability to effectively execute a product recall, if required in the future. To the extent that any disruption or ~~security~~ **cybersecurity** incident were to result in the loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed. Applicable data privacy and security obligations may require us to notify relevant stakeholders **, regulatory authorities and other individuals** of ~~security~~ **cybersecurity** incidents **, and take other remedial measures** . Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Any such event could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates. Our business, operations and clinical development timelines and plans are subject to risks arising from epidemic or pandemic diseases. **Our business, financial condition, and results of operations could be adversely affected by public health threats, including epidemics and pandemics, that disrupt our**

commercial operations, supply chains, clinical trials, and other essential activities. COVID- 19, which **is** ~~was recently declared~~ no longer **considered** a public health emergency both globally and in the United States, presented substantial public health and economic challenges and affected our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U. S. and global economies and financial markets. **During the COVID- 19 pandemic,** ~~International~~ **international** and U. S. governmental authorities in impacted regions took multiple and diverse actions in an effort to slow the spread of COVID- 19 and variants of the virus, including issuing varying forms of " stay- at- home " orders. ~~To date we have not experienced material disruptions in our business operations due to COVID- 19.~~ Such measures taken by the governmental authorities to respond to any future epidemic or pandemic disease outbreaks could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for ~~furmonertinib~~ **firmonertinib and our other product candidates** for use in our clinical trials and research and nonclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, including due to measures taken that may limit social interaction or prevent reopening of high- transmission settings, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our nonclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any future epidemic or pandemic disease outbreak could also potentially further affect the business of the FDA, the European ~~Medical Association~~ **Medicines Agency** (EMA) or other **comparable** regulatory authorities, which could result in delays in meetings related to our planned clinical trials. Any future epidemic disease outbreak may have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. 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. Our business could be affected by litigation, government investigations and enforcement actions. We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign ~~jurisdictions~~ **106jurisdictions** , including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti- kickback, anti- bribery, securities, commercial, employment and other claims ~~99and~~ -- **and** legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and / or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations. Legal proceedings, government investigations and enforcement actions can be expensive and time- consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources. Our employees and independent contractors, including principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could harm our business, financial condition and results of operations. We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar foreign regulatory authority requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad (iv) laws that require the true, complete and accurate reporting of financial information or data, or (v) laws that prohibit insider trading. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible

exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, 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 curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. We may engage in strategic transactions that could increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, subject us to other risks, adversely affect our liquidity, increase our expenses and present significant distractions to our management. From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out- licensing or in- licensing of intellectual property, products or technologies. Additional potential transactions that we may consider include a variety of business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. Any future transactions could increase our near and long- term expenditures, result in potentially dilutive issuances of our equity ~~securities~~ **107securities** , including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in- process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available ~~100on~~ **on** favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Furthermore, we may experience losses related to investments in other companies, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects. Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection **our** ~~with the recent~~ initial public offering **completed in January 2024** or other ownership changes. We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, subject to limitations, until such unused losses expire, if at all. At December 31, ~~2023~~ **2024** , we had **gross** net operating loss (NOL) carryforwards of $ ~~38~~ **67** . ~~7~~ **4** million for federal income tax purposes and $ ~~1~~ **58** . ~~1~~ **8** million for state income tax purposes. Our federal NOL carryforwards will not expire but may generally only be used to offset 80 % of taxable income, which may require us to pay federal income taxes in future years despite generating federal NOL carryforwards in prior years. We also had research and development tax credit carryforwards of $ ~~3~~ **7** . ~~4~~ **1** million that will begin to expire in 2041. In addition, our NOL carryforwards and other tax attributes are subject to review and possible adjustment by the Internal Revenue Service (IRS) and state tax authorities. Furthermore, in general, under Section 382 of the U. S. Internal Revenue Code of 1986, as amended (the Code), our federal **and state** NOL **carryforwards and research and development tax credit** carryforwards may be or become subject to an annual limitation in the event we have had or have in the future an " ownership change. " For these purposes, an " ownership change " generally occurs if one or more stockholders or groups of stockholders who own at least 5 % of a company' s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period. Similar rules may apply under state tax laws. We have not yet determined the amount of the cumulative change in our ownership resulting from our ~~recently completed~~ initial public offering **completed in January 2024** or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes including changes related to our ~~recently completed~~ initial public offering **completed in January 2024** . If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL **and credit** carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets. New tax legislation may impact our results of operations and financial condition. The IRA introduced, among other changes, a 15 % corporate minimum tax on certain United States corporations and a 1 % excise tax on certain stock redemptions by United States corporations. The U. S. government may enact further significant changes to the taxation of business entities. The likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict the ultimate impact of the **IRA** ~~Inflation Reduction Act~~ or any such further changes on our business. Inflation could adversely affect our business and results of operations. While inflation in the United States has been relatively low in recent years, from 2021 to 2023, the economy in the United States encountered a material level of inflation. **Inflation and fluctuations in inflation rates have had in the past, and may in the future have, negative effects on economies and financial markets, particularly in emerging economies. For example, increases in inflation raise our costs for commodities, labor, materials and services and other costs required 108to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Governmental efforts to curb inflation often have negative effects on the level of economic activity. There can be no assurance that inflation will not become a serious problem in the future and have an adverse impact on the Company' s returns.** The ~~impact of COVID- 19,~~ geopolitical developments such as the Russia- Ukraine and Middle East conflicts and global supply chain disruptions continue to increase uncertainty in the outlook of near- term and long- term economic activity, **as** ~~including whether inflation will~~ **well as** ~~continue and how long, and at what rate. Increases in inflation raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial 101condition. Additionally, increases in inflation, along with the~~

~~uncertainties surrounding COVID- 19, geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about~~ the interest rate environment, which may make it more difficult, costly or dilutive for us to secure additional financing. A failure to adequately respond to these risks **could have a material adverse impact on our financial condition, results of operations or cash flows. In light of the presidential transition in 2025, global trade disputes may be magnified, including the continuing trade dispute between the United States and China, pursuant to which both countries have, among other things, imposed tariffs on one another, has had an adverse economic effect on U. S. markets and international trade more broadly. This adverse economic effect is likely to become more pronounced if the dispute remains unresolved, which** could have a material adverse impact on our financial condition, results of operations or cash flows. Risks Related to Our Intellectual PropertyIf we are unable to obtain and maintain, sufficient intellectual property protection for ~~furmonertinib~~ **firmonertinib , our other product candidates** or future product candidates or technology, or if the scope of our intellectual property rights is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates may be adversely affected. Our commercial success depends in large part on our ability to obtain, maintain, enforce, and defend patent rights, trademarks and our proprietary know- how of sufficient scope in the United States and other countries with respect to our product candidates and other proprietary technologies we may develop. If we are unable to obtain, maintain or enforce our intellectual property rights of sufficient scope, our business, financial condition, results of operations and prospects could be materially harmed. We rely on patent rights in- licensed from Allist to protect ~~furmonertinib~~ **firmonertinib , in- licensed from Lepu Biopharma to protect ARR- 217 and in- licensed from Aarvik to protect ARR- 002** . Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our or our licensor' s ability to protect our intellectual property, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patents we have in- licensed from Allist will provide sufficient protection against competitors or other third parties, or if these patents are challenged by our competitors, will be found to be invalid, unenforceable, or not infringed. We also cannot predict whether patent application our licensor is currently pursuing or patent application we may in the future pursue or in- license will issue as patents in any particular jurisdiction. The patent prosecution process is expensive, time- consuming, and complex, and we or our licensors may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications or reissue applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection before public disclosures are made. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, third- party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our or our licensors' ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with ~~furmonertinib~~ **firmonertinib , other current product candidates,** and any future product candidates or technologies. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to invent the inventions ~~claimed~~ **109claimed** in any of our licensed patents or pending patent applications, or that we or our licensors were the first to make the inventions claimed in those owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. 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. We cannot be certain that the claims covering compositions of matter in any of our issued or reissued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing ~~102a~~ **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 biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued. Any issued patents may not 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, products or product candidates. Further, even if these patents are granted, they may be difficult to enforce. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. In the event we experience noncompliance events that cannot be corrected and we lose our patent rights, competitors could enter the market, which would have a material adverse effect on our

business. Further, any issued patents that we license or may license or own covering our ~~furmonertinib~~ **firmonertinib** or any **other current or** future product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other countries, including the United States Patent and Trademark Office (USPTO). Also, patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position on our product candidates for an adequate amount of time, and we may be subject to claims challenging the inventorship, validity, or enforceability of our patents and / or other intellectual property. Changes in United States patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. Further, if we encounter delays in our clinical trials or delays in obtaining regulatory approval, the period of time during which we could market our product candidates under patent protection would be reduced. Thus, the patents that we own and license may not afford us any meaningful competitive advantage. Moreover, the claim coverage in a patent application can be significantly narrowed before the corresponding patent is granted. Even if our owned or in- licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch- Waxman Amendments) to conduct research and clinical trials. Consequently, we do not know whether ~~furmonertinib~~ **firmonertinib** or any of our **other current or** future product candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non- infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. In addition, given the amount of time required for the development, testing and regulatory review of our **current and** future product candidates, patents protecting the product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. ~~The~~ **110The** issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability and our patent rights may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third- party post- issuance submission of prior art to the USPTO challenging the validity of one or more claims of our in- licensed patents or patents we may own in the future. Such submissions may also be made prior to a patent' s issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. A third party may also claim that our patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In addition, we may become involved in opposition, derivation, revocation, reexamination, reissue, post- grant and inter partes review or interference proceedings and other similar proceedings in foreign jurisdictions challenging the validity, priority or other features of patentability of our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or ~~103invalidate~~ **invalidate** or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and other proprietary technologies we may develop and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our products without infringing third- party patent rights. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing, could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, some of our patent rights are, and may in the future be, co- owned with third parties, including Allist. In the United States, each co- owner has the freedom to license and exploit the technology. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in such patent rights, such co- owners may be able to license their rights to other third parties without our consent, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. We depend heavily on intellectual property licensed from ~~a~~ third ~~party~~ **parties** , and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated or if disputes regarding these licenses arise, we could lose significant rights that are important to our business. We are a party to the Allist License Agreement **, the Amended and Restated Aarvik Collaboration Agreement and the Lepu Biopharma Agreement (collectively, License Agreements)** under which we are granted rights to intellectual property that are critical to ~~furmonertinib~~ **our product candidates** and our business and we may enter into additional license agreements in the future with other third parties. The ~~Allist~~ License ~~Agreement~~ **Agreements** ~~imposes~~ **impose** , and we expect that any future license agreements where we in- license intellectual property, will impose on us, various development, regulatory and / or commercial diligence obligations, payment of milestones and / or royalties and other obligations. We may need to devote substantial time and attention to ensuring that we are compliant with our obligations under such agreements, which may divert management' s time and attention away from our research and development programs or other day- to- day activities. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy- related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, or we may be subject to litigation for breach of these agreements. If we or our licensors fail to adequately prosecute, maintain and protect our licensed intellectual property, our ability to commercialize ~~furmonertinib~~ **our current** or any future product candidates could suffer. We do not have complete control over the maintenance, prosecution and litigation of our in- licensed patents and patent applications and may have limited control over future intellectual property that may be in- licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our 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. It is possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests. In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any ~~contract~~ **111contract** interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know- how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes that may arise between us and our licensors regarding intellectual property subject to a license agreement could include disputes regarding: ● the scope of rights granted under the license agreement and other interpretation- related issues; ● whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; ● our right to sublicense patent and other rights to third parties under collaborative development relationships; ~~104~~ ● our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of ~~furmonertinib~~ **our current** or any future product candidates and what activities satisfy those diligence obligations; and ● the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected technology or ~~furmonertinib~~ **our current product candidates** or any future product candidates. As a result, any termination of or disputes over our intellectual property licenses could result in the loss of our ability to develop and commercialize ~~furmonertinib~~ **our current product candidates** or any future product candidates, or we could lose other significant rights, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may not be able to protect our intellectual property and proprietary rights throughout the world. Filing, prosecuting, maintaining, enforcing and defending patents covering or relating to ~~furmonertinib~~ **our current product candidates** and any future product candidates in all countries throughout the world is expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Prosecution of patent applications is often a longer process and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, unlike patent law in the United States, patent law in most European countries and many other jurisdictions precludes the patentability of methods of treatment and diagnosis of the human body. Other countries may impose substantial restrictions on the scope of claims, limiting patent protection to specifically disclosed embodiments. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, or from selling or importing products made using our intellectual property in and into the United States or other jurisdictions. Competitors may use our or our licensors' intellectual property in jurisdictions where we or our licensors have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our owned and in- licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions. ~~Proceedings~~ **112Proceedings** to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value ~~105of~~ **of** such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. In addition, geo- political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia' s conflict in Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing

Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. 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. The USPTO and various non- U. S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some circumstances, we are dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and 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 or licensed patents and applications or any patents and applications we may own in the future. In certain circumstances, we rely on our licensors to pay these fees due to U. S. and non- U. S. patent agencies. In some 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 a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. The USPTO and various non- U. S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e. g., items related to national security or national defense). In some cases, a foreign filing license may be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant ~~jurisdiction~~ **113jurisdiction** . In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We are also dependent on our licensors to take the necessary actions to comply with these requirements with respect to our licensed intellectual property. Changes in patent laws or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to ~~106invent~~ --- **invent** the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability 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. Since March 2013, a third party that files a patent application in the USPTO, but before us or our licensors could be awarded a patent covering an invention of ours or our licensors 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 ~~furmonertinib~~ **our current product candidates** or any of our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications. The America Invents Act also included a number of significant changes that affected the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO- administered post- grant proceedings, including post- grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO 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 sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the 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. Therefore, the America Invents Act and its implementation increased the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of patents issuing from those patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. We cannot predict how decisions by the courts, the U. S. Congress or the USPTO may impact the value of our patent rights. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our

ability to protect and enforce our intellectual property 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 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. In addition, in 2012, the European Union Patent Package (EU Patent Package) regulations were passed with the goal of providing a single pan- European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the European Patent Package, now by default automatically fall under the ~~jurisdiction~~ **114jurisdiction** of the UPC. The UPC provides third parties, including our competitors, with a new forum to seek to centrally revoke our European patents and to seek to obtain pan- European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the current EU Patent Package, we have the right to opt our patents out of the UPC for the first seven years of the UPC' s existence, but doing so may preclude us from realizing the benefits of this new unified court. ~~107Issued~~ --- **Issued** patents covering ~~furmonertinib~~ **our current product candidates** or our future product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad. Our patent rights may be subject to priority, validity, inventorship and enforceability disputes. Legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time- consuming and likely to divert significant resources from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. If we or our licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated or held unenforceable, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or we may be required to cease the development, manufacture and commercialization of ~~furmonertinib~~ **our current product candidates** or future product candidates. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. If we or our licensors initiate legal proceedings against a third party to enforce a patent covering ~~furmonertinib~~ **our current product candidates** or any of our future product candidates, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non- enablement, lack of sufficient written description, failure to claim patent- eligible subject matter or obviousness- type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post- grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patent rights in such a way that they no longer cover our product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on ~~furmonertinib~~ **our current product candidates** and any future product candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects. We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that our patents will not be challenged and rendered invalid and / or unenforceable. We have pending in- licensed 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; **115** ● 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; and / or ● whether the patent applications that we own, or in- license will result in issued patents with claims that cover ~~furmonertinib~~ **our current product candidates** or any of our future product candidates or uses thereof in the United States or in other foreign countries. ~~108The~~ **The** claims in our pending patent applications directed to ~~furmonertinib~~ **our current product candidates** and any of our future 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 issue 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 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. 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. In the event of litigation or administrative proceedings, the claims in any of our issued patents may not be considered valid by courts in the United States or foreign countries. Patent terms may be inadequate to protect the competitive position of our product candidates

for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations, and prospects will be adversely affected. If we do not obtain patent term extension in the United States and equivalent extensions outside of the United States for our product candidates, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of ~~furmonertinib or~~ **our** ~~any~~ **current product candidates or** future product candidate we may develop, one or more of our in- licensed issued U. S. patents or issued U. S. patents we may own in the future may be eligible for limited patent term extension under the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate. However, we may not be granted an extension for various reasons, including failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or failing to satisfy other applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in- license from a third- party, we may need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our ~~competitors~~ **116competitors** may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We or our licensors may be subject to claims that former employees, consultants, collaborators or other third parties have an interest in our patent rights, any potential trade secrets, or other intellectual property as an inventor, co- inventor or owner of any potential trade secrets. For example, we may have inventorship disputes arise from conflicting ~~109obligations~~ **obligations** of consultants or others who are involved in developing our product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, any potential trade secrets or other intellectual property. If we or our licensors 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, intellectual property that is important to our product candidates and other proprietary technologies we may develop. 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. Any of the foregoing 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 and product candidates. We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we or our licensors have identified each and every third- party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover product candidates or the use of our product candidates. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, 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 patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or product candidates are not covered by a third- party patent or may incorrectly predict whether a third party' s pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third- party patent is invalid and unenforceable. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non- practicing entities, commonly referred to as " patent trolls, " have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or " invitations to license, " or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We

cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that we no longer infringe the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. ~~Third~~ **117Third** - party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators could be expensive and time consuming and may prevent or delay the development and commercialization of our product candidates. Our commercial success depends in part on our ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings ~~110before~~ --- **before** the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and techniques without payment, or limit the duration of the patent protection of our technology. As discussed above, recently, due to changes in U. S. law referred to as patent reform, new procedures including inter partes review and post- grant review have also been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patent rights in the future. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we ~~are commercializing or~~ plan to commercialize ~~furmonertinib~~ **our current product candidates** . As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that ~~furmonertinib~~ **our current product candidates** or any future product candidates, and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot assure you that ~~furmonertinib~~ **our current product candidates** or any future product candidates will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing ~~furmonertinib~~ **our current product candidates** or our future product candidates, might accuse us of infringing. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third- party patent does not pose a material risk, but in another country, the corresponding third- party patent may pose a material risk to ~~furmonertinib~~ **our current product candidates** and any future product candidates. As such, we monitor third- party patents in the relevant pharmaceutical markets. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe. In the event that any third- party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by us. Defense of infringement 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, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and / or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms or at all, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third- party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable. Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time- consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the ~~costs~~ **118costs** of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations. ~~111We~~ **We** may become involved in lawsuits to protect or enforce our patent and other intellectual property rights, which could be expensive, time- consuming and unsuccessful. Third parties, such as a competitor, may infringe our patent rights. In an infringement proceeding, a court may decide that a patent owned by us or licensed to us is invalid or unenforceable or may refuse to stop the other party from using the invention at issue on the grounds that the patent does not cover the technology in question. In addition, our or our licensors' patent rights may become involved in inventorship, priority or validity disputes. To counter or

defend against such claims can be expensive and time- consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing, misappropriating or violating other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. 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, which may not survive such proceedings. Moreover, any name we may propose to use with ~~furmonertinib~~ **our current product candidates** or any future product candidate 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, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate or otherwise violate the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration ~~may~~ **119may** not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. We may not be able to obtain, protect or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, misappropriation, dilution or other claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable ~~112to~~ **to** establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to obtain, enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects. We may not be successful in obtaining or maintaining necessary rights to technology for our development pipeline through acquisitions and in- licenses. The growth of our business may depend in part on our ability to acquire, in- license or use third- party intellectual property and proprietary rights. For example, ~~furmonertinib~~ **our current product candidates** or any future product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing our compounds and pre- existing pharmaceutical compounds, or we may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our product candidates, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patent or other intellectual property rights we may co- own with third parties, we may require licenses to such co- owners' interest to such patents. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe, misappropriate or otherwise violate those 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, it may be non- exclusive, which means that our competitors may also receive 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. Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution 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 others, potentially blocking our ability to pursue our program. The licensing and acquisition of third- party intellectual property rights is a competitive area, 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 in order to commercialize ~~furmonertinib~~ **our current product candidates** or any future product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to develop or market. 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 certain programs and our business financial condition, results of operations and prospects could suffer. ~~Our~~ **120Our** intellectual property licensed from third parties may be subject to retained rights. Our current or 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. For example, pursuant to the Allist License Agreement, Allist retains its rights for any and all purposes in certain retained territories regarding its patent rights, improvements and know- how related to any product containing ~~furmonertinib~~ **firmonertinib** or any of its derivatives as an active ingredient, including to research, develop, make, have made, use, sell, have sold, offer for sale, import, export and license products and processes in such retained territory. **The the Lepu Biopharma Agreement contain similar provisions in which Lepu Biopharma retains certain rights in the retained territory.** It is difficult to ~~113monitor~~ --- **monitor** whether our licensors will 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. For example, 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 any potential university partners in projects in which there is a risk that government funds may be commingled, we cannot be sure that any such co- developed intellectual property will be free from government rights. 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 government funds subject to certain government rights, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. 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 or permit us to maintain our competitive advantage. For example: ● others may be able to make products that are similar to ~~furmonertinib~~ **our current product candidates** or any future product candidates or utilize similar technology but that are not covered by the claims of the patents that we license or may own; ● we or our licensors might not have been the first to make the inventions covered by our or our licensors' current or future patent applications; ● we or our licensors might not have been the first to file patent applications covering our or their inventions; ● others may independently develop similar or alternative technologies or duplicate any of our or our licensors' technologies without infringing our intellectual property rights; ● it is possible that our or our licensors' current or future patent applications will not lead to issued patents; ● any patent issuing from our or our licensors' current or future patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; ● others may have access to the same intellectual property rights licensed to use in the future on a non- exclusive basis; ● our competitors or other third parties might conduct research and development activities in countries where we or our licensors do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; **121** ● we may not develop additional proprietary technologies that are patentable; ● the patents or other intellectual property rights of others may harm our business; and ● we may choose not to file for patent protection in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent application covering such intellectual property. Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects. ~~114We~~ **We** may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Some of our employees, consultants and advisors are currently or were previously employed at universities or other 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. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, 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 our management. 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. Our reliance on third parties requires us to share potential trade secrets, which increases the possibility that a competitor or other third party will discover them or that potential trade secrets will be misappropriated or disclosed. Because we currently rely on **, or expect to rely on,** a third ~~party~~ **parties** to manufacture ~~furmonertinib~~ **our current product candidates** and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including potential trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees 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 any potential 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 or other third parties, are intentionally or 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 despite our efforts to protect any potential trade secrets, a competitor' s or other third party' s discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects. If we are unable to protect the confidentiality of any potential trade secrets, our business and competitive position would be harmed. In addition to seeking patent protection for our product candidates and proprietary technologies, we may also rely on trade secret protection and confidentiality agreements to protect our unpatented know- how, technology, and other proprietary information and to maintain our competitive position. We seek to protect any potential trade secrets and ~~other~~ **122other** proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, third- party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Trade secrets and know- how can be difficult to protect. We may need to share our trade secrets and proprietary know- how with current or future 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 cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to any potential trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary ~~115information~~ --- **information** , including any potential trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to any potential trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our potential 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, others may independently discover any potential trade secrets and proprietary information. If any of our potential 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, or those to whom they communicate it, from using that technology or information to compete with us. If any of our potential trade secrets were to be disclosed or misappropriated or if any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. We may be subject to claims that third parties have an ownership interest in any potential trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing our product candidate. Litigation may be necessary to defend against these and other claims challenging ownership of any potential trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to our product candidates and other proprietary technologies we may develop. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Risks Related to Our Common Stock An active, liquid and orderly market for our common stock may not develop, or we may in the future fail to satisfy the continued listing requirements of Nasdaq and our stock may be delisted, and you may not be able to resell your common stock at your purchase price or at all. Our common stock only recently began trading on the Nasdaq Global Market, and we can provide no assurance that we will be able to develop an active trading market for our common stock. Even if an active trading market is developed, it may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business. 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 common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by ~~us~~ **123us** to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non- compliance with the listing requirements of Nasdaq. ~~116The~~ **The** trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses. The trading price of our common stock is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The market price for our common stock may be influenced by those factors discussed in this " Risk Factors " section and others, including: ● results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector; ● our ability to enroll subjects in our future clinical trials; ● our ability to obtain and maintain regulatory approval of ~~furmonertinib~~ **our current product candidates** or any future product candidates or additional indications thereof, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process; ● regulatory or legal developments in the United States and foreign countries, particularly in China; ● changes in the structure of healthcare payment systems; ● the success or failure of our efforts to identify, develop, acquire or license additional product candidates; ● innovations, clinical trial results, product approvals and other developments by our competitors; ● announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments; ● the degree and rate of physician and market adoption of any of our current and future product candidates; ● manufacturing, supply or distribution delays or shortages, including our inability to obtain adequate product supply, at acceptable prices or at all; ● any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners; ● achievement of expected product sales and profitability; ● variations in our financial results or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors; ● market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations; ● trading volume of our common stock; ● an inability to obtain additional funding or obtaining funding on unattractive terms; ● sales of our stock by us, our insiders or our stockholders, ~~as well as the anticipation of lock- up releases~~ ; ● general economic, industry and market conditions other events or factors, many of which are beyond our control; ● actual or anticipated fluctuations in our financial condition and results of operations; ● publication of news releases by **our partners, including** Allist, other companies in our industry, and especially direct competitors, including about adverse developments related to safety, effectiveness, accuracy and usability of their products, reputational concerns, reimbursement coverage, regulatory compliance, and product recalls; **124** ● announcement or progression of geopolitical events, including in relation to the conflicts in the Middle East and between Russia and Ukraine; ● additions or departures of senior management or key personnel; ~~117~~ ● intellectual property, product liability or other litigation against us or our inability to enforce our intellectual property; ● changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and ● changes in accounting standards, policies, guidelines, interpretations or principles. These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their common stock and may otherwise negatively affect the liquidity of the trading market for our common stock. In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management' s attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation. Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval and may prevent new investors from influencing significant corporate decisions. As of ~~March 22~~ **February 28** , ~~2024~~ **2025** , our executive officers, directors and greater than 5 % stockholders, in the aggregate, own a substantial portion of our outstanding common stock. As a result, such persons, acting together, have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transactions, as well as our management and business affairs, which may prevent new investors from influencing some or all of the foregoing. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders. Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock. We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. For the foreseeable future, any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares. Investors seeking cash dividends should not purchase our common

stock. See " Dividend Policy " under Item 5 of Part II of this Annual Report for additional information. ~~Sales~~ **125Sales** , or the possibility of sales, of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity or equity- linked securities. ~~118In connection with our initial public offering, our directors and executive officers and holders of substantially all of our outstanding securities have entered into lock- up agreements with the underwriters pursuant to which they may not, with limited exceptions, for a period of 180 days from the date of our initial public offering, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of Goldman Sachs & Co. LLC, Jefferies LLC and Citigroup Global Markets Inc.~~ **In addition** ~~. Such underwriters may permit our officers~~ , ~~directors and other securityholders who~~ **as of December 31, 2024, we had 2, 531, 144 shares of common stock that** are subject to **outstanding options under our employee benefit plans. All of** the ~~lock~~ **shares of common stock issuable upon the exercise of stock options and the shares reserved for future issuance under our employee benefit plans have been registered on a registration statement on Form S** - **8 under** ~~up agreements to sell shares prior to the expiration of the lock- up agreements at any time in their~~ -- **the** ~~sole discretion~~ **Securities Act** . ~~Sales of~~ **Accordingly,** these shares **can** ~~, or perceptions that they will~~ be **freely** sold ~~, could cause the trading price of our common stock to decline. After the lock- up agreements expire, these shares of common stock will be eligible for sale~~ in the public market **upon issuance** , ~~except that shares held by directors, executive officers and other affiliates will be~~ subject to volume limitations under Rule 144 ~~under the Securities Act of 1933, as amended (the Securities Act). In addition, as of December 31, 2023, 1, 683, 156 shares of common stock that are subject to outstanding options under our employee benefit plans will become eligible~~ for **our executive officers and directors and applicable** ~~sale in the public market to the extent permitted by the provisions of various~~ vesting **requirements** ~~schedules, the lock- up agreements and Rule 144 and Rule 701 under the Securities Act~~ . If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. ~~The holders of 19, 567, 306 shares of our outstanding common stock, or approximately 58. 4 % of our total outstanding common stock based on shares outstanding as of December 31, 2023, are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180- day lock- up agreements entered into in connection with our initial public offering. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders, or the registration of such shares, could have a material adverse effect on the trading price of our common stock.~~ We are an emerging growth company and a smaller reporting company, and the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors. We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the closing of our ~~recently completed~~ initial public offering **completed in January 2024** . However, if certain events occur prior to the end of such five- year period, including if we become a " large accelerated filer ", as defined under the Exchange Act, our annual gross revenues exceed $ 1. 235 billion or we issue more than $ 1. 0 billion of non- convertible debt in any three- year period, we will cease to be an emerging growth company prior to the end of such five- year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include: ● being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure in connection with registered securities offerings; ● not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes- Oxley Act; ● not being required to comply with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements, unless the SEC determines the new rules are necessary for protecting the public; ● reduced disclosure obligations regarding executive compensation; 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 have taken advantage of reduced reporting burdens in this Annual Report. In particular, in this Annual Report, we have provided only two years of audited financial statements and have not included all of the executive compensation ~~119related~~ --- **related** information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this exemption and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley Act. ~~We~~ **126We** 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 voting and non- voting common stock 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

voting and non- voting common stock held by non- affiliates is less than $ 700. 0 million measured on the last business day of our second fiscal quarter. Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a merger, acquisition, or other change in control of our company or changes in our board of directors that our stockholders might consider favorable, including transactions in which you might otherwise receive a premium for your shares. Some of these provisions include: ● a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; ● a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders; ● a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office; ● advance notice requirements for stockholder proposals and nominations for election to our board of directors; ● a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than 75 % of all outstanding shares of our voting stock then entitled to vote in the election of directors; ● a requirement of approval of not less than 75 % of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and ● the authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These anti- takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other ~~120stockholders~~ --- **stockholders** to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change in control transaction or changes in our board of directors could cause the market price of our common stock to decline. Our amended and restated certificate of incorporation designates certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our amended and restated certificate of incorporation provides that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action or proceeding asserting a claim of breach of ~~fiduciary~~ **127fiduciary** duty owed by any of our current or former directors, officers, employees or agents to us or our stockholders, (iii) any action or proceeding asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws (in each case, as they may be amended from time to time), (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws, (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware, or (vi) any action asserting a claim against us or any of our directors, officers or employees that is governed by the internal affairs doctrine; provided, however, that this exclusive forum provision does not apply to any action arising under the Exchange Act. Our amended and restated certificate of incorporation further provides that, unless we consent in writing to an alternative forum, the United States District Court for the Eastern District of Pennsylvania will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We have chosen the United States District Court for the Eastern District of Pennsylvania as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Newtown Square, Pennsylvania. In addition, our amended and restated certificate of incorporation provides that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We recognize that the forum selection clause in our amended and restated certificate of incorporation may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the State of Pennsylvania, as applicable. Additionally, the forum selection clause in our amended and restated certificate of incorporation may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Court of Chancery of the State of Delaware or the United States District Court for the Eastern District of Pennsylvania may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. Alternatively, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition. Because the applicability of the exclusive forum provision is limited to the extent permitted by applicable law, we do not intend that the exclusive forum provision would apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We also acknowledge that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder and that there is uncertainty as to whether a court would enforce an exclusive forum provision for actions arising under the Securities Act. General Risk FactorsOur disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within ~~121the~~ **the** time periods specified in the rules and ~~even if we are successful in remediating our material weaknesses,~~ any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. ~~We~~ **128We** 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 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 the establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd- Frank Wall Street Reform and Consumer Protection Act (Dodd- Frank Act) was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act concerning areas such as " say on pay " and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period, which may be up to five years from the pricing of our initial public offering in January 2024. Stockholder 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 an adverse effect on our business. The increased costs could 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. ~~We have identified material weaknesses in our internal control over financial reporting related to our control environment.~~ If we ~~do not remediate the material weaknesses in our internal control over financial reporting, or if we~~ fail to ~~establish and~~ maintain effective internal control over financial reporting, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock. Pursuant to Section 404 of the Sarbanes- Oxley Act, our management **is** ~~will be~~ required to report on the effectiveness of our internal control over financial reporting ~~beginning with the annual report for our fiscal year ending December 31, 2024~~. When we lose our status as an " emerging growth company " and do not otherwise qualify as a " smaller reporting company " with less than $ 100. 0 million in annual revenue, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, ~~122investors~~ --- **investors** may lose confidence in our financial reporting and the trading price of our common stock may decline. The identification of material weaknesses could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. The PCAOB has defined a material weakness as " 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 statements will not be prevented or detected on a timely basis. " ~~We~~ **Although we** determined that **our internal controls over financing reporting were effective as of December 31, 2024,** we ~~had~~ **may in the future identify internal control deficiencies that could rise to the level of a material weakness or uncover other errors in financial reporting. During the course of our evaluation of these** material weaknesses ~~relating~~ **, we may identify areas requiring improvement and may be required** to **design additional enhanced processes and controls to address issues identified through this review. There can be no assurance that such remediation efforts will be successful, that** our **129internal** control **over financial reporting will be** ~~environment, risk assessment and control activities. Specifically, we had insufficient accounting resources which resulted in the following ineffective~~ -- **effective as** ~~risk assessment activities: (~~ a ~~) We did~~ **result of these efforts or that any such future deficiencies identified may** not **be** ~~effectively design and implement controls related to the review and approval of manual journal entries. (b) We had ineffectively designed process- level controls associated with accounting for certain non- routine transactions. We are in the process of implementing our remediation plans with respect to the~~ material weaknesses **that would be required** ~~. We have increased the number of resources (internal and third- party) dedicated~~ to **be reported in future periods. In** ~~our accounting and finance team, including personnel with additional~~ -- **addition** ~~knowledge, experience, and training, to ensure we have~~

~~adequate staff, to segregate key duties, and to comply with company policies and procedures. We also plan to engage a third- party provider to help us assess and improve our internal controls in preparation for compliance with the Sarbanes- Oxley Act. Additionally, we are in the process of developing written policies and implementing process level and management review controls for our manual journal entries. However~~ , we cannot assure you that ~~we~~ **our independent registered public accounting firm** will be **able to attest** ~~successful in remediating the material weaknesses we identified or~~ that **such internal controls are effective when they are required to do so. If we fail to maintain effective disclosure controls and procedures** ~~our~~ **or** internal control over financial reporting ~~, as modified, will enable us to identify~~ or ~~avoid~~ **remediate any future** material weaknesses ~~, in the future. We cannot assure~~ you **may not** ~~that management will~~ be **able to rely on the integrity of** ~~successful in identifying and retaining appropriate personnel; that newly engaged staff or~~ **our** ~~outside consultants will be successful~~ **financial results, which could result** in **inaccurate or late reporting of** ~~identifying material weaknesses in the future; or~~ **our** ~~that appropriate personnel~~ **financial results, as** ~~will~~ **well** ~~be identified and retained prior~~ **as delays or the inability** to **meet our reporting obligations or to comply with the rules and regulations of the Securities and Exchange Commission. Any of** these ~~deficiencies~~ **events could** ~~resulting~~ --- **result** in ~~material~~ **delisting actions by the Nasdaq Stock Market, investigation** and **sanctions by regulatory authorities, and stockholder investigations and lawsuits, in addition to** ~~adverse~~ **adversely affecting** ~~effects on~~ our business ~~. Any failure to remediate the material weaknesses we identified or develop or to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to remediate the material weaknesses we identified or to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, investors may lose confidence in the accuracy~~ and ~~completeness of our financial reports,~~ the ~~market~~ **trading** price of our common stock ~~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~~ . We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. If we fail to comply with these laws, we could face civil or criminal liability and other serious consequences for violations, which could harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, and various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls and anti- corruption and anti- money laundering laws and regulations, including the FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. ~~123We~~ **We** may engage third parties for clinical trials outside of the United States, to sell our products abroad if and when 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. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences **. In February 2025, President Trump issued an executive order directing the DOJ to pause enforcement of the FCPA and to issue new enforcement guidelines that take into consideration U. S. national security and the competitiveness of U. S. companies abroad. It is unclear how this presidential directive may affect the biopharmaceutical industry as a whole or our business in particular** . Furthermore, U. S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U. S. sanctions. U. S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at future clinical trial sites within regions covered by such 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. These export and import controls and economic sanctions could also adversely affect our supply chain. Our third- party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time- consuming or costly. Our third- party manufacturers or suppliers use, and potential future collaborators will use, biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. The operations of our third- party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable ~~environmental~~ **130environmental** laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, our third- party manufacturers and suppliers cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of

contamination or injury at our manufacturers' or suppliers' sites, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our third- party manufacturers' and suppliers' storage or disposal of biologic, hazardous or radioactive materials. In addition, our third- party manufacturers and suppliers may need to incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time, which may increase the cost of their services to us. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities for our third- party manufacturers and suppliers, which could in turn materially adversely affect our business, financial condition, results of operations and prospects. To the extent we develop our own manufacturing operations in the future, we may similarly incur substantial costs to ensure compliance with these laws, and all the foregoing risks will further apply to us, as well. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations and the operations of our suppliers, CROs, CMOs and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self- insured. We rely on **, or expect to rely on,** third- party manufacturers or suppliers to produce ~~furmonertinib~~ **our current product candidates** and its components and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of our ~~124product~~ **product** candidate. Our ability to obtain clinical or, if approved, commercial, supplies of ~~furmonertinib~~ **our current product candidates** or any future product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. The global credit and financial markets have recently 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. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflicts in the Middle East and between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the ones in the Middle East and in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce, or terminate our product development

~~or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves, or on less favorable terms than we would otherwise choose. In addition, one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our clinical development goals on schedule and on budget. Uncertainty about global economic conditions could result in increased costs related to the manufacture of our product candidates and, if our drug candidates are approved and made available for sale, customers may postpone purchases of our drug candidates in response to tighter credit, unemployment, negative financial news and / or declines in income or asset values and other macroeconomic factors, which could have a material adverse effect on demand for our drug candidates. Changes in tax law may materially adversely affect our financial condition, results of operations and cash flows, or adversely impact the value of an investment in our common stock. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. We urge our investors to consult with their legal and tax advisors with respect to any changes in tax law and the potential tax consequences of investing in our common stock. If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, or if we fail to meet the expectations of one or more of these analysts, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline. 125~~