Risk Factors Comparison 2025-03-13 to 2024-03-05 Form: 10-K

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You should carefully consider the following risk factors, together with the other information contained in this annual report on Form 10- K, including our financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before making a decision to purchase or sell shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and growth prospects. If that were to happen, the trading price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations or financial condition. Summary Risk Factors The risk factors described below are a summary of the principal risk factors associated with an investment in us. These are not the only risks we face. You should carefully consider these risk factors, together with the risk factors set forth in this Item 1A. • We have a limited operating history, a history of losses and expect to incur additional losses in the future. • We will require substantial additional financing to achieve our goals. • We depend heavily on the ability to successfully advance seralutinib through clinical development. • Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. • Our business may be adversely affected by difficulties or delays in enrolling patients in our current or planned clinical trials or the commencement or completion, or termination or suspension, of our current or planned clinical trials. • We operate in a highly regulated industry and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize seralutinib. • We are dependent on third parties to conduct our pre- clinical and clinical trials. • Our business activities could be adversely affected by a global pandemic and other epidemic diseases. • We are dependent on third parties to manufacture seralutinib. • We may not be successful in entering into or maintaining collaborations, licenses and other similar arrangements **, including the maintenance of our collaboration with Chiesi** . • If approved, the success of seralutinib will depend on meeting ongoing regulatory obligations, market acceptance and adequate coverage by governmental authorities and insurers. • We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. • Our results of operations may fluctuate significantly. • Our business relies on our ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. • If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of seralutinib. • Our business relies on our ability to protect our intellectual property and our proprietary technologies. • We must comply with our license agreements or we could lose our license rights to seralutinib. • Our stock price is volatile, and investors may incur substantial losses. • We have been involved in securities class action litigation and could be subject in the future to securities class action litigation. Risks Related to Our Limited Operating History, Financial Position and Capital Requirements We have a **relatively** limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical- stage biopharmaceutical company with a **relatively** limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2017, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, identifying, acquiring and in- licensing product candidates and conducting preclinical studies and clinical trials. Seralutinib is in active clinical development. We have not yet demonstrated an ability to successfully complete any clinical trials beyond Phase 2, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products. We have incurred significant operating losses since our inception. If seralutinib is not successfully developed and approved, we may never generate any revenue. Our net losses were $ **56. 5 million and $** 179. 8 ~~million and $ 229. 4~~ 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 $ 1, ~~212~~ **268** . ~~0~~ **6** million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Seralutinib 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 seralutinib and seek to identify, assess, acquire, in- license or develop additional product candidates. To become and remain profitable, we must succeed in developing 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 and preclinical studies of seralutinib, obtaining regulatory approval for seralutinib and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are 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 would depress 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 beyond seralutinib or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment. We will require substantial additional financing to achieve 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 seralutinib development program, commercialization efforts or other operations. The development of biopharmaceutical product candidates is capital- intensive. We expect our expenses to remain high in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials of seralutinib, continue research and development, and seek regulatory approval for seralutinib. In addition, as seralutinib progresses through development and toward commercialization, we will need to make milestone payments to Pulmokine from whom we have in- licensed seralutinib. Furthermore, if and to the extent we seek to acquire or in- license additional product candidates in the future, we may be required to make significant upfront payments, milestone payments, and / or licensing payments. If we obtain regulatory approval for seralutinib, 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 reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of seralutinib. 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. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operations for at least the next 12 months from the date this annual report is filed with the SEC. In particular, we expect that these funds will allow us to ~~continue~~ **complete** our registrational Phase 3 clinical trial in PAH for seralutinib. 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, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. 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 ~~. For example, in July 2020, we, and certain of our subsidiaries, as borrowers, amended our credit, guaranty and security agreement, or the Credit Facility, with MidCap Financial Trust, or MidCap, an agent and as a lender, and the additional lenders party thereto from time to time, or together with MidCap, the Lenders, pursuant to which the Lenders, including affiliates of MidCap and Silicon Valley Bank agreed to make a $ 30. 0 million term loan that was funded in May 2019~~ . Attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop seralutinib. Our future capital requirements will depend on many factors, including: • the type, number, scope, progress, expansions, results, costs and timing of, our clinical trials and preclinical studies of seralutinib or product candidates we may choose to pursue in the future; • the costs and timing of manufacturing for seralutinib, including commercial manufacturing if seralutinib is approved; • the costs, timing and outcome of regulatory review of seralutinib; • the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights; • our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting; • the costs associated with hiring additional personnel and consultants as our clinical activities increase; • the timing and amount of the milestone or other payments we must make to Pulmokine from whom we have in- licensed seralutinib; • the costs and timing of establishing or securing sales and marketing capabilities if seralutinib is approved; • our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third- party payors and adequate market share and revenue for seralutinib, if approved; • 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 preclinical studies 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 achieve product sales. In addition, seralutinib, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that 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, including as a result of financial and credit market deterioration or instability, market- wide liquidity shortages, geopolitical events or otherwise. In addition, we may seek additional capital due to favorable market conditions or liquidity or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. ~~The terms of our Credit Facility place restrictions on our operating and financial flexibility. On May 2, 2019, we entered into the Credit Facility, as further amended on September 18, 2019, July 2, 2020 and December 7, 2022. The outstanding principal balance under the credit facility was $ 12. 6 million as of December 31, 2023. The Credit Facility includes affirmative and negative covenants applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage, maintain property, pay taxes, satisfy certain requirements regarding accounts and comply with laws and regulations. The negative covenants include, among others, restrictions on transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, amending material agreements and organizational documents, selling assets and suffering a change in control, in each case subject to certain exceptions. The Credit Facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 3. 0 % and would provide MidCap, as agent, with the right to exercise remedies against us,~~

~~and the collateral securing the Credit Facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the Credit Facility, our insolvency or the occurrence of insolvency events, the occurrence of a change in control, the occurrence of certain FDA and regulatory events, our failure to remain registered with the SEC and listed for trading on Nasdaq, the occurrence of a material adverse change, the occurrence of a default under a material agreement reasonably expected to result in a material adverse change, the occurrence of certain defaults under certain other indebtedness in an amount greater than $ 2. 5 million and the occurrence of certain defaults under subordinated indebtedness and convertible indebtedness. The occurrence of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.~~ Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under the notes. As of December 31, ~~2023~~ **2024**, we have sold $ 200. 0 million **in** aggregate principal amount **of** 5. 00 % convertible senior notes due 2027 ~~,~~ and **have** ~~, excluding intercompany indebtedness, we, including our subsidiaries, had~~ approximately $ ~~52~~ **88**. ~~6~~ **3** million of ~~additional indebtedness and~~ other liabilities, including trade payables ~~, of which approximately $ 12. 4 million was secured indebtedness under our Credit Facility~~. We may also incur additional indebtedness **or liabilities** to meet **our** future financing needs. Our indebtedness **and liabilities** could have significant negative consequences for our stockholders and our business, results of operations and financial condition by, among other things: • increasing our vulnerability to adverse economic and industry conditions; • limiting our ability to obtain additional financing; • requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes; • limiting our flexibility to plan for, or react to, changes in our business; • making it more difficult or expensive for a third party to acquire us; • diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the notes; and • placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital. Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the notes, and our cash needs may increase in the future. In addition, ~~our existing Credit Facility contains, and~~ any future indebtedness that we may incur may contain, financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or seralutinib. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings or other capital sources ~~, such as our Credit Facility,~~ including potentially collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. 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. If we raise funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams or grant licenses on terms that may not be favorable to us and / or that may reduce the value of our common stock. Risks Related to the ~~Discovery,~~ Development and Regulatory Approval of Seralutinib We depend ~~heavily~~ **entirely** on the success of seralutinib, which is currently in Phase 3 clinical development. If we are unable to advance seralutinib in clinical development, obtain regulatory approval and ultimately commercialize seralutinib, or experience significant delays in doing so, our business will be materially harmed. Our only product candidate is currently in Phase 3 clinical development. We are conducting an open- label extension of our Phase 2 clinical trial of seralutinib in PAH which commenced in 2020, and we commenced a registrational Phase 3 clinical trial of seralutinib in PAH in the fourth quarter of 2023. **We expect to activate clinical sites for a global registrational Phase 3 for the treatment of PH- ILD in the second half of 2025.** Our assumptions about why seralutinib is worthy of future development and potential approval in PAH, or any **additional** indications **including PH- ILD**, are based in part on data collected by other companies. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of seralutinib. The success of seralutinib will depend on several factors, including the following: • successful enrollment in clinical trials and completion of clinical trials and preclinical studies with favorable results; • regulatory authority acceptance of our proposed design of future clinical trials and allowance to proceed with such clinical trials under INDs by the FDA or under similar applications by comparable regulatory authorities; • demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities; • receipt of marketing approvals from applicable regulatory authorities, including ~~new drug applications, or~~ NDAs ~~,~~ from the FDA and maintaining such approvals; • making arrangements with our third- party manufacturers for, or establishing, commercial manufacturing capabilities; • establishing sales, marketing and distribution capabilities and launching commercial sales of seralutinib, if and when approved, whether alone or in collaboration with others; • establishment and

maintenance of patent and trade secret protection or regulatory exclusivity for seralutinib; • maintaining an acceptable safety profile of seralutinib following any approval; and • maintaining and growing an organization of people who can develop seralutinib and our technology. Seralutinib is subject to regulation as **a** combination product, which means that it is composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. Seralutinib, will therefore require review and coordination by FDA' s drug and device centers prior to approval, which may delay approval. Under FDA regulations, combination products are subject to current good manufacturing practice, or cGMP, requirements applicable to both drugs and devices, including the Quality System regulation currently applicable to medical devices in the United States. The EU regulates medical devices and medicinal products separately, through different legislative instruments, and the applicable requirements will vary depending on the type of drug- device combination product. Problems associated with the device component of seralutinib may delay or prevent approval. If the manufacturer of the device products make modifications, or if we elect to change a device component or develop our own proprietary device component, we will need to perform validation testing and obtain FDA and other regulatory authorization or certification prior to using the modified device component. If the FDA, any other regulatory authority or notified body fails to authorize or certify use of those modified devices in combination with seralutinib or take significant enforcement action against the manufacturer of the device component, we would not be able to market or may have to suspend marketing seralutinib in certain jurisdictions. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of seralutinib, which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for seralutinib in clinical trials or in obtaining marketing approval thereafter. Given our current stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a treatment sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize seralutinib, we may not be able to generate sufficient revenue to continue our business. Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. In addition, some of our assumptions about why seralutinib is worthy of future development and potential approval are based on data collected by other companies. Seralutinib may not have favorable results in its Phase 3 clinical trial in PAH **or the anticipated Phase 3 clinical trial in PH- ILD** , or receive regulatory approval on a timely basis, if at all. Clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, seralutinib may unexpectedly fail. The historical failure rate for product candidates in our industry is high. The results from preclinical studies or clinical trials of seralutinib or a competitor' s product candidate in the same class may not predict the results of later clinical trials of seralutinib, 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. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. For example, our decision to advance seralutinib as a potential treatment for PAH is based in part on the efficacy of imatinib (Gleevec), a tyrosine kinase inhibitor with known activity against PDGF and marketed for oncology indications, observed by Novartis in a Phase 3 clinical trial; however, we may not observe similar efficacy in our Phase 3 clinical trial of seralutinib. Moreover, these and any future preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and preclinical studies 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 seralutinib in PAH and other indications **including PH- ILD** , which could have a material adverse effect on our business, financial condition and results of operations. Any difficulties or delays in the commencement or completion, or termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before obtaining marketing approval from regulatory authorities for the sale of seralutinib, we must conduct extensive clinical studies to demonstrate the safety and efficacy of seralutinib in humans. For example, we are currently conducting a registrational Phase 3 clinical trial of seralutinib in PAH patients. In addition, before we can initiate clinical development for our product candidates, and in some cases, before we can pursue clinical development of a product candidate for a new potential indication, we must submit the results of preclinical studies to the FDA along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND, and we are also required to submit regulatory filings to foreign regulatory authorities for clinical trials outside of the United States. We do not know whether our **ongoing or** planned trials will begin on time or be completed on schedule, if at all. The commencement **, data readouts** and completion of clinical trials can be delayed for a number of reasons including delays related to: • the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies, including the doses and endpoints of our **ongoing and planned** Phase 3 clinical trial of seralutinib; • obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design; • any failure or delay in reaching an agreement with contract research organizations, or 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; • obtaining approval or positive opinion from one or more institutional review boards, or IRBs or ethics committees; • IRBs refusing to approve, suspending or terminating a trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of a trial; • changes to

clinical trial protocol; • clinical sites deviating from trial protocol or dropping out of a trial; • manufacturing sufficient quantities of seralutinib or obtaining sufficient quantities of combination therapies for use in 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; • subjects choosing an alternative treatment for PAH or other indications **including PH- ILD** for which we are developing seralutinib, or participating in competing clinical trials; • lack of adequate funding to continue a clinical trial; • subjects experiencing severe or unexpected drug- related adverse effects; • occurrence of serious adverse events in trials of the same class of agents conducted by other companies; • selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data; • a facility manufacturing seralutinib or any of its components, including the device component of orally inhaled seralutinib, being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP or similar foreign regulations or other applicable requirements, or infections or cross- contaminations of seralutinib in the manufacturing process; • any changes to our manufacturing process that may be necessary or desired; • third- party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements; third- party contractors not performing data collection or analysis in a timely or accurate manner; or • third- party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications. Such delays or regulatory feedback on our trial designs could also significantly increase the costs of our clinical trials, including our Phase 3 clinical trial of seralutinib. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials 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 regulatory requirements or our clinical 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, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial. In addition, the FDA' s and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application concerned for multi- center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state' s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR ~~foresees a three- year~~ transition period **ended on** ~~. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to~~ January 31, ~~2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31,~~ 2025 ~~. After this date~~ , **and** all clinical trials (~~including those which~~ **and related applications)** are **now fully** ~~ongoing) will become~~ subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third- party service providers, such as contract research organizations, or CROs, may impact our developments plans. It is currently unclear to what extent UK will seek to align its regulations with the EU. The UK ~~,~~ regulatory framework in relation to clinical trials is derived from ~~existing~~ **the now-repealed** EU ~~legislation~~ **Clinical Trials Directive** (as implemented into UK law, through ~~secondary legislation~~ **the Medicines for Human Use (Clinical Trials**) **Regulations 2004** ~~. On January 17~~ , ~~2022,~~ **as amended). The extent to which** the ~~UK MHRA launched an eight- week consultation on reframing the UK legislation~~ **regulation** ~~for~~ **of** clinical trials ~~. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement~~ in ~~clinical trials. The outcome of~~ the **UK** ~~consultation is being closely watched and~~ will **mirror** ~~determine whether the UK chooses to align with~~ the (EU) CTR **in the long term is not yet certain, however, on December 12, 2024, the UK government introduced a legislative proposal- the Medicines** ~~or~~ **for** ~~diverge from~~ **Human Use (Clinical Trials) Amendment Regulations 2024- that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make** it **easier** to ~~maintain regulatory flexibility~~ **conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. The UK government has provided the legislative proposal to the UK Parliament for its review and approval. Once the legislative proposal is approved (with or without amendment), it will be adopted into UK law which is expected in early 2026** . Under the terms of the Protocol on Ireland / Northern Ireland, provisions of the (EU) CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products apply in Northern Ireland. A decision by the UK ~~Government~~ **government** not to closely align its regulations with the new approach that has been adopted in the EU may have

an effect on the cost of conducting clinical trials in the UK as opposed to other countries. Clinical trial submissions in the UK will not be able to be bundled with those of EU member states within the EMA CTIS, adding further complexity, cost and potential risk to future clinical and development activity in the UK ~~. Significant political and economic uncertainty remains about how much the relationship between the UK and EU will differ as a result of the UK' s withdrawal~~ . If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted. Further, conducting clinical trials in foreign countries, as we currently and may continue to do for seralutinib, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks, including war, relevant to such foreign countries. For example, we are currently conducting our registrational Phase 3 study of seralutinib in PAH at sites outside the United States. If we experience delays in the completion of, or termination of, any clinical trial of seralutinib, the commercial prospects of seralutinib will be harmed, and our ability to generate product revenues from seralutinib will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down development and approval process for seralutinib and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of seralutinib. We may make formulation or manufacturing changes to seralutinib, in which case we may need to conduct additional preclinical studies to bridge our modified seralutinib to an earlier version. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize seralutinib and our competitors may be able to bring products to market before we do, and the commercial viability of seralutinib could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly. We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We may not be able to initiate or continue clinical trials for seralutinib if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as may be required by the FDA or similar regulatory authorities outside the United States. Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators and associated staff with the appropriate competencies and experience, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating as well as any drugs under development. We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials. Potential subjects for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. For example, a limited number of patients are affected by PAH **and other indications including PH- ILD** , which ~~is~~ **are** our target indication for seralutinib, and we have encountered difficulties enrolling patients in our previous clinical trials of seralutinib in PAH patients. We also may encounter difficulties in identifying and enrolling subjects with a stage of disease appropriate for our Phase 3 trial of seralutinib and monitoring such subjects adequately during and after treatment. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding and diagnosing subjects may prove costly. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow- up periods. The eligibility criteria of our clinical trials, once established, will further limit the pool of available trial participants. For example, PAH is a rare disease with limited patient pools from which to draw for our registrational Phase 3 trial. If patients are unwilling to participate in our trials for any reason, including the existence of concurrent clinical trials for similar patient populations in PAH, if they are unwilling to enroll in a clinical trial with a placebo- controlled design or the availability of approved therapies, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of seralutinib may be delayed. Our inability to enroll a sufficient number of subjects for our Phase 3 trial of seralutinib or any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance. We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines. Use of seralutinib could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon seralutinib, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, results of operations and financial condition. As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with seralutinib' s use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by seralutinib could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, based upon the benefit / risk profile and in response to serious adverse events observed, we decided to terminate the Phase 1b / 2 study for GB5121. Drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Moreover, if

seralutinib is associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon its development or limit its development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective, which may limit the commercial expectations for seralutinib if approved. We may also be required to modify our study plans based on findings in our ongoing clinical trials. For example, although we believe seralutinib has been generally well tolerated in completed clinical trials, future clinical trials, including our Phase 3 trial of seralutinib in PAH patients may reveal adverse events inconsistent with the safety findings observed to date. For example, in 2013, results from a Phase 3 clinical trial in PAH of imatinib (Gleevec) showed statistically significant improvement in its primary efficacy endpoint, but systemic toxicities were also observed. Although we have not observed the systemic toxicities associated with imatinib, we cannot be certain that seralutinib will not exhibit similar or other toxicities in a larger Phase 3 clinical trial. Many compounds that initially showed promise in early- stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations. It is possible that as we test seralutinib in our Phase 3 trial in PAH, or as the use of seralutinib becomes more widespread if it receives regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly. In addition, if seralutinib receives marketing approval, and we or others later identify undesirable side effects caused by seralutinib, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw, suspend or limit approvals of seralutinib; • we may be required to recall a product or change the way seralutinib 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 implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients, or similar risk management measures; • we may be required to change the way seralutinib is distributed or administered, conduct additional clinical trials or change the labeling of seralutinib or be required to conduct additional post- marketing studies or surveillance; • we could be sued and held liable for harm caused to patients; • sales of seralutinib may decrease significantly or seralutinib could become less competitive; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of seralutinib, if approved, and could significantly harm our business, results of operations and prospects. Although we have completed Phase 2 clinical trials for multiple product candidates including seralutinib, we have not , as an organization , completed later- stage clinical trials or submitted an NDA, and we may be unable to do so for seralutinib. We will need to successfully complete a pivotal clinical trial in order to obtain FDA or comparable foreign regulatory approval to market seralutinib. Carrying out later- stage clinical trials and the submission of a successful NDA or other comparable foreign regulatory submission is a complicated process. As an organization, we have completed four Phase 2 clinical trials, including a Phase 2 clinical trial of seralutinib, and are conducting a Phase 3 clinical trial of seralutinib in PAH. We have not yet completed any pivotal clinical trials for seralutinib or previous product candidates. We also have limited experience as a company in preparing, submitting marketing applications and have not previously submitted an NDA or other comparable foreign application for any product candidate. We may also conduct a number of clinical trials for seralutinib in parallel over the next several years, which may be a difficult process to manage with our limited resources and which may divert the attention of management. In addition, we have had limited interactions with the FDA and cannot be certain our Phase 3 clinical trial of seralutinib will be sufficient to support an NDA submission, even if we believe the results are sufficiently positive. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of seralutinib. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of seralutinib. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs or other comparable foreign regulatory submissions for and commercializing seralutinib. Seralutinib is subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize seralutinib. The clinical development, manufacturing, labeling, storage, record- keeping, advertising, promotion, import, export, marketing and distribution of seralutinib are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market seralutinib in foreign jurisdictions until we receive regulatory approval from the FDA and similarly, we are not permitted to market seralutinib until we receive foreign regulatory authorities' approval. The process of obtaining 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 foreign regulatory authorities have substantial discretion in the drug 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 is never guaranteed. Prior to obtaining approval to commercialize seralutinib 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 seralutinib is safe and effective for its intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for seralutinib are promising, such data may not be sufficient to support approval by 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 studies or clinical trials for seralutinib either prior to or post- approval, or may object to elements of our clinical development program. The FDA or comparable foreign regulatory authorities could delay, limit or deny approval of seralutinib for many reasons, including: • such authorities may

disagree with the design or implementation 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 seralutinib; • 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 which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States; • we may be unable to demonstrate that seralutinib' 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 seralutinib 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 regarding the formulation, labeling and / or the specifications of seralutinib; • approval may be granted only for indications that are significantly more limited than what we apply for and / or with other significant restrictions on distribution and use; • such authorities may find deficiencies in the manufacturing processes or facilities of our third- party manufacturers with which we contract for clinical and commercial supplies; or the approval policies; • regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; 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. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing seralutinib. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market seralutinib, which would significantly harm our business, financial condition, results of operations and prospects. Even if we eventually complete clinical trials and receive approval of an NDA or foreign marketing application for seralutinib, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and / or the implementation of a REMS or similar risk management measures, which may be required to ensure safe use of the drug after approval. The FDA or the comparable foreign regulatory authority also may approve seralutinib for a more limited indication or patient population than we originally requested, and the FDA or comparable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of seralutinib and would materially adversely impact our business and prospects. We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, 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 may in the future seek an accelerated approval for seralutinib. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life- threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that seralutinib has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. 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 morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor' s agreement to conduct, in a diligent manner, confirmatory studies to verity and describe the drug' s predicted clinical benefit. If such confirmatory studies fail to verify the drug' s predicted clinical benefit or of the sponsor fails to conduct such studies in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, ~~in December 2022, President Biden signed an omnibus appropriations bill to fund the U. S. government through fiscal year 2023. Included in the omnibus bill is~~ the Food and Drug Omnibus Reform Act of 2022, ~~which~~ among other things, provided FDA ~~new~~ statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted. If we decide to submit an application seeking accelerated approval, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for seralutinib would result in a longer time period to commercialization of seralutinib, if any, could increase the cost of development of seralutinib and could harm our competitive

position in the marketplace. Moreover, in the EU, a " conditional " marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a " standard " marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed. Furthermore, marketing authorizations may also be granted " under exceptional circumstances " when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to the introduction of specific procedures. This may arise when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This type of marketing authorization is close to a conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike a conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although a marketing authorization " under exceptional circumstances " is granted definitively, the risk- benefit balance of the medicinal product is reviewed annually, and the marketing authorization may be withdrawn where the risk- benefit ratio is no longer favorable. We may not be able to obtain or maintain orphan drug designations for seralutinib, and we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity. Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals in the United States, or a patient population of greater than 200, 000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EC grants orphan designation based on the EMA' s Committee for Orphan Medicinal Products' opinion to promote the development of products (1) that are intended for the diagnosis, prevention or treatment that is life- threatening or chronically debilitating, and (2) either (a) such condition affects no more than five in 10, 000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the EU to justify the necessary investment, and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. We have received orphan drug designation in the United States and the EU for seralutinib for treatment of PAH and may seek additional orphan designations for seralutinib in the future. There can be no assurance that we will be able to maintain or obtain such designations. In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user- fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. Upon grant of a marketing authorization in the EU, orphan medicinal products are entitled to ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. This period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the orphan designation criteria, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same condition if such regulatory authority concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. We are currently conducting, and may in the future conduct, certain of our clinical trials for seralutinib outside of the United States. 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. We are currently conducting, and may in the future conduct, one or more of our clinical trials for seralutinib outside the United States. 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, for such clinical trials not subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data

from trials conducted outside of the U. S. or the applicable jurisdiction. 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 seralutinib not receiving approval for commercialization in the applicable jurisdiction. Conducting clinical trials outside the United States 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; • cultural differences in medical practice and clinical research; • diminished protection of intellectual property in some countries; and • interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism. Interim, topline and preliminary data from our clinical trials 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 or cause us not to proceed into further clinical development. From time to time, we may publicly disclose preliminary or topline or data from our clinical 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. 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 preliminary or topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between topline, preliminary or interim data and final data could significantly harm our business prospects. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of seralutinib, the approvability or commercialization of seralutinib and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding seralutinib or our business. If the topline, preliminary or interim 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, seralutinib may be harmed, which could harm our business, results of operations, prospects or financial condition. Disruptions at the FDA and other government agencies caused by funding shortages **, staffing limitations** 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, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA and foreign regulatory authorities to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies ~~, such as the EMA following its relocation to Amsterdam and resulting staff changes,~~ may also slow the time necessary for new drugs or modifications to ~~cleared or~~ approved drugs and biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, **in recent** ~~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 FDA employees and stop critical activities. Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. ~~Even though the FDA has since resumed standard inspection operations any resurgence of the virus or emergence of new variants may lead to inspectional or administrative delays.~~ If a prolonged government shutdown occurs, or if **staffing or funding shortages or renewed** global health concerns 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. Our business is subject to risks arising from pandemic and epidemic diseases ~~. The COVID- 19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, clinical trial subjects, physicians and other healthcare providers, communities and business operations, as well as the United States and global economies, financial markets, labor markets and supply chains~~ . Any future pandemic or epidemic disease outbreaks, and any supply chain disruptions or staffing shortages, could disrupt the manufacture or shipment of supplies of seralutinib for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing or timely advancing research and development activities, impede our clinical trial initiation and recruitment and the ability of subjects to continue in clinical trials, impact the results of the clinical trial based on participants contracting the disease or otherwise increasing the number of observed adverse events, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any future pandemic or future epidemic disease outbreaks could also potentially further affect the business of the FDA or other regulatory authorities, which could result in delays in meetings related to planned clinical trials or other regulatory matters. Risks Related

to Our Reliance on Third Parties We rely on third parties to conduct many of our **clinical trials and** preclinical studies ~~and clinical trials~~ . Any failure by a third party to conduct the clinical trials according to GCPs and other requirements and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize seralutinib. We are dependent on third parties to conduct our clinical trials and preclinical studies, including our ongoing ~~or~~ **and** potential future clinical trials for seralutinib. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we 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 our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for seralutinib. Regulatory authorities enforce these 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 GCPs, 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 clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP or similar regulations. Our 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 such CROs, investigators or other third parties will devote adequate time and resources to such trials 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 performs 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 drug development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may 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 or foreign regulatory authorities conclude 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 of any NDA or similar foreign applications we submit by the FDA or foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing seralutinib. If any of our relationships with these third parties terminate or their services are delayed, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical and preclinical development timelines. Though we 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 rely on third parties for the manufacture of seralutinib for clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of seralutinib or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of seralutinib and related raw materials for clinical and preclinical development, as well as for commercial manufacture if seralutinib receives marketing approval. The facilities used by third- party manufacturers to manufacture seralutinib must be approved by the FDA or foreign regulatory authorities for the manufacture of seralutinib pursuant to inspections that will be conducted after we submit an NDA to the FDA or similar applications to foreign regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, third- party manufacturers for compliance with cGMP or similar requirements for manufacture of drug products. If these third- party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, including requirements related to the manufacturing of high potency compounds, 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 a comparable foreign regulatory authority does not approve these facilities for the manufacture of seralutinib 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 seralutinib, if approved. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of seralutinib, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of seralutinib. Our or a third party' s failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and comply with cGMP or similar requirements outside of the United States could adversely affect our business in a number of ways, including: • an inability to initiate or continue clinical trials of seralutinib, or any future product candidates under development; • delay in submitting regulatory applications, or receiving marketing approvals, for seralutinib; • subjecting third- party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities; • requirements to cease development or to recall batches of seralutinib; and • in the event of approval to market and commercialize seralutinib, an inability to meet

commercial demands for seralutinib. In addition, we do not have long- term commitments or supply agreements with all of our third- party manufacturers. We may be unable to establish any supply agreements with third- party manufacturers or to do so on acceptable terms, which increases the risk of timely obtaining sufficient quantities of seralutinib 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 seralutinib according to our specifications; • failure to manufacture seralutinib according to our schedule or at all; • misappropriation of our proprietary information, including our 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. Seralutinib and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP or similar foreign regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, 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 seralutinib. Further, our third- party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments, or public health epidemics. If our current 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. Our current and anticipated future dependence upon others for the manufacture of seralutinib may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. ~~Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we currently rely on other third parties to manufacture seralutinib and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them.~~ We **have entered** ~~seek to protect our proprietary technology, in part, by entering~~ into ~~confidentiality agreements~~, ~~consulting agreements or~~ **and may in** ~~other~~ -- **the future** similar agreements with our advisors, employees..... of operations and prospects. We may seek to enter into **,** collaborations, licenses and other similar arrangements and ~~may not be successful in doing so, and even if we are,~~ we may not realize the benefits of such relationships ~~.~~ ~~We are currently seeking~~ **, or may not be successful in entering into such relationships On May 3, 2024, we entered into the collaboration agreement with Chiesi for the development and commercialization of seralutinib around the world, and we may in the future seek** to enter into **other** collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize such product candidates or manufacturing constraints. **For additional information regarding our collaboration with Chiesi, see the section titled " Business — License and Collaboration Agreements " included in this Form 10- K.** We may not be successful in our efforts to establish or maintain ~~such~~ collaborations **, including our collaboration with Chiesi,** because 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. Further, **in connection with any such collaborations,** we may have to relinquish valuable rights to our future revenue streams, or grant licenses ~~on terms~~ 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 potential collaborators. We cannot be certain that, following ~~a~~ **the entry into our collaboration with Chiesi or any other** strategic transaction or license, we will achieve an economic benefit that justifies such transaction. **If** ~~Even if~~ we are successful in our efforts to establish ~~such~~ **any additional** collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of seralutinib is delayed, the safety of seralutinib is questioned or sales of seralutinib, if approved, are unsatisfactory. In addition, **our collaboration with Chiesi and** any potential future collaborations may be terminable by **Chiesi** ~~our~~ - **or our other** strategic partners **in certain circumstances** , and we may not be able to adequately protect our rights under these agreements. Furthermore, **our** strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of seralutinib **. For example** , ~~if approved~~ **under the Chiesi collaboration** , **Chiesi received such rights** and may not conduct ~~those~~ **development and commercialization** activities in the same manner as we do. Any termination of **the collaboration with Chiesi or of any other** collaborations we enter into in the future, or any delay in entering into collaborations related to seralutinib, could delay the development and commercialization of seralutinib and reduce its competitiveness if it reaches the market, which could have a material adverse effect on our business, financial condition and results of operations ~~consulting agreements or other~~ similar agreements with our 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.Despite the contractual provisions employed when working with third parties,the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors,are 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 trade secrets and despite our efforts to protect our trade secrets,a competitor' s discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business,financial condition,results of operations and **prospects.We may** . Risks Related to Commercialization of Seralutinib Even if we receive regulatory approval for seralutinib, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, seralutinib, 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 seralutinib, when and if it is approved. Following potential approval of seralutinib, the FDA or foreign regulatory authorities may impose significant restrictions on its indicated uses or marketing or impose ongoing requirements for potentially costly and time- consuming post- approval studies, post- market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA or foreign regulatory authorities may also require a REMS or similar risk management measures as a condition of approval of seralutinib, which could include requirements for a medication guide, physician 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 seralutinib, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for seralutinib will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMPs or similar requirements and GCP requirements for any clinical trials that we conduct post- approval. Later discovery of previously unknown problems with seralutinib, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: • restrictions on the marketing or manufacturing of seralutinib, withdrawal of seralutinib 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; • fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials; • refusal by the FDA or foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals; • product seizure or detention, or refusal to permit the import or export of seralutinib; and • injunctions or the imposition of civil or criminal penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize seralutinib and generate revenue and 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 enacted that could prevent, limit or delay regulatory approval of seralutinib. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission' s proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before 2026. The revisions may however have a significant impact on the biopharmaceutical industry in the long term. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States 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 commercial success of seralutinib will depend upon the degree of its market acceptance by physicians, patients, healthcare payors and others in the medical community. Seralutinib may not be commercially successful. Even if seralutinib receives regulatory approval, it may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The commercial success of seralutinib will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree of market acceptance of seralutinib will depend on a number of factors, including: • demonstration of clinical efficacy and safety compared to other more- established products; • the indications for which seralutinib is approved; • the limitation of our targeted patient population and other limitations or warnings contained in any FDA- or foreign regulatory authorities- approved labeling; • acceptance of a new drug for the relevant indication by healthcare providers and their patients; • the pricing and cost- effectiveness of seralutinib, as well as the cost of treatment with seralutinib in relation to alternative treatments and therapies; • 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 seralutinib in the absence of sufficient third- party coverage and adequate reimbursement; • any restrictions on the use of seralutinib, and the prevalence and severity of any adverse effects; • potential product liability claims; • the timing of market introduction of seralutinib as well as competitive drugs; • the effectiveness of our or any of our potential future collaborators' sales and marketing strategies; and • unfavorable publicity relating to seralutinib. If seralutinib is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from seralutinib and may not become or remain profitable. Our efforts to educate the medical community and third- party payors regarding the benefits of seralutinib may require significant resources and may never be successful. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we are found or alleged to have improperly promoted off- label uses, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, as seralutinib would be, if approved. 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. If we are found to have promoted such off- label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of seralutinib, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. The successful commercialization of seralutinib, 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 seralutinib could limit our ability to market seralutinib 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 seralutinib, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for seralutinib by third- party payors will have an effect on our ability to successfully commercialize seralutinib. Even if we obtain coverage for seralutinib by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for seralutinib, and any reimbursement that may become available may be decreased or eliminated in the future. Third- party payors increasingly are challenging prices charged for pharmaceutical 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. It is possible that a third- party payor may consider seralutinib as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with seralutinib, pricing of existing drugs may limit the amount we will be able to charge for seralutinib. These payors may deny or revoke the reimbursement status of seralutinib 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 reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize seralutinib and may not be able to obtain a satisfactory financial return on seralutinib. 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 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 devices or drug therapies 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 seralutinib. 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 seralutinib 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, in some cases at short notice, and we believe that changes in these rules and regulations are likely. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of products. 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 seralutinib. Accordingly, in markets outside the United States, the reimbursement for seralutinib 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 seralutinib. We expect to experience pricing pressures in connection with the sale of seralutinib 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, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize seralutinib may be adversely affected. The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with seralutinib. Seralutinib, if approved, will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In particular, there is intense competition in the fields of PAH and other ~~pulmonary~~ **PH** indications **including PH- ILD** . 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 the indications we are targeting and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which 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 new product candidates. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. We expect to face competition for seralutinib from existing products and products in development. Seralutinib is a PDGFR, CSF1R and c- KIT inhibitor initially targeted for PAH and PH- ILD patients. We expect competition within the PAH indication will include prostanoids / prostacyclin receptor agonists, including Orenitram (United Therapeutics), Uptravi (Janssen), Tyvaso (United Therapeutics), and Remodulin (United

Therapeutics) **, and activin ligand traps, including Winrevair (Merck)** . We also may face some competition from products used in **Functional** ~~class~~ **Class** I and II patients, such as the oral PDE5 inhibitors, including Revatio (Pfizer Inc.) and Adcirca (United Therapeutics); the sGC stimulator Adempas (Bayer AG); and oral ERAs, including Tracleer (Janssen), Letairis (Gilead Sciences, Inc.) and Opsumit (Janssen) **; and combination PDE5 inhibitor / ERA therapies, such as Opsynvi (Janssen)** . We believe that, if approved, seralutinib could be used alongside all ~~three~~ classes of approved therapies. PAH is also an active indication for investigational drugs, and we may face competition in the future from CS1 (Cereno Scientific), ~~KER- 012 (Keros Therapeutics, Inc.),~~ L606 (**Liquidia /** Pharmosa Biopharm Inc.), **treprostinil palmitil** ~~MK- 5475~~ (**Insmed** ~~Merck & Co., Inc.~~), ralinepag (~~Pfizer and~~ United Therapeutics) **,** and ~~sotatercept~~ **REGN13335** (~~Merck~~ **Regeneron Pharmaceuticals, Inc.**). Additionally, although not approved for the treatment of PAH, we may face competition from formulations of imatinib **, including the one** in development ~~for the treatment of PAH, including those~~ from ~~Acrami~~ **Tenax** Therapeutics ~~, Acrovate Therapeutics~~ and ~~Tenax~~ **Inhibikase** Therapeutics. We expect to face competition from Tyvaso (United Therapeutics) within the PH- ILD indication, as it is the only approved therapy for PH- ILD in the ~~US~~ **United States** . There are no approved therapies for PH- ILD in the EU. PH- ILD is also an active indication for investigational drugs, and we may face competition in the future from L606 (**Liquidia /** Pharmosa Biopharm Inc ~~.), MD- 711 (Mochida Pharmaceutical Co., Ltd~~ .), sirolimus (OrphAI Therapeutics) ~~and~~ **,** treprostinil palmitil (Insmed, Inc.) ~~. Additionally~~ , **MK** ~~although not approved for the treatment of PH - ILD 5475 (Merck)~~ , ~~we may face competition from formulations of imatinib, including those from Acrami Therapeutics, Acrovate Therapeutics~~ and ~~Tenax Therapeutics~~ **mosliciguat (Pulmovant, Inc.)** . There may be other earlier stage clinical programs that, if approved, would compete with seralutinib. Many of our competitors have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy. If the market opportunities for seralutinib are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. The precise incidence and prevalence for all the conditions we aim to address with seralutinib are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with seralutinib, are based on our beliefs and 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 diseases. The total addressable market of seralutinib will ultimately depend upon, among other things, the diagnosis criteria included in the final label for seralutinib, the availability of alternative treatments and the safety, convenience, cost and efficacy of seralutinib 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 seralutinib or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for seralutinib, because our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share. We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have 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 seralutinib, we may not be able to generate product revenue. ~~We~~ **Although we have started to build a commercial infrastructure, we** have no **formal** internal sales, marketing or distribution capabilities, nor have we commercialized a product. If seralutinib ultimately receives regulatory approval, we **, in collaboration with Chiesi,** must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize seralutinib in ~~major markets~~ **the United States** , which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of seralutinib. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute seralutinib. 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 seralutinib effectively. If we are not successful in commercializing seralutinib, either on our own **in partnership with Chiesi** or through arrangements with one or more third parties, we may not be able to generate any future product revenue, and we would incur significant additional losses. Our future ~~growth~~ **profitability** may depend, in part, on ~~our~~ **Chiesi' s** ability to operate in foreign markets, where ~~we~~ **they** would be subject to additional regulatory burdens and other risks and uncertainties. Our future ~~growth~~ **profitability** may depend, in part, on ~~our~~ **Chiesi' s** ability to develop and commercialize seralutinib in foreign markets **and pay us royalties on commercial sales** . ~~We are~~ **Chiesi is** not permitted to market or promote seralutinib before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for seralutinib. To obtain separate regulatory approval in many other countries, ~~we~~ **Chiesi** 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 seralutinib. If we obtain regulatory approval of seralutinib

and **Chiesi** ultimately ~~commercialize~~ **commercializes** seralutinib in foreign markets, we **and Chiesi** would be subject to additional risks and uncertainties, including: • different regulatory requirements for approval of drugs in foreign countries; • reduced protection for intellectual property rights; • the existence of additional third- party patent rights of potential relevance to our business; • **new or** unexpected changes in tariffs **(including recent U. S. tariffs imposed or threatened to be imposed on other countries and any retaliatory actions taken by such countries)** , trade barriers and regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; • foreign reimbursement, pricing and insurance regimes; • workforce uncertainty in countries where labor unrest is common; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geopolitical actions, including war and terrorism, health epidemics ~~such as COVID- 19~~ , or natural disasters including earthquakes, typhoons, floods and fires. Risks Related to Our Business Operations and Industry Our results of operations may fluctuate significantly, which makes our future results of operations difficult to predict and could cause our results of operations to fall below expectations or any guidance we may provide. Our quarterly and annual results of operations may fluctuate significantly, which makes it difficult for us to predict our future results of operations. 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 seralutinib, which may change from time to time; • coverage and reimbursement policies with respect to seralutinib, if approved, and potential future drugs that compete with seralutinib; • the cost of manufacturing seralutinib, which may vary depending on the quantity of production and the terms of our agreements with third- party manufacturers; • the timing and amount of the milestone or other payments we must make to Pulmokine and other third parties from whom we have in- licensed seralutinib, including payments due upon a change in control of our subsidiaries **as well as timing and amount of the milestone or other payments we receive from Chiesi** ; • expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies; • the level of demand for any approved products, which may vary significantly; • future accounting pronouncements or changes in our accounting policies; and • the timing and success or failure of preclinical studies or clinical trials for seralutinib or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual results of operations. As a result, comparing our results of operations 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 results of operations 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. Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. ~~We are highly dependent upon our senior management, particularly our Chief Executive Officer, as well as our senior scientists and other members of our senior management team.~~ The loss of services of any of these ~~individuals~~ **personnel** could delay or prevent the successful development of seralutinib, initiation or completion of our clinical trials or the commercialization of seralutinib. Executive leadership transitions can be inherently difficult to manage and, as a result, we may experience disruption or have difficulty in maintaining or developing our business. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain " key person " life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals. We will need to 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 unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the increasingly intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses, particularly in the San Diego area. Our industry has experienced a high rate of turnover for all 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 may encounter difficulties in managing our growth and expanding our operations successfully. We had ~~135~~ **144** full- time employees as of ~~February 27~~ **March 6** , ~~2024~~ **2025** . As we continue development and pursue the potential commercialization of seralutinib, as well as function as a public company, we may need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize seralutinib and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We are subject to various federal, state and foreign healthcare laws and regulations, and our failure to comply with these laws and regulations 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 and customers expose us to broadly applicable federal, state and foreign 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, which prohibits, 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, or 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; • the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or 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 the physicians described above and their immediate family members; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives. Ensuring that our internal operations and business arrangements with third- parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our consulting and advisory board arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U. S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, 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, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations. We are subject to governmental regulation and other legal obligations related to privacy, data protection and information security. Actual or perceived failures to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations. The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Compliance with these data privacy and security requirements is rigorous and time- intensive and may increase our cost of doing business. Despite our efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm for actual or perceived failures to comply with such requirements, which could materially and adversely affect our

business, financial condition and results of operations. As our operations and business grow, we may be subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and regulations promulgated thereunder, or collectively, HIPAA, imposes requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA- covered healthcare provider or research institution that has not satisfied HIPAA' s requirements for disclosure of individually identifiable health information. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts. Further, we may also be subject to other state laws governing the privacy, processing and protection of personal information. By way of example, California enacted the California Consumer Privacy Act, ~~or CCPA, effective January 1, 2020, which gives California consumers expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations,~~ as **amended by** ~~well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Additionally,~~ the California Privacy Rights Act, or **collectively, the** ~~CPRA~~ **CCPA** , ~~generally went~~ **requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business' s collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter** into ~~effect~~ **specific contractual provisions with service providers that process California resident personal information** on ~~January 1, 2023, and significantly amends~~ the ~~CCPA. The CPRA imposes additional data protection obligations on companies doing~~ business **' s behalf** ~~in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement~~ . Additional compliance investment and potential business process changes may also be required. Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, the General Data Protection Regulation, or GDPR, went into effect in May 2018, and imposes stringent requirements for controllers and processors of personal data. The GDPR allows EU and EEA member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to € 20 million or 4 % of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States ~~;~~, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union, or CJEU, states that reliance on the standard contractual clauses, or SCCs- a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism- alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case- by- case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU- US Data Privacy Framework, or DPF, rendering the DPF effective as a GDPR transfer mechanism to U. S. entities self- certified under the DPF. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and / or start taking enforcement action, we could suffer additional costs, complaints and / or regulatory investigations or fines, and / or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. Since the beginning of 2021, we have also been subject to the United Kingdom' s data protection regime, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £ 17. 5 million or 4 % of a noncompliant company' s global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the United Kingdom Government), as a data transfer mechanism from the United Kingdom to U. S. entities self- certified under the DPF. Other foreign jurisdictions, such as China and Russia, are increasingly implementing or developing their own privacy regimes with complex and onerous compliance obligations and robust regulatory enforcement powers. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize seralutinib 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. Among the provisions of the ACA of importance to seralutinib, 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 Public Health program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; ~~created a new Medicare Part D coverage gap discount 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 and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Since its enactment, there have been judicial and political challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. ~~Prior to the Supreme Court' s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021, through August 15, 2021, for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.~~ In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020, through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100 % of a drug' s average manufacturer price. 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 programs, and reform government program reimbursement methodologies for products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was enacted into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (~~beginning~~ **which began** in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. ~~In August~~ **CMS has published the negotiated prices for the initial ten drugs, which will first be effective in** ~~2023~~ **2026** , **and** ~~HHS announced~~ the list of the ~~first ten~~ **subsequent 15** drugs that will be subject to ~~price negotiations~~ **negotiation** , although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. We expect that 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 seralutinib, if approved. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure **, drug price reporting** and **other** transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing **. Some states have enacted legislation creating so- called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states** . Legally mandated price controls on payment amounts by third- party payors or other restrictions 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 seralutinib, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. In the EU, similar political, economic and regulatory developments may affect our **or Chiesi' s** ability to profitably commercialize, or co- commercialize, seralutinib, if approved. For instance, on December 13, 2021, Regulation No 2021 / 2282 on Health Technology Assessment, or HTA, amending Directive 2011 / 24 / EU, was adopted. **The** ~~While the~~ Regulation entered into force in January 2022 **and has been applicable since** ~~, it will only begin to apply from~~ January 2025 ~~onwards~~, with ~~preparatory and implementation- related steps to take place in the interim. Once applicable, it will have a~~ phased implementation ~~depending~~ **based** on the ~~concerned~~ **type of product, i. e. oncology and advanced therapy medicinal** products **as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030** . The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non- clinical (e. g., economic, social,

ethical) aspects of health technology, and making decisions on pricing and reimbursement. We face an inherent risk of product liability as a result of the clinical trials of seralutinib and will face an even greater risk if we commercialize seralutinib. For example, we may be sued if seralutinib allegedly causes injury or is 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 seralutinib, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of seralutinib. 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 seralutinib; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • significant negative financial impact; • the inability to commercialize seralutinib; and • a decline in our stock price. We currently hold approximately $ 10 million in aggregate product liability insurance coverage. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of seralutinib. 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 seralutinib. Although we 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. We **, Chiesi** and any of our potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business. If we **, Chiesi** and any of our potential future collaborators are successful in commercializing seralutinib, the FDA and foreign regulatory authorities would require that we **, Chiesi** and any of our potential future collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We **, Chiesi** and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we **, Chiesi** or any of our potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of seralutinib or delay in approval or clearance of future products. 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. 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: (1) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, including cGMP and similar requirements, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (4) laws that require the true, complete and accurate reporting of financial information or data. 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 preclinical 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, individual 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 impact 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, similar to our approach in in- licensing seralutinib. Any future transactions could increase our near and long- term expenditures, result in potentially dilutive issuances of our equity securities, 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. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin- offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Future

acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of 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 of the acquisition. 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. Risks Related to Our Intellectual Property Our success depends on our ability to protect our intellectual property and our proprietary technologies. Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for seralutinib, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or seralutinib, our competitive position could be harmed. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to seralutinib, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents if issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and / or limitations in our ability to properly protect the intellectual property rights relating to seralutinib could have a material adverse effect on our financial condition and results of operations. Although we own issued patents in the United States and foreign countries, we cannot be certain that the claims in our U. S. pending patent applications and patent applications in foreign countries and jurisdictions will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries and jurisdictions, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting seralutinib by obtaining and defending patents. These risks and uncertainties include the following: • the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction; • patent applications may not result in any patents being issued; • patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage; • our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell seralutinib; • there may be significant pressure on the U. S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and • countries and jurisdictions other than the United States may have patent laws less favorable to patentees than those upheld by U. S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products. The patent prosecution process is also expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license from third parties. We may also require the cooperation of our licensor in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in- license, and as a result our ability to develop and commercialize seralutinib may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products. In addition, although we enter into non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third- party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. If we fail to comply with our obligations in the agreements under which we license intellectual property rights for seralutinib from third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights for seralutinib. Additionally, our license agreement for seralutinib includes sublicenses from a third party, and we must rely on Pulmokine' s compliance with its obligations under its original license agreement. In October 2017, we entered into an exclusive license agreement with Pulmokine, Inc. to obtain an exclusive license to certain intellectual property rights to develop and commercialize seralutinib. This license agreement imposes, 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. 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 market products covered by the license. Additionally, our existing license agreement with Pulmokine includes sublicenses from a third party who is not the original licensor of the seralutinib intellectual property. Under this agreement, we must rely on Pulmokine to comply with its obligations under the primary license agreements under which it obtained rights in the applicable intellectual property, where we do not have a relationship with the original licensor of such rights. If Pulmokine fails to comply with its obligations under the upstream license agreement, the original third- party licensor may have the right to terminate the original license, which may terminate our license. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize seralutinib. We may need to obtain licenses from third parties to advance our research or allow commercialization of seralutinib, and we cannot provide any assurances that third-party patents do not exist which might be enforced against seralutinib in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the seralutinib, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including: • 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 patents and other rights to third parties; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of seralutinib, and what activities satisfy those diligence obligations; • our right to transfer or assign the license; and • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners. 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 not be able to successfully develop and commercialize seralutinib, which would have a material adverse effect on our business. In addition, our license agreement with Pulmokine may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, if we choose to sublicense or assign to any third parties our rights under our existing license agreement with Pulmokine with respect to any licensed product, we may be required to pay to Pulmokine, as applicable, a specified percentage of all revenue to be received in connection with such transaction. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected. The patent position of biopharmaceutical 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 which protect seralutinib or which effectively prevent others from commercializing competitive product candidates. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or license currently or in the future 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 that we own or license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether seralutinib will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents 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. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may not cover seralutinib or may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre- issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post- grant review, or PGR, and inter parties review, or IPR, or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. 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 predecessors and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found. There is also no assurance that there is not prior art of which we, our predecessors or licensors are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or those of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize seralutinib and compete directly with us, without payment to us. Such loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of seralutinib. 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. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless

of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize seralutinib. The patent protection and patent prosecution for seralutinib may be dependent on third parties. We or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position with respect to seralutinib. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. Pursuant to the terms of the license agreement with Pulmokine, Gilead Sciences and Rensselaer the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our licensors or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering seralutinib, our ability to develop and commercialize seralutinib may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution. Our technology acquired or licensed from various third parties may be subject to retained rights. Our predecessors or licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in- licensed technology, we may be unable to successfully develop, out- license, market and sell seralutinib, which could prevent or delay new product introductions. Our business strategy depends on the successful development of seralutinib, which is a licensed technologies, into a commercial product. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out- license or market and sell seralutinib. Some of our intellectual property has been discovered through government- funded programs and thus may be subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- U. S. manufacturers. Some of the intellectual property rights we have licensed or may acquire or license in the future may have been generated through the use of U. S. government funding and may therefore be subject to certain federal regulations. For example, some of the research and development work on seralutinib was funded by government research grants. As a result, the U. S. government may have certain rights to intellectual property embodied in seralutinib pursuant to the Bayh- Dole Act of 1980, or Bayh- Dole Act. These U. S. government rights include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). The U. S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U. S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U. S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. industry may limit our ability to contract with non- U. S. product manufacturers for products covered by such intellectual property. To the extent any of our future intellectual property is also generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. 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 develop products that are similar to seralutinib but that are not covered by the claims of the patents that we own or license; • we or our licensors or predecessors might not have been the first to make the inventions covered by the issued patents or patent application that we own or license; • we or our licensors or predecessors might not have been the first to file patent applications covering certain of our inventions; • others may independently develop

similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending patent applications will not lead to issued patents; • issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we 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; • we may not develop additional proprietary technologies that are patentable; and • the patents of others may have an adverse effect on our business. Should any of these events occur, it could significantly harm our business, results of operations and prospects. Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts. Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import seralutinib and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and / or foreign patent offices. Numerous third- party U. S. and foreign issued patents and pending patent applications exist in the fields in which we are developing seralutinib. There may be third- party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of seralutinib. As the biopharmaceutical industry expands and more patents are issued, the risk increases that seralutinib may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third- party patents that may be infringed by commercialization of seralutinib, and we cannot be certain that we were the first to file a patent application related to seralutinib or related technology. Moreover, because patent applications can take many years to issue, there may be currently- pending patent applications that may later result in issued patents that seralutinib may infringe. In addition, identification of third- party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could: • result in costly litigation that may cause negative publicity; • divert the time and attention of our technical personnel and management; • cause development delays; • prevent us from commercializing seralutinib until the asserted patent expires or is held finally invalid or not infringed in a court of law; • require us to develop non- infringing technology, which may not be possible on a cost- effective basis; • subject us to significant liability to third parties; or • require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non- exclusive, which could result in our competitors gaining access to the same technology. Although no third party has asserted a claim of patent infringement against us as of the date of this annual report on Form 10- K, others may hold proprietary rights that could prevent seralutinib from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to seralutinib or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop seralutinib. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign seralutinib or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing seralutinib, which could harm our business, financial condition and results of operations. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can, because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court. Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we and / or our licensors may be required to file infringement claims, which can be expensive and time consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and / or is not infringed. If we or any of our licensors or potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at seralutinib, the defendant could counterclaim that our patent is invalid and / or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. If a defendant

were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on seralutinib. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize seralutinib or future product candidates. Such a loss of patent protection would have a material adverse impact on our business. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline. During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business. Derivation or interference proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party. Derivation or interference proceedings provoked by third parties or brought by us or declared by the USPTO or similar proceedings in foreign patent offices may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring seralutinib to market. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy- Smith Act, the United States transitioned in March 2013 to a " first inventor to file " system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to seralutinib or (2) invent any of the inventions claimed in our patents or patent applications. The Leahy- Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. 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. Thus, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, a Unitary Patent and Unified Patent Court (UPC) system were implemented in Europe on June 1, 2023. This new regime may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, by default automatically fall under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a competitor to obtain pan- European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package, we will have the right to opt our patents out of the UPC over the first seven

years of the court' s existence, but doing so may preclude us from realizing the benefits of the new unified court. Changes in U. S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect seralutinib. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third- party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. For example, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the U. S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. 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 distraction to management and other employees. Patent terms may be inadequate to protect our competitive position on seralutinib 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 filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering seralutinib are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of seralutinib, patents protecting seralutinib might expire before or shortly after seralutinib is commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not obtain patent term extension for seralutinib, our business may be materially harmed. Depending upon the timing, duration and specifics of FDA marketing approval of seralutinib, one or more of our U. S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the 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, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of seralutinib. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. We may not be able to protect our intellectual property rights throughout the world. Although we have issued patents pending patent applications in the United States and certain other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not 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 seralutinib, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Many

countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and / or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition, we rely on the protection of our trade secrets, including unpatented know- how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know- how, including entering into confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of seralutinib. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. Risks Related to Our Common Stock An active, liquid and orderly market for our common stock may not be maintained. Our common stock only began trading on the Nasdaq Global Select Market, or Nasdaq, in February 2019, and we can provide no assurance that we will be able to maintain an active trading market for our common stock. 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. 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 stock price has been and is likely to be volatile. Since the shares were sold in our initial public offering, or IPO, in February 2019 at a price of $ 16. 00 per share, the price per share of our common stock has ranged as low as $ 0. 45 and as high as $ 27. 15 through ~~February 27~~ **March 6** , ~~2024~~ **2025** . The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid. The market price for our common stock may be influenced by those factors discussed in this " Risk Factors " section and many others, including: • our ability to enroll subjects in our ongoing and planned clinical trials; • 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; • regulatory approval of seralutinib, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process; • regulatory developments in the United States and foreign countries; • changes in the structure of healthcare payment systems, especially in light of current reforms to the U. S. healthcare system; • the success or failure of our efforts to acquire, license or develop additional product candidates; • innovations or new products developed by us or our competitors; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments; • manufacturing, supply or distribution delays or shortages; • any changes to our relationship with **Chiesi or** any manufacturers, suppliers, licensors, future 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; • 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; • sales of our stock by insiders and stockholders; • general economic, industry and market conditions other events or factors, many of which are beyond our control, such as **health** ~~the COVID- 19 pandemic~~ **pandemics** , the military conflict between Russia and Ukraine **and Israel and Hamas** , inflation and interest changes and financial institution instability; • additions or departures of key personnel; and • intellectual property, product liability or other litigation against us. In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management' s attention and resources, which could have a material adverse effect on our business, financial condition and results of operations. Our failure to meet the continued listing requirements of the Nasdaq could result in a delisting of our common stock. If we fail to satisfy the continued listing requirements of the 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 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 Nasdaq' s listing requirements. Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval. Furthermore, many of our current directors were appointed by our principal stockholders. Our executive officers, directors and greater than 5 % stockholders, in the aggregate, own approximately ~~27~~ **20** . ~~6~~ **0** % of our outstanding common stock as of ~~February 27~~ **March 6** , ~~2024~~ **2025** . As a result, such persons or their appointees to our board of directors, acting together, have the ability to control or 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 transaction, as well as our management and business affairs. 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 acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit 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, the terms of our Credit Facility preclude us from paying dividends, subject to certain exceptions, as may any future debt agreements we enter into~~ . 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. 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 securities. 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 significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following: • a classified board of directors with three- year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors; • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; • the required approval of at least 66- 2 / 3 % of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause; • the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror; • the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval; • the required approval of at least 66- 2 / 3 % of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings; • the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and • advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror' s own slate of directors or otherwise attempting to obtain control of us. We are also subject to the anti- takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general,

engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, and our amended and restated bylaws provide that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated bylaws also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. Our ability to use net operating loss carryforwards and other tax attributes may be limited. 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 losses for tax purposes, such losses will carry forward to offset future taxable income, if any, until such losses are used to offset taxable income (if ever) or expire (if at all). As of December 31, ~~2023~~ **2024**, we had federal and state net operating loss carryforwards, or NOLs, of approximately $ ~~532~~ **398** . 1 million and $ ~~1~~ **3** . ~~8~~ **3** million, respectively. Our ~~federal and~~ state NOLs that are subject to expiration will begin to expire in ~~2034~~ **2036**, unless previously utilized. Our federal NOLs ~~generated in taxable years beginning after December 31, 2017~~ are not subject to expiration but may only be used to offset 80 % of our taxable income **. As of** ~~in taxable years beginning after~~ December 31, ~~2020~~ **2024** ~~. As of December 31, 2023~~ , the Company has foreign NOLs of approximately $ ~~89~~ **113** . ~~1~~ **0** million. The foreign NOLs can be carried forward indefinitely. As of December 31, ~~2023~~ **2024**, we also had orphan drug credit and federal research tax credit carryforwards of approximately $ 48. ~~6~~ **2** million and California research tax credits of $ ~~12~~ **13** . ~~4~~ **2** million. The federal research tax credit carryforwards begin to expire in 2038. The California research tax credit carryforward does not expire and can be carried forward indefinitely until utilized. Our NOLs and credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, our federal NOLs and credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders (or groups of stockholders) in excess of 50 percentage points over a rolling three- year period. Similar rules may apply under state and foreign tax laws. In connection with our IPO in February 2019, we experienced an ownership change for purposes of Section 382 and 383 of the Code. **We also experienced an ownership change in July 2023.** Consequently, our federal NOLs and tax credits generated through ~~February 2019~~ **July 2023** will be subject to annual limitations. **Our** ~~However, our~~ NOLs ~~and tax credits~~ are not expected to expire unused as a result of such annual limitations, assuming we otherwise have taxable income or income tax liabilities in future periods ~~. We are currently completing~~ **; however, we expect that some** ~~our~~ - **or** ~~review~~ **all** of ~~whether we experienced an ownership change for purposes of Section 382 and 383 of~~ the ~~Code~~ **federal credits generated** through **July** 2023 **will expire prior to utilization** . If ~~additional ownership changes have occurred, including as a result of our private placements of common stock in 2022 and 2023, or~~ additional ownership changes occur in the future as a result of changes in our stock ownership, many of which are outside our control, the NOL and credit carryforwards could be subject to further annual limitations. If we earn taxable income, such annual limitations could result in increased future tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. On April 3, 2020, we, certain of our executive officers and directors, and the underwriters of our IPO were named as defendants in a purported securities class action lawsuit. The complaint, as amended, was filed on behalf of all investors who purchased our securities pursuant to or traceable to our February 8, 2019 IPO, and alleged that we, and such executive officers and directors and the underwriters of our IPO, made false and / or misleading statements and failed to disclose material adverse facts about our business, operations and prospects. On September 30, 2022, the court entered a judgment approving the class action settlement in which we agreed to pay approximately $ 2. 4 million, in exchange for customary releases and settlement terms. This lawsuit and any future lawsuits to which we may become a party are subject to inherent uncertainties and may be expensive and time- consuming to investigate, defend and resolve, and may divert our management' s attention and financial and other resources. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of future litigation, and we may not

prevail. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal, or in payments of substantial monetary damages or fines, or we may decide to settle this or other lawsuits on similarly unfavorable terms, which could adversely affect our business, financial condition, results of operations or stock price. We are a smaller reporting company within the meaning of the Securities Act, and if we decide to take advantage of certain exemptions from various reporting requirements applicable to smaller reporting companies, our common stock could be less attractive to investors. We are a smaller reporting company. For so long as we qualify as a smaller reporting company, we will have the option to take advantage of certain exemptions from various reporting and other requirements that are applicable to other public companies that are not smaller reporting companies, including, but not limited to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, for as long as we are deemed neither a large accelerated filer nor accelerated filer, we may continue to use the exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended, or the Sarbanes- Oxley Act. We will remain a smaller reporting company and non- accelerated filer until we have a public float of $ 700 million or more as of the last business day of our most recently completed second fiscal quarter and annual revenues of less than $ 100 million, or a public float of $ 250 million or more as of the last business day of our most recently completed second fiscal quarter and annual revenues of $ 100 million or more. We will need to reassess, as of June 30, ~~2024~~ **2025**, whether we will continue to qualify as a smaller reporting company and a non- accelerated filer for filings beyond the fiscal year ending December 31, ~~2024~~ **2025**. We cannot predict if investors will find our common stock less attractive because we may 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 more volatile. General Risk Factors We and any of 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. We and any of our third- party manufacturers or suppliers 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. Our operations and 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 laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we 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, 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 the use of hazardous materials or other 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 storage or disposal of biologic, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. 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, which could materially adversely affect our business, financial condition, results of operations and prospects. Our information technology **, or IT,** systems, or those of any of our CROs, manufacturers, other contractors or consultants **or Chiesi** or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our seralutinib development program, which could materially affect our results. We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on **IT** ~~information technology~~ systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, clinical trial data, and personal information, or collectively, Confidential Information, of customers and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information. There can be no assurance that our cybersecurity program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and Confidential Information. Despite the implementation of security measures as part of our cybersecurity program, our **IT** ~~information technology~~ systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to attack and damage from computer viruses and malware (e. g., ransomware), misconfigurations, " bugs " or other vulnerabilities, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon **IT** ~~information technology~~ systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We **, Chiesi** and certain of our service providers are from time to time subject to cyberattacks and security incidents **, including but**

not limited to persistent brute force attempts and password spraying, targeted spearphishing and smishing (text message phishing), email phishing including malware attempts, and third- party vendor cybersecurity incidents and related data breaches. . While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access Confidential Information, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We could also incur liability and the further development and commercialization of seralutinib could be delayed. In addition, we also rely on third parties to manufacture seralutinib, so similar events relating to their computer systems could also have a material adverse effect on our business. Some of the federal, state and foreign government requirements under data privacy and security laws include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our service providers or organizations with which we have formed strategic relationships. Notifications and follow- up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. To the extent that any disruption or security breach were to result in violations of privacy and security laws, we could also be subject to significant fines, penalties or liabilities, which could adversely affect our business, financial condition, results of operations and prospects. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, and other natural or manmade disasters or business interruptions, for which we are predominantly self- insured. We rely on third- party manufacturers to produce seralutinib. Our ability to obtain clinical supplies of seralutinib could be disrupted if the operations of these suppliers were affected by a man- made or natural disaster or other business interruption. In addition, our corporate headquarters is located in San Diego, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Unfavorable global economic conditions and adverse developments with respect to financial institutions and associated liquidity risk could adversely affect our business, financial condition and stock price. The global credit and financial markets are currently, and have from time to time experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, 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 ongoing conflict between Russia and Ukraine **and Israel and Hamas** , terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one 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. **Additionally** ~~More recently~~ , **any** ~~the closures of Silicon Valley Bank, or SVB, and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation, or FDIC created bank- specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future~~ adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages, impair the ability of companies to access near- term working capital needs, and create additional market and economic uncertainty **. For example, in 2023 the closures of Silicon Valley Bank, or SVB, and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation, or FDIC created bank- specific and broader financial institution liquidity risk and concerns** . There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short- term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants 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 or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget. 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. We could face 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 U. S. Foreign Corrupt Practices Act of 1977, as amended, 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, clinical research organizations, 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. We may engage third parties for clinical trials outside of the United States, to sell seralutinib abroad once we enter a commercialization phase, and / or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. 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. 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 clinical trial sites within regions covered by such sanctions. For example, as a result of the military conflict between Russia and Ukraine, the United States and its European allies have recently announced the imposition of sanctions on certain industry sectors and parties in Russia and the regions of Donetsk and Luhansk in Ukraine, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls, as well as any economic countermeasures by the governments of Russia or other jurisdictions, could adversely impact our ability to continue activities at clinical trial sites within regions covered by such sanctions or directly or indirectly disrupt our supply chain. 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. We incur significant 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. 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, Sarbanes- Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes- Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory " say on pay " voting requirements that apply to us. 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. The rules and regulations applicable to public companies have increased and may continue to increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it 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. 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 will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If these analysts cease coverage of our company, the trading price for our stock would be negatively impacted. If one or more of the analysts who covers us downgrades our stock, 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. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. Pursuant to Section 404 of Sarbanes- Oxley, our management is required to annually report upon the effectiveness of our internal control over financial reporting. However, as a smaller reporting company and a non- accelerated filer and in accordance with new SEC rules effective in 2020, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 for as long as we are not deemed an " accelerated filer " or " large accelerated filer. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. Although we have determined that our internal control over financial reporting was effective as of December 31, ~~2023~~ **2024** , we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure 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 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 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. Changes in tax laws may materially adversely affect our financial condition, results of operations and cash flows. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances, including in the United States ~~,~~ **or** Ireland ~~or Luxembourg~~, 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 are currently unable to predict whether such changes will occur and, if such changes do occur, the ultimate impact on our business. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flows.