

Risk Factors Comparison 2025-02-24 to 2024-02-20 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text** Section

Risks Related to our Financial Position and Need for Additional Capital We ~~do not currently~~ **are a development-stage company and** have **incurred significant losses since** ~~sufficient working capital to fund our~~ **inception. We expect to incur losses** ~~planned operations, including fulfilling our debt obligations, for at least the next several years and may never generate~~ **twelve months. There is uncertainty regarding our** ~~or ability~~ **maintain profits. We are a development-stage company and we cannot assure profitability. We expect to continue to generate operating losses for the foreseeable future. Until we can generate substantial revenue and achieve profitability, we will need** ~~to raise additional capital to fund ongoing~~ **operations and capital needs. Since inception, we have incurred significant operating losses. During the year ended December 31, 2024, we incurred a net loss of \$ 221. 3 million, and cash flows used in operating activities was \$ 142. 1 million. As of December 31, 2024 we had ~~and~~ **an accumulated deficit of \$ 1, 214. 6 million, cash and cash equivalents of \$ 104. 9 million, short-term investments in U. S. treasury securities of \$ 307. 5 million, and current and long-term research and development tax credits receivable of \$ 1. 3 million. These losses could continue for the next several years** ~~as we invest in clinical development of ivonescimab. We expect to continue to generate operating losses for the foreseeable future. Until we can generate substantial revenue and achieve profitability, we will need to raise additional capital to fund ongoing operations and capital needs. To become and remain profitable, we must succeed in developing and eventually either commercializing or partnering with other organizations to commercialize products that generate significant revenue. This will require us to be successful in a range of challenging activities, including but not limited to completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical products and biological 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 our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. We have not yet demonstrated an ability to successfully complete development of any product candidates, which may make it difficult for you to evaluate our success and future viability. We have not yet demonstrated an ability to successfully complete development of any product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities or otherwise obtain a partner to do so, as is necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. Assuming we obtain marketing approval for any of our product candidates, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities or seek an appropriate partner or partners to maximize the commercial opportunity of our products with a deal structure that maximizes our opportunities for profitability. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in~~ **such** ~~a transition. We will need substantial additional capital to fund our operations and to make payments under the License Agreement, and if we fail to obtain necessary financing, we could be forced to delay, reduce or eliminate the development and commercialization of our product candidates. Conducting preclinical testing and clinical trials 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 marketing approval or achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we are not planning to have commercially available for several years, if at all. Additional financing may not be available to us on acceptable terms, or at all. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly in connection with the License Agreement. In addition, if we obtain marketing approval for our potential future product candidates where we retain commercial rights or any other product candidates we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Accordingly, we will need to continue to rely on additional financing in connection with our continuing operations. Additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We expect to continue to generate operating losses for the foreseeable future. Our primary future capital requirements will be related to our obligations under the License Agreement and funding research and development efforts. The License Agreement, as amended, calls for initial consideration payments of \$ 515 million (of which \$ 500 million was paid in 2023 and \$ 15 million was paid in 2024), as well as total contingent payments by the Company of up to \$ 4. 56 billion, as Akeso will be eligible to receive regulatory milestones of up to \$ 1. 05 billion and commercial milestones of up to \$ 3. 51 billion, many of which will be due before the~~**

Company anticipates generating any revenue from the License Agreement. We will need additional capital to fund our operations and payments under the License Agreement, which we may do via issuances of equity or debt or through global or regional partnerships in the Licensed Territory. Raising additional capital may cause dilution to our investors, restrict our operations or require us to relinquish rights to our product candidates. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, collaborations, strategic alliances, grants and clinical trial support from government entities, philanthropic, non-government and not-for-profit organizations and patient advocacy groups, debt financings, and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. We will need to seek additional funding in the future to fund operations. Additional capital, when needed, may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends or other distributions. If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings, or other arrangements when needed based on our liquidity needs, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Worldwide economic, social and geopolitical instability could adversely affect our operations, revenue, financial condition, results of operations or ability to raise capital. Generally, worldwide economic conditions remain uncertain, particularly due to the effects of the conflict between Russia and Ukraine and the conflicts in the Middle East, including those in Gaza, Lebanon and Yemen, and disruptions in the banking system and financial markets, increased inflation and rising interest rates. The general economic and capital market conditions, both in the U. S. and worldwide, have been volatile in the past and at times have adversely affected the Company's access to capital and increased the cost of capital. The ongoing geopolitical conflicts in various parts of the world, including but not limited to Russia, Ukraine and Middle East, are difficult to predict and could adversely affect our business in the Licensed Territory as well as our ability to enroll patients and supply ivonescimab to various clinical sites in the world, resulting in adverse effects on our business and financial condition. The capital and credit markets may not be available to support future capital raising activity on favorable terms. If economic conditions decline, the Company's future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, adverse economic conditions, such as recent supply chain disruptions and labor shortages and persistent inflation, may negatively impact our business. These economic conditions make it more difficult for us to accurately forecast and plan our future business activities. We depend heavily on the success of ivonescimab. If we are unable to successfully develop or commercialize ivonescimab, or experience significant delays in doing so, we may continue to incur significant financial losses. We have and plan to continue investing a significant portion of our efforts and financial resources in the development of ivonescimab, which is still in clinical development. Our ability to generate product revenues, which may not occur for several years, if ever, will depend heavily on the successful development and commercialization of ivonescimab. The success of this product candidate depends on a number of factors, including, but not limited to, the following: • our ability to use preclinical data and data of patients from Akeso's clinical trials in China supporting registration studies and regulatory approval; • successful completion of global clinical development; • receipt of clinical trial approvals and future marketing approvals from applicable regulatory authorities in all the countries where we intend to conduct clinical trials or seek marketing approval; the costs of post-marketing studies, if any, that could be required by regulatory authorities in jurisdictions where approval is obtained; • establishing supply chain and commercial manufacturing arrangements with third-party manufacturers; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity; • protecting our rights in our intellectual property portfolio; • establishing sales, marketing and distribution capabilities; • launching commercial sales of ivonescimab if and when approved, whether alone or in collaboration with others; • acceptance of ivonescimab, if and when approved, by patients, the medical community and third-party payors; • obtaining timely and adequate pricing and reimbursement from payors; • ensuring no disruption in supply or lack of sufficient quantities of ivonescimab; • effectively competing with other therapies; and • maintaining an acceptable safety profile of ivonescimab during development and following approval. Risks and uncertainties related to these factors could cause us to experience significant delays or an inability to successfully commercialize ivonescimab, which would materially harm our business.

Risks Related to the Development and Commercialization of our Product Candidates Clinical development is a lengthy process with an uncertain outcome, and results of earlier studies and trials, conducted by us or Akeso, as well any interim results thereof, may not be predictive of future trial results and may negatively impact the size and scope of our ongoing or future Phase III clinical trials. Clinical development can take several years to complete and is an expensive process with inherent uncertainty in outcomes. Failure can occur at any time during the clinical development process. The results of preclinical studies and early clinical trials of ivonescimab, conducted by us or Akeso, may not be predictive of the results of our later-stage clinical trials. Similarly, initial or interim results of a clinical trial may not be predictive of the final results and results for one indication, in one cohort, or in one of the primary endpoints or secondary endpoints, may not be predictive of the success in additional indications, with different cohorts or in additional primary or secondary endpoints. Drug candidates in later stages of clinical trials may fail to show the desired safety and

efficacy traits despite having progressed through preclinical studies and initial clinical trials. Several factors can lead to significant variability in safety and / or efficacy results between different trials of the same drug candidate, including changes in trial procedures set forth in protocols, differences in the size, type and geographic location of the patient populations, including genetic differences, patient adherence to the dosing regimen, and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries involved in such later trials. Results may differ materially in clinical trials held across multiple cohorts or subgroups, which could lead to unfavorable regulatory or health authority decisions. If ongoing Phase II or Phase III clinical trials conducted by Summit or Akeso involving ivonescimab, or future clinical trial results, are unfavorable, the size and scope, including the number of patients, primary and secondary endpoints, and population of patients, of ongoing and future clinical trials could be impacted. Further, we may incur additional product development costs, experience delays or become unable to obtain regulatory approval of ivonescimab for the whole clinical trial or the approved label may be restricted to one cohort or subgroup, thereby adversely affecting our business. If we experience delays or difficulties in the enrollment of patients in our clinical trials, our receipt of necessary marketing approvals could be delayed or prevented. We may not be able to initiate or continue clinical trials for our product candidates for several factors including inability to get required regulatory approvals to initiate clinical trials in all the planned countries, as well as inability to locate and enroll a sufficient number of eligible patients to participate in these clinical trials. For our clinical trials of ivonescimab, we need to identify potential patients, potentially test them for specific diagnoses and enroll them. In addition, our competitors in NSCLC have ongoing clinical trials for product candidates that could be competitive with our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates or choose not to enroll in any clinical trials for various reasons, including due to fears of contagious diseases, illnesses or side effects. Patient enrollment is affected by several factors, including, but not limited to: • severity of the disease under investigation; • eligibility criteria for the clinical trial in question; • perceived risks and benefits of the product candidate under study; • competition for patients, time and resources at clinical trials sites from other investigational therapies in clinical trials that target the same patient population; • changes in the standard of care, including new clinical trial data; • approval of other therapies to treat the indication that is being investigated in the clinical trial; • efforts to facilitate timely enrollment in clinical trials; • patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; and • proximity and availability of clinical trial sites for prospective patients. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients in our planned clinical trials of ivonescimab or any other planned clinical trials would result in significant delays, may generate a limited data set from which no meaningful conclusions could be made, or may require us to abandon one or more clinical trials altogether. If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays, or ultimately be unable to, develop and commercialize any product candidate. In connection with obtaining marketing approval from regulatory authorities (including the FDA, EMA, PMDA or any other regulatory authority in the Licensed Territory) for the sale of ivonescimab, or any other product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In particular, due to the small number of patients in our early clinical trials, results from such trials may not be predictive of the outcome of later clinical trials. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. To date, we have not completed a clinical trial for ivonescimab in the Licensed Territory and cannot predict the results of such trials. Regulatory requirements and timelines may affect the scope and timeline of our trials and the potential market for our product candidates. As we expand into additional countries and sites for our current and additional clinical trials, we are required to obtain the regulatory approval of the applicable clinical trial applications with the respective regulatory authorities and approvals from central or local institutional review boards. We may decide to modify our plans to enter certain regions or countries based on the timelines and requirements from the respective regulatory regions. If the process to obtain regulatory approvals in a given region or country places onerous requirements on the Company or if the Company cannot reasonably obtain such approvals without material delays to its plans, we may choose not to enter certain regions or countries for our clinical trials, which may delay the development of our product in those countries and impact the scope of our dataset and market for our products. If we experience any number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to complete the clinical trials and receive marketing approval for or commercialize our product candidates, including: • clinical trials of our product

candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs; • in clinical trials that include multiple endpoints, unfavorable results in any individual endpoint may limit any regulatory approval or commercialization of the applicable product candidate; • the number of patients required for clinical trials of our product candidates may be larger, and the diversity of the patient population required for our clinical trials may be higher, than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate for various reasons, including due to contagious diseases or illnesses; • our ability to combine data from different regions and countries may be limited due to lack of consistency in data in these regions and countries, potentially delaying or preventing marketing approval for our product in some or all of the Licensed Territory; • in our multi- regional trials, we may experience delays in enrollment across one or more countries and / or regions that could lead to variability in data or the trial missing the required endpoints resulting in lack of approval from regulatory authorities in some or all of the Licensed Territory; • we may be unable to enroll a sufficient number of patients in our clinical trials to ensure adequate statistical power to detect any statistically significant treatment effects; • we or our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • regulators, institutional review boards or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; • we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with multiple prospective trial sites; • we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks; • regulators, institutional review boards or independent ethics committees may require that we or our investigators materially modify the terms of our clinical research in order to meet additional requirements for receiving marketing approval, including by requiring that we enlarge our trials, broaden the scope of our research, or perform studies in addition to those we currently anticipate, which may delay our ability to obtain marketing approval or impose additional costs; • regulators, institutional review boards or independent ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; • the supply or quality of our product candidates, comparator drugs or other materials necessary to conduct clinical trials of our product candidates in adolescent patients may be insufficient or inadequate, which may occur if, for example, enrollment for our clinical trial programs are delayed and the clinical supply of ivonescimab or related comparator drug manufactured for such trials was not utilized prior to its expiration and needed to be replaced, or if there were disruptions in our supply chain due to weather conditions, natural disasters or contagious diseases or illnesses, or pandemics or epidemics; • our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators, institutional review boards or independent ethics committees to suspend or terminate the clinical trials; and • preclinical tests or clinical trials not beginning as planned, needing to be restructured or not being completed on schedule, or at all. If serious adverse or inappropriate side effects are identified during the development of any product candidate, we may need to abandon or limit our development of that product candidate. All of our product candidates are in clinical or early- stage development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain 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. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause side effects or other safety issues that prevented further development of the compound. If we elect or are forced to suspend or terminate any clinical trial of our product candidates, the commercial prospects of such product candidate will be harmed and our ability to generate product revenues from such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business. Even if a product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If ivonescimab or any of our other product candidates receive marketing approval, such products may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, it could make it more difficult to enter into third- party partnership arrangements, and we may not generate significant product revenues or revenue from collaboration agreements or any income from operations. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and potential advantages compared to alternative treatments or competitive products; • the prevalence and severity of any side effects; • the ability to offer our product candidates for sale at competitive prices; • convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; • the strength of marketing and distribution support; • the availability of third- party coverage and adequate reimbursement; • the timing of any such marketing approval in relation to other product approvals; • support from patient advocacy groups; and • any restrictions on concomitant use of other medications. The ability to negotiate, secure and maintain third- party coverage and reimbursement may be affected by political, economic and regulatory developments in the United States, the E. U., Japan and other jurisdictions in the Licensed Territory. Governments continue to impose cost containment measures, and third- party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of

payor acceptance of ivonescimab or any of our other product candidates that receive marketing approval. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing a product candidate if and when such product candidates are approved. We do not have a sales or marketing infrastructure and have no experience as a company in the sale or marketing of pharmaceutical products, although certain employees do have experience in the sale and marketing of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. If ivonescimab receives marketing approval, we may seek commercialization partners in some parts of the Licensed Territory. There are risks involved with establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. Biologics, such as ivonescimab, carry unique risks and uncertainties that could negatively impact our business. The successful development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture. Failure to successfully, develop, manufacture and sell ivonescimab could adversely affect our business. We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success. Notwithstanding our large investment to date and anticipated future expenditures in proprietary technologies, we have not yet developed, and may never successfully develop, any marketed drugs. As a result of pursuing the development of product candidates using our proprietary technologies, we may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success. Research programs to identify new product candidates require substantial doubt regarding technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We face substantial competition, which may result in others discovering, developing or commercializing products before us or more successfully than we do. The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and any products we may seek to develop or commercialize whether ourselves or through third-party partners, in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Several pharmaceutical and biotechnology companies have established themselves in the market for the treatment of NSCLC, and several additional companies are developing products for the treatment of NSCLC. Currently, the most commonly used treatments for first-line NSCLC without genomic alterations are several immuno-oncology drugs and chemotherapies, administered either individually as monotherapy, in combination with each other, or in combination with other approved therapeutics. In addition to various chemotherapies, several immunotherapies have been approved by the FDA for these treatments, including, but not limited to pembrolizumab, atezolizumab, nivolumab, durvalumab, cemiplimab and ipilimumab. There are anti-angiogenic therapies which are approved for the treatment of certain lung cancers, including bevacizumab in front-line non-squamous NSCLC as well as ramucirumab for patients who have progressed after platinum-based chemotherapy. The proposed indications for ivonescimab in the HARMONI-3 and HARMONI-7 clinical trial settings in first-line NSCLC may face competition from clinical candidates such as novel immunotherapy targets including various clinical candidates targeting T-cell immunoreceptors with Ig and ITIM domains (TIGIT) and lymphocyte activation gene 3 (LAG-3) each of which have

various developers for different candidates as either monoclonal antibodies or multispecific antibodies, a bispecific antibody, volrustomig (AstraZeneca), and antibody drug conjugates (ADCs) with novel targets such as datopotamab deruxetecan (AstraZeneca and Daiichi Sankyo), sacituzumab tirumotecan (Merck), and sigvotatug vedotin (Pfizer), each having announced, are currently enrolling in, or having completed enrollment in Phase III clinical trials. For those patients EGFR mutations, there are several targeted therapies that have also been approved in the front-line setting, including, but not limited to, osimertinib (AstraZeneca) with or without chemotherapy and amivantamab and lazertinib (both from Johnson & Johnson). The proposed indication for ivonescimab in the HARMONi clinical trial setting, post third-generation EGFR-TKIs such as osimertinib or lazertinib, may face competition from amivantamab plus chemotherapy, as well as clinical candidates such as datopotamab deruxetecan (AstraZeneca and Daiichi Sankyo) and patritumab deruxetecan (Merck and Daiichi Sankyo). There are several PD-(L)1/VEGF(R2) bispecific antibodies in development or with planned development globally. These include, but are not limited to BNT327, which is owned by BioNTech SE, which has begun conducting Phase III clinical studies globally, and LM-299, which was licensed globally by Merck & Co., Inc. in November 2024. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, safer, have fewer or less severe side effects, are approved for broader indications or patient populations, or are more convenient or less expensive than any products that we develop and commercialize. Our competitors may also obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. We believe that many competitors are attempting to develop therapeutics for the target indications of our product candidates, including academic institutions, government agencies, public and private research organizations, large pharmaceutical companies and smaller more focused companies. Multiple in-class and related competitors for our product candidates are and can be developed, our competitive position could be compromised because it may be more difficult for us to obtain marketing approval for that product candidate and market acceptance of that product candidate due to a similar competitor. In addition, any product that competes with another approved product typically must demonstrate compelling advantages in efficacy, convenience, tolerability or safety, or some combination of these factors, to gain regulatory approvals, overcome price competition and be commercially successful. Many of our competitors may have significantly greater financial and operational resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining approvals from regulatory authorities and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our programs. If we fail to plan, execute and manage our growth effectively, our ability to develop and commercialize products could suffer. We expect that if our clinical product candidates continue to progress in development, and we continue to build our clinical operations and invest in our commercial operations, we will require significant additional investment in personnel, infrastructure and resources. Our ability to achieve our research, development and commercialization objectives depends on our ability to respond timely and effectively to these demands and expand our internal organization, systems and controls to accommodate additional anticipated growth. The expansion of our operations may lead to significant costs and may divert our management and business resources. Failure to effectively manage our growth may impact our ability to successfully develop and commercialize our product candidates.

Risks Related to our Dependencies on Third Parties We depend on our relationship with, and the comprehensiveness of the intellectual property licensed from, Akeso, and termination of the License Agreement, or issues related to intellectual property could have a material adverse effect on our business. We depend on the know-how and other intellectual property licensed from Akeso through the License Agreement for the development and, if approved, commercialization of the bispecific antibody, ivonescimab. If the License Agreement is terminated, or found to be unenforceable, it could result in the loss of significant rights and could harm our ability to commercialize ivonescimab. The License Agreement imposes certain obligations on us, including obligations to use diligent efforts to meet development thresholds, funding requirements, payment obligations, and commercialization. If we are unable to meet our obligations, some or all of our rights under the License Agreement may be restricted or terminated. Our primary product candidate, ivonescimab, is subject to the License Agreement from Akeso, which is revocable in certain circumstances, including in the event we do not achieve certain payment deadlines. Without the patents under the License Agreement, we will not be able to continue to develop ivonescimab. The License Agreement may be terminated by Akeso in the event of a material breach by Summit or if we default in the performance of any of our material obligations under the License Agreement, and such default continues for 90 days, or with respect to any breach of any undisputed payment obligations, for 60 days, or with respect to any breach of a supply requirement, for 30 days after written notice thereof. Additionally, the ability of Summit to realize the full potential of the License Agreement may be severely limited by factors involving intellectual property rights, including: • whether and to what extent our technology and processes infringe on intellectual property rights of other third parties that are not subject to the License Agreement; • whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of intellectual property without their authorization; • our right to sublicense patent and other intellectual property rights to

third parties under collaborative development relationships; • our compliance with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates; • ownership of specific intellectual property; and • the impact on payments and costs associated with commercialization if there is blocking intellectual property in or costs associated with prosecution, maintenance and enforcement under the Akeso License Agreement. These issues, if they arise, could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement, or increase our costs to develop, manufacture and commercialize products under the License Agreement. We may be reliant on Akeso for knowledge transfer relating to any improvements in manufacturing of ivonescimab. The loss of any of the knowledge transferred relating to ivonescimab from Akeso may cause us to incur additional transition costs or result in delays in the manufacturing and delivery of ivonescimab. We have entered into the License Agreement pursuant to which we agreed to purchase a certain portion of drug substance and / or drug product for clinical and commercial supply, and the termination or Akeso's breach of these agreements could have a material adverse effect on our business. Akeso's drug substance and drug product may not comply with regulatory authority quality requirements or have sufficient stability for commercialization which may require additional investment and delay our development, approval and commercialization plans. Further, failure of Akeso to adequately transfer knowledge to Summit relating to any improvements in producing ivonescimab could have a material adverse effect on our business. Manufacturing of biological compounds is inherently complex and establishing new manufacturing relationships with a third- party manufacturer may take longer, resulting in higher costs and potential inventory issues. Manufacturing processes may use materials which Summit may not be able to secure, requiring Summit to develop alternative processes and delay manufacturing. The product may not comply with regulatory authority quality requirements or have sufficient stability for commercialization, which may require additional manufacturing development and delays. As Summit is relying initially on supply from Akeso, any delays in obtaining import or export licenses may delay development. We depend on collaborations with third parties for the development and commercialization of some of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates. We may enter into third- party collaborations for the development and commercialization of ivonescimab. Additionally, we may seek third- party collaborators for development and commercialization of any other product candidates. Our likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Under our license and commercialization agreements we have, and under any such arrangements we enter into with any third parties in the future we will likely have, limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Our current collaborations pose, and any future collaboration likely will pose, numerous risks to us, including the following: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected; • collaborators may de- emphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a going concern result of a sale or disposition of a business unit or development function, or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products; • collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • disputes may arise between the collaborator and us as to the ownership of intellectual property arising during the collaboration; • we may grant exclusive rights to our collaborators, which would prevent us from collaborating with others; • disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and • collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. We rely on the use of third parties, including Akeso, to manufacture our product candidate, which may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable time and cost, which could delay, prevent or impair our development or commercialization efforts. We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of our product candidates. We have limited

personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties for supply of the active pharmaceutical ingredients ("API"), drug substance or drug product, in our product candidates. Our financial statements strategy is to outsource all manufacturing of our product candidates and products to third parties. We have supply agreements with Akeso for supply of ivonescimab for use in clinical trials as well as for commercial supply. We have agreements with third-party manufacturers for development, validation and manufacturing of ivonescimab to secure the long-term clinical or commercial supply of our product candidates. We are in the process of setting up agreements with third party manufacturers for the long-term clinical and commercial supply of ivonescimab. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. The third-party manufacturers may not successfully carry out their contractual duties or obligations, the occurrence of which could substantially increase our costs and limit our supply of such product candidates. The demand for third-party manufacturer's services is very high, and such manufacturers could be subject to market transactions including mergers, acquisitions and other market consolidation transactions that limit their ability to provide products and services to us thereby increasing the time and cost it could take us to manufacture our product. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers, including Akeso, entails additional risks, including: • reliance on the third party for regulatory compliance and quality assurance; • the possible breach of the manufacturing agreement by the third party; • the possible diversion of manufacturing capacity to other customers by the third party; • the possible misappropriation of our proprietary information, including our trade secrets and know-how; and • the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us. Third-party manufacturers, including Akeso, may not be able to comply with current good manufacturing practice ("cGMP"), regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, including Akeso, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our product candidates 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 regulations and that might be capable of manufacturing for us. In addition, in order to conduct late-stage clinical trials of our product candidates, we will need to have them manufactured in large quantities. Our third-party manufacturers, including Akeso, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. Moreover, if our third-party manufacturers, including Akeso, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business. If the third parties, including Akeso, that we engage to manufacture product for our preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the novel coronavirus or another outbreak, we likely would experience delays in advancing these clinical trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. Large pharmaceutical companies with greater resources, either through acquisitions, market consolidation or otherwise, may be able to obtain privileged access to manufacturing capacity and supply of material needed for the manufacture of ivonescimab or other similar competing drugs. If our competitors are able to use their resources to secure preferential access to the supply capacity of third party manufacturers, or if third party manufacturers elect to terminate their contracts with us in favor of exclusive contracts with other larger pharmaceutical companies, our ability to obtain a supply of ivonescimab or any other future product candidates may be impacted resulting in significant delays and higher costs for development and commercialization of our products. We may not be able to complete our clinical trials or market our products at scale without stable partnerships with third party manufacturers who produce ivonescimab or other drug compounds necessary for our product candidates. Shifting manufacturing relationship to another third-party manufacturer takes significant time and resources, and could delay development and commercialization of our product. We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials. We do not independently conduct clinical trials for our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the clinical trial. Moreover, the FDA requires us to comply with standards, commonly referred to as GCP, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity of data and confidentiality of clinical trial participants are protected. The EMA and PDMA impose similar requirements on us for products that are the subject of clinical trials in the E. U., including the U. K., and Japan. Furthermore, third parties that we rely on for our clinical

development activities may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Our product development costs will increase if we experience delays in testing or obtaining marketing approvals. We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue. If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans. Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate further with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been prepared under the assumption a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Legal, Tax, Regulatory, and Compliance Risks Even if we are able to commercialize a product candidate, it may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize ivonescimab or any other product candidate successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U. S. and E. U. healthcare industries and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for ivonescimab or any other product that we commercialize and, if coverage and reimbursement are available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In addition, third-party payors are likely to impose strict requirements for reimbursement of a higher priced drug. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the applicable regulatory authority. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including, but

not limited to, research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the E. U., reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any. In some countries, particularly the E. U. Member States, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various E. U. Member States and parallel distribution, or arbitrage between low-priced and high-priced E. U. Member States, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected. Our business is subject to the risks associated with doing business in China. As a result of our reliance on Akeso, located in China, our results of operations, financial condition, and prospects are subject to a significant degree to economic, political, and legal developments in China including government control over capital investments or changes in tax regulations that are applicable to us. China's economy differs from the economies of most developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate and control of foreign exchange, and allocation of resources. Since we rely on an entity located in China, our business is subject to the risks associated with doing business in China, including: • adverse political and economic conditions, particularly those potentially negatively affecting the trade relationship between the United States and China; • trade protection measures, such as tariff increases, and import and export licensing and control requirements; • potentially negative consequences from changes in tax laws; • difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China; • historically lower protection of intellectual property rights; • requirements relating to China's data security rules and regulations; • requirements relating to China personal information protection laws; • changes and volatility in currency exchange rates; • unexpected or unfavorable changes in regulatory requirements; and • difficulties in managing foreign relationships and operations generally. We are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U. S. or Chinese governments, political unrest or unstable economic conditions in China. New legislation, regulations or court decisions may impede, delay, limit, or increase the cost of manufacturing our therapeutic candidates. Such events could result in our clinical or commercial supply of drug being interrupted or limited, which could harm our business. U. S.- China trade relations may adversely impact our supply chain operations and business. The U. S. and Chinese governments have taken certain actions that change trade policies, including tariffs and threats of additional tariffs that affect certain products which are manufactured in China and mutual exchange of certain types of data. Due to our collaboration with Akeso, we are reliant on collaborating with a company with significant operations in China. We do not know whether and to what extent the Trump administration will implement or alter any tariffs, laws or regulations that may increase the cost or feasibility of importing and exporting products, components and information from China to the United States and vice versa. Further, the effect of any such new tariffs or actions on our industry and customers is unknown and difficult to predict. As additional tariffs, legislation and regulations are implemented, or if existing trade agreements are renegotiated, or if China or other affected countries take retaliatory trade actions, such changes could have a material adverse effect on our clinical development plans, business, financial condition, results of operations or cash flows. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • reduced resources of our management to pursue our business strategy; • decreased demand for any product candidates or products that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • significant costs to defend the related litigation; • substantial monetary awards to clinical trial participants or patients; • loss of revenue; • increased insurance costs; and • the inability to commercialize any products that we may develop. The insurance policies covering our clinical trials are subject to a per claim deductible.

The amount of insurance that we currently hold may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage when and if we begin commercializing ivonescimab or any other product candidate that receives marketing approval. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations currently, and may in the future, involve the use of hazardous and flammable materials, including chemicals and medical and biological materials, and produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and wastes, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials or disposal of hazardous wastes, we could be held liable for any resulting damages, and any liability could exceed our resources. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Recent and potential future changes to U. S. and non- U. S. tax laws or the interpretation thereof or the imposition of new or increased taxes or fees could increase our future tax liabilities and adversely affect our operating results and cash flows. From time to time, U. S. federal, state and non- U. S. legislation has been proposed that would continue, if enacted into law, make significant changes to tax laws, including certain key U. S. federal, state and non- U. S. income tax provisions currently applicable to companies like us. It is unclear whether these or similar changes will be enacted and, if enacted, how soon any such changes could take effect. The passage of any legislation as a going concern. However, result of these proposals and other changes in tax laws or the imposition of new or increased taxes or fees could affect our effective tax rates in countries where we have concluded operations and could have an adverse effect on our overall tax position in the future, along with increasing the complexity, burden and cost of tax compliance, in each case potentially increasing our future tax liabilities and adversely affect our operating results and cash flows. Recent changes in tax law may adversely affect our business or financial condition. On December 22, 2017, the U. S. government enacted the Tax Cuts and Jobs Act (the " TCJA "), which significantly reformed the Code. The TCJA, among other things, contained significant changes to corporate taxation, including certain limitations on interest deductions, limitations of the deduction for certain net operating losses, and the modification or repeal of many business deductions and credits. Beginning with costs incurred in 2022, the TCJA also eliminated the option to deduct research and development expenditures and requires taxpayers to capitalize and amortize them over five or fifteen years. If this requirement is not modified, it may impact our effective tax rate and our cash tax liability in future years. More recently, the IRA contained, among other things, a corporate alternative minimum tax, which imposes a 15 % minimum tax will be imposed on certain financial statement income of " applicable corporations " in taxable years beginning after December 31, 2022. The IRA also imposes a 1 % non- deductible excise tax on the fair market value of any stock repurchased by a publicly traded domestic corporation during any taxable year, with the fair market value of such repurchased stock reduced by the fair market value of certain stock issued by such corporation during such taxable year. The U. S. Department of the Treasury and the IRS have released proposed and final regulations and other interpretive guidance relating to the TCJA and the IRA. Any significant variance from our current interpretation of such regulations and interpretive guidance could result in a change in our analysis of the application of the TCJA and the IRA to us and its impact on our operations and cash flows. Recent announcements of changes in the U. K. research and development (" R & D ") regime are likely to impact the level of cash benefit that the Company will be able to receive in respect of the R & D activity. As a result of a reduction in rates applied in the Small and Medium Enterprise (" SME ") regime, the cash credit that the Company will be able to obtain is likely to reduce if the qualified spending remains consistent. This will be partly offset by an increase in the Research and Development Expenditure Credit (" RDEC ") regime. In addition, there is a refocus of relief towards U. K. activity and therefore costs outside the U. K. are expected to be restricted going forward with further changes anticipated following a government consultation being launched with the intention of merging the SME and RDEC schemes. Our future tax liabilities may be greater than expected if our net operating loss carryforwards and other tax attributes are limited, we do not generate expected deductions, or tax authorities challenge our tax positions. As of December 31, 2024, we have U. S. federal and state net operating loss (" NOL ") carryforwards of approximately \$ 44. 3 million and \$ 7. 0 million, respectively, U. S. federal research and development tax credit carryforwards of approximately \$ 7. 0 million, and U. K. NOL carryforwards of approximately \$ 198. 7 million. Our ability to utilize these tax attributes to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, which cannot be assured. In addition, our ability to use NOL carryforwards and other tax attributes may be subject to significant limitations under Sections 382 and 383 of the Code. Under those sections of the Code, if a corporation undergoes an " ownership change " (as defined in Section 382 of the Code), the corporation' s ability to use its pre- change NOL carryforwards and other tax attributes may be substantially limited. An ownership change generally occurs if one or more stockholders (or groups of stockholders) who are each deemed to own at least 5 % of such corporation' s stock change their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period. In the event that

we were to undergo an ownership change, utilization of our NOL carryforwards and other tax attributes would be subject to an annual limitation under Section 382 of the Code and Section 383 of the Code (as applicable), determined by multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate in effect during the month in which the ownership change occurs, subject to certain adjustments, which could result in a portion of our tax attributes expiring prior to their utilization. Any unused annual limitation may be carried over to later years. Any limitation on our ability to utilize our NOL carryforwards or other tax attributes against income or gain we generate in the future could increase our future tax liabilities and adversely affect our operating results and cash flows. Furthermore, we are subject to various complex and evolving U. S. federal, state, local and non- U. S. tax laws. U. S. federal, state, local and non- U. S. tax laws, policies, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us, in each case, possibly with retroactive effect. Any significant variance in our interpretation of current tax laws, including as result of the release of final Treasury Regulations or other interpretive guidance implementing, or a successful challenge of one or more of our tax positions by the IRS or other state, local or non- U. S. tax authorities could increase our future tax liabilities and adversely affect our operating results and cash flows. In the event that our NOL carryforwards or other tax attributes are subject to future limitation (including due to an ownership change under Sections 382 and 383 of the Code), deductions are not generated as expected, or if one or more of our tax positions are successfully challenged by the IRS or other tax authorities (in a tax audit or otherwise), our future tax liabilities may be greater than expected, which could adversely affect our operating results and cash flows. Laws and regulations affecting government contracts make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws and regulations could result in significant civil and criminal penalties and adversely affect our business. We must comply during the term of such government contracts and upon expiration / termination of such contracts, as to continuing obligations, with numerous laws and regulations. These laws, regulations and obligations include, for example, the Federal Acquisition Regulation, compliance regulations, business ethics and public integrity obligations, export and import laws and regulations, etc. Additionally, government agencies routinely audit and investigate government contractors for compliance with the applicable laws and standards. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties including fines, debarment and exclusion from government funding and administrative sanctions, such as long-term monitoring arrangements and exclusion from regulatory approvals. In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could jeopardize our other research programs, deter research institutions from engaging with us, and cause our stock price to decrease. The marketing approval process is expensive, time-consuming and uncertain, and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are unsuccessful or delayed in obtaining required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired. Our product candidates, including ivonescimab, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us or our collaborators from commercializing the product candidate. We have only limited experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates and expect to rely on third-party contract research organizations to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Regulatory authorities may determine that ivonescimab or any of our other product candidates are not effective or only moderately effective, or have undesirable or unintended side effects, toxicities, safety profiles or other characteristics that preclude us from obtaining marketing approval or that prevent or limit commercial use. The process of obtaining marketing approvals is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a U. S. government-sponsored database, www. ClinicalTrials. gov, within certain timeframes. Failure to comply would violate federal requirements and could result in fines and / or civil and criminal sanctions, which would delay the regulatory approval process and result in adverse publicity. Our failure to obtain marketing approval in a jurisdiction would prevent our product candidates from being marketed in such jurisdiction, and any approval we are granted for our product candidates in one jurisdiction would not assure approval of our product candidates in any other jurisdictions. In order to market and sell ivonescimab and our other product candidates

in foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements in those jurisdictions. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA or EMA approval. The regulatory approval process outside the United States and Europe generally includes all of the risks associated with obtaining FDA and EMA approval. In addition, some countries outside the United States and Europe require approval of the sales price of a drug before it can be marketed. In many countries, separate procedures must be followed to obtain reimbursement. We may not obtain marketing, pricing or reimbursement approvals outside the United States and Europe on a timely basis, if at all. Approval by the FDA or the EMA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States and Europe does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA or the EMA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. Marketing approvals in countries outside the United States and Europe do not ensure pricing approvals in those countries or in any other countries, and marketing approvals and pricing approvals do not ensure that reimbursement will be obtained. Our ability to obtain and maintain conditional marketing authorizations in the E. U. is limited to specific circumstances and subject to several conditions and obligations. A failure to renew any conditional approval that we obtain prior to full approval for the applicable indication would prevent us from continuing to market our products. Conditional marketing authorizations based on incomplete clinical data may be granted for a limited number of listed medicinal products for human use, including products designated as orphan medicinal products under E. U. law, if (1) the risk- benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) unmet medical needs will be fulfilled and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. Specific obligations, including with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data, may be specified in the conditional marketing authorization. Conditional marketing authorizations are valid for one year and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions. Even if we, or a third- party collaborator, obtain conditional approval for ivonescimab, or any other product candidate, we or they may not be able to renew such conditional approval. Even if we obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue. Even if marketing approval of a product candidate is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including the requirement to implement a risk evaluation and mitigation strategy or to conduct costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We and our collaborators must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved labeling. Thus, neither we nor our collaborators will be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to ensure that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP. Accordingly, assuming we receive marketing approval for one or more of our product candidates, we and our contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we are not able to comply with post- approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post- approval regulations may have a negative effect on our operating results and financial condition. Any product candidate for which we obtain marketing approval will be subject to strict enforcement of post- marketing requirements and we could be subject to substantial penalties, including withdrawal of our product from the market, if we fail to comply with all regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved. Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post- approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include, but are not limited to, restrictions governing promotion of an approved product, submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. The FDA and other federal and state agencies, including the DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off- label use, and if we do not market our products for their approved indications, we may be subject to enforcement action for off- label marketing. Violations of such requirements may lead to investigations

alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws. Our failure to comply with all regulatory requirements, and later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, may yield various results, including:

- litigation involving patients taking our products;
- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Non-compliance with E. U. requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the E. U.'s requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Our relationships with customers, healthcare providers and professionals and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates, including ivonescimab, for which we obtain marketing approval. Our future arrangements with customers, healthcare providers and professionals and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, and are not limited to, the following:

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federally funded healthcare programs such as Medicare and Medicaid. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and formulary managers, among others. Several other countries, including the U. K., have enacted similar anti-kickback, fraud and abuse, and healthcare laws and regulations.
- The federal False Claims Act imposes civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. The government and qui tam relators have brought False Claims Act actions against pharmaceutical companies on the theory that their practices have caused false claims to be submitted to the government. There is also a separate false claims provision imposing criminal penalties.
- HIPAA, as amended by the HITECH, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- HIPAA also imposes criminal liability for 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.
- The federal Physician Sunshine Act requirements under the ACA require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Payments made to physicians and research institutions for clinical trials are included within the ambit of this law. Failure to submit timely, accurate and required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of pharmaceutical sales representatives in the jurisdiction. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Exclusion,

suspension and debarment from government funded healthcare programs would significantly impact our ability to commercialize, sell or distribute any drug. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Inadequate funding for or other disruptions to government agencies could hinder or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of reviewing regulatory agencies, including the FDA, to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key leadership and other personnel and the acceptance of user fees payments, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. If funding is inadequate, a prolonged government shutdown occurs, the FDA is required to furlough review staff or necessary employees, or if the agency operations are otherwise disrupted, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our ability to successfully develop and commercialize ivonescimab or any other product candidate in our pipeline. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Current and future legislation may increase the difficulty and cost to obtain marketing approval of and commercialize our product candidates and could affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more limits on reimbursement and additional downward pressure on the price that we, or any future collaborators, may receive for any approved products. We expect that recently enacted healthcare reforms, as well as 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 as well as impact reimbursement to stakeholders that administer any approved product we might bring to market. Any reductions in reimbursement may negatively impact physicians, hospitals and other provider's ability to purchase and appropriately prescribe our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several U. S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. In the U. S., the ACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Since its passage, there have been significant ongoing efforts to modify or eliminate the ACA and potential future legislative, judicial or regulatory actions related to the ACA, and any effects on us, are uncertain. Other legislative changes have been proposed and adopted since passage of the ACA. These have, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and ~~oncology~~ cancer treatment centers, because and increased the statute of limitations period for the government to recover overpayments to providers. Further legislative, regulatory and other legal changes remain possible. President Biden signed into law the Inflation Reduction Act of 2022 (the "IRA") on August 16, 2022, which includes several provisions to lower prescription drug costs for Medicare patients and reduce drug spending by the federal government. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, the U. S. Centers for Medicare and Medicaid Services ("CMS"), will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. Negotiations will occur for products that have been on the market for seven years for Part D drugs and for eleven years for Part B drugs. Revised prices will take effect two years after these negotiations occur. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. It is unknown what form any future changes or any law would take under the Trump Administration and how or whether it may affect our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. In addition, the ACA has also been subject to challenges in the courts, which remain ongoing. At the state level, individual

states are increasingly aggressive in passing legislation and implementing 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 and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care 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. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional sources of funding—state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates ~~our~~ or ~~cash~~ additional pricing pressures. Legislative and ~~cash~~ ~~equivalents~~ regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U. S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent product labeling and post-marketing testing and other requirements. In the E. U., similar political, economic and regulatory developments may affect our ability to profitably commercialize our products. In addition to continuing pressure on prices and cost containment measures, legislative developments ~~at December 31~~ the E. U. or Member State level may result in significant additional requirements or obstacles that may increase our operating costs. We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition. Our operations are subject to anti-corruption laws, including the FCPA, the U. K. Bribery Act 2010 (the "Bribery Act"), and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA, Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the U. S. and the U. K., and authorities in the E. U., including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the "Trade Control laws". There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA, the Bribery Act and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control laws by U. S., U. K. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. Environmental, social and governance ("ESG") matters may impact our business and reputation. Governmental authorities, nongovernmental organizations, customers, investors, external stakeholders and employees are increasingly aware of ESG concerns, such as climate change, water use, recyclability or recoverability of packaging, and plastic waste. The ESG landscape is uncertain and constantly evolving due to changes in executive action, legislation, regulations and court orders. ESG concerns may lead to new requirements that could result in increased costs associated with developing, manufacturing and distributing our products. Our ability to compete could also be affected by changing customer preferences and requirements or by failure to meet such customer expectations or demand. We risk negative stockholder reaction, including from proxy advisory services, as well as damage to our brand and reputation, if we do not act responsibly, or if we are perceived to not be acting responsibly in key ESG areas. If we do not meet the ESG expectations of government agencies, our investors, customers and other stakeholders, we could experience reduced demand for our products, loss of customers, and other negative impacts on our business and results of operations. The Company's reputation or relationships with its stakeholders and other third parties could also be adversely impacted as a result of, among other things, (i) stakeholder or third-party perceptions of statements, if any, made by the Company, its employees, agents, any industry trade associations, or other third parties; or (ii) public pressure from investors or policy groups to change the Company's policies. Such statements or initiatives with respect to ESG matters are increasingly subject to heightened scrutiny from the public and governmental authorities, as well as other parties. Certain regulators, such as the SEC and various state agencies, as well as nongovernmental organizations and other private actors have filed lawsuits under various securities and consumer protection laws alleging that certain ESG statements, goals or standards were misleading, false or otherwise deceptive. On the other hand, the Company could face criticism from certain "anti-ESG" parties if it were to make environmental or social commitments or pursue certain environmental or social initiatives that are alleged to be inherently political or polarizing in nature and could subject the Company to pressure in

the media or through other means, which could adversely affect our reputation, business, financial performance, market access and growth. Risks Related to Our Intellectual Property, Cybersecurity and Data Privacy If we are unable to obtain and maintain patent protection for our technology and product candidates, our competitors could develop and commercialize technology and drug products similar or identical to ours, and our ability to successfully commercialize our technology and drug product candidates may be impaired. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in strategic jurisdictions, including the United States, Europe and other key markets. However, this process is inherently costly, time-consuming, and uncertain. We may not successfully identify patentable aspects of our research in a timely manner, potentially missing opportunities to secure meaningful protection. Additionally, challenges such as high costs, delays in prosecution, and changes in the law could compromise our ability to file and prosecute all necessary or desirable applications. These factors may limit the scope of protection we achieve, increasing our vulnerability to competition and undermining the commercial potential of our products. Moreover, if we license technology or product candidates from third parties in the future, we may have limited control over the preparation, filing, prosecution, or enforcement of the associated patents, leaving us vulnerable to decisions that may not align with our goals or interests. For example, under our License Agreement with Akeso, patent prosecution and enforcement in the Licensed Territory are subject to consultation and cooperation with Akeso. If we cannot align on our patent strategy, this could impact the patentability or enforcement of the licensed intellectual property. Actions or statements during patent prosecution outside of the Licensed Territory could significantly influence the validity of any patent obtained within the Licensed Territory, potentially undermining our competitive position. Additionally, Akeso owned patents and patent applications, which are non-exclusively licensed to Summit under the License Agreement, are under the control of Akeso. Akeso's prosecution, enforcement, and licensing strategies with regard to their owned patents and patent applications may conflict with our objectives. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and is currently the focus of extensive litigation. This unpredictability makes the issuance, scope, validity, enforceability and commercial value of our patent rights highly uncertain. While we strive to secure patents that protect our technology and products, our pending and future patent applications may not yield issued patents that provide meaningful protection. Even when patents are granted, they may fail to effectively prevent competitors from developing and commercializing similar or identical technologies and products. Furthermore, ongoing changes in patent laws or their interpretation due to changing administrations, specifically in the United States and internationally, may diminish the value of our patents, restrict the scope of our patent protection, or complicate our enforcement efforts. The laws of foreign countries may offer less robust protection for patent rights compared to those in the United States, potentially exposing us to heightened competition. For example, European patent law imposes stricter limitations on the patentability of methods of treatment for the human body when compared with U. S. law, which may leave aspects of our technology and products vulnerable in certain markets. Additionally, differences in national patent laws and enforcement mechanisms may make it more difficult to obtain and maintain comprehensive protection across all major markets. This patchwork of international protection may hinder our ability to prevent the entry of third parties into the market. Assuming the other requirements for patentability are met, under current U. S. law, the first to file a patent application is generally entitled to the patent. This framework, implemented after March 16, 2013, replaced the previous "first to invent" system which granted rights to the original inventor regardless of the filing date. Unfortunately, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. This lack of clarity makes it difficult to ascertain whether we were the first to make the inventions claimed in our U. S. patents or pending U. S. patent applications. We face similar uncertainties when seeking patent protection outside of the United States, where filing dates are critical to determining patent rights. Moreover, we may be subject to third-party pre-issuance submissions of prior art to the USPTO or become involved in opposition, derivation, reexamination, reissue, inter parties review, post grant review, interference proceedings or other patent office proceedings, court litigation or International Trade Commission proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. Adverse determinations in any of these proceedings could severely restrict or invalidate our patents, reducing their enforceability and allowing third parties to commercialize similar or identical technologies without compensation to us. Furthermore, when third-party patents are involved, such disputes may result in our inability to manufacture, market, or commercialize our products without infringing on third-party rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened or narrowed by operation of any of the foregoing, such an event could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Third parties may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents. Resolving intellectual property disputes, such as infringement claims, can be costly and time consuming. Such disputes may force us to design around third-party patents, incurring additional expenses, or seek licenses on terms that may not be commercially reasonable, favorable, or even obtainable. A successful claim of patent or other intellectual property infringement could result in substantial damages, disrupt our operations, or lead to an injunction preventing the manufacture, sale, or use of the affected product. We may choose not to file patents for certain intellectual property to maintain trade secrets or know-how, leaving a risk that third parties may subsequently patent those innovations. Even if our patent applications issue as patents, they may not issue in a form that would provide us with adequate protection against competition. Our competitors may circumvent our owned or licensed patents by

developing similar, improved or alternative technologies or products in a non-infringing manner, eroding our competitive advantage. In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity, such as orphan drug exclusivity in the United States, which we obtain under applicable legislation, which may require us to allocate significant resources to preventing such circumvention. These efforts can divert attention and financial resources away from other critical business activities, potentially slowing our overall progress. Legal and regulatory developments in the E. U. and elsewhere may also result in clinical trial data submitted as part of a marketing authorization application becoming publicly available. Such developments could enable other companies to use our clinical trial data to assist in their own product development and to obtain marketing authorizations in the E. U. and in other jurisdictions. Loss of market exclusivity, particularly through the entry of generic or biosimilar competitors, could significantly reduce our revenue and market share. Such developments may also require us to allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights. Despite our best efforts, our attempts to prevent third parties from circumventing our intellectual property and other rights may ultimately be unsuccessful. Additionally, any failure to take the required actions, such as paying necessary maintenance fees or addressing administrative formalities, could jeopardize the longevity and enforceability of our patents, further exposing us to risks of market erosion and reduced exclusivity. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Future changes in U. S. statutory or case law beyond our control could affect some or all of the foregoing possibilities. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. This could be the case even after giving effect to patent term extensions and data exclusivity provisions preventing third parties from relying on clinical trial data filed by us for regulatory approval in support of their own applications for such approval. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We may become involved in lawsuits or other enforcement proceedings to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and potentially unsuccessful. Competitors may infringe our patents, trademarks, copyrights or other intellectual property rights. To counter infringement or unauthorized use, we may be required to initiate legal claims or enforcement actions, which can be expensive and time-consuming. Such actions are not always successful. Any claims we assert against perceived infringers may prompt these parties to assert counterclaims against us, alleging that we infringe their intellectual property or that our patent and other intellectual property rights are invalid or unenforceable, including counterclaims based on antitrust or other legal theories. In a patent infringement proceeding, a court or administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, or may construe the patent's claims narrowly. Such rulings could allow the other party to continue using the disputed technology at issue on the grounds that our patents do not cover the competitor's activities or products. Antitrust considerations may also hinder our ability to settle such matters on favorable terms, as certain types of settlement agreements, particularly in the pharmaceutical sector, are subject to heightened scrutiny by antitrust authorities. In the E. U., for instance, antitrust regulators closely monitor settlement agreements for compliance with competition laws, adding another layer of complexity and potential risk to these proceedings. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business. Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies, including our in-licensed drug candidate ivonescimab, without infringing the intellectual property and other proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference, derivation, inter parties review, reexamination, reissue or post-grant review proceedings before the USPTO or similar proceedings in other jurisdictions. The risks of being involved in such disputes may increase as our product candidates approach commercialization, and as we gain greater visibility as a publicly traded company in the United States. Third parties may assert infringement claims against us based on their existing or future intellectual property rights, potentially restricting our freedom to operate or delaying our progress. Moreover, they may seek injunctive relief to bar us from practicing our technologies altogether while litigation against us is pending, potentially causing significant disruptions to our operations. If we are found to infringe third party's intellectual property rights, or if we choose to settle a dispute to avoid prolonged litigation, we may be required to obtain a license to enable us to continue developing and marketing our products and technology. However, obtaining such licenses may be challenging or unattainable on commercially reasonable terms. Even if we were able to obtain a license, it could be non-exclusive, which would enable our competitors access to the same technologies and we may be required to pay substantial upfront or ongoing royalties. Absent a license, we could be forced, including by court order, to cease commercializing the infringing technology or product entirely. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, particularly if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties, or claims that we

derived our inventions from another, could have a similar negative impact on our business. We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees were previously employed at universities, research institutions or other biotechnology or pharmaceutical companies, including competitors or potential competitors. Although we take measures to ensure that our employees do not use the proprietary or otherwise confidential information or know-how from former employers, we may be subject to claims that we or our employees have, without authorization, misappropriated intellectual property, trade secrets or other proprietary or confidential information. Litigation may be necessary to defend against these claims. In addition, while we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us and agreeing to cooperate and assist us with securing and defending our intellectual property, certain risks may arise. We may be unsuccessful in executing such an agreement from all relevant parties who develop intellectual property for us, and certain agreements may not be enforceable under applicable laws or may be subject to challenges from third parties. Furthermore, assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims third parties may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management. Intellectual property litigation could cause us to spend substantial resources and could distract our personnel from their normal responsibilities. Even if we are successful in defending against intellectual property claims, litigation or related legal proceedings can still impose significant financial and operational burdens. These disputes often require us to allocate substantial resources, including legal fees and other expenses, which can strain our finances and reduce funds available for our working capital needs for critical business functions like development, sales, and marketing. Moreover, these proceedings can pull key technical and management personnel away from their normal responsibilities, disrupting our operations and slowing our progress. In addition, public announcements of the outcomes of hearings, motions or other interim proceedings or developments could have far reaching consequences. If securities analysts or investors interpret these developments negatively, it could have a substantial adverse effect on the price of our shares of common stock. Beyond the reputational impact, such litigation or proceedings could severely impact our business by diverting critical resources away from development, sales, marketing, and distribution efforts. Our ability to manage these legal challenges effectively may be constrained by limited financial and operational resources, especially when compared to competitors with deeper financial reserves who may weather such disputes more effectively. As a result, the cumulative costs, management distraction, and lingering uncertainties stemming from patent litigation or similar proceedings could substantially impair our ability to compete and succeed in the marketplace. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary and confidential information, to maintain our competitive position. To safeguard these trade secrets, we employ non-disclosure and confidentiality agreements with parties who have access to them next twelve months after, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. However, despite these measures, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Even with these protections, any party with whom we have executed such an agreement may breach their obligations and disclose our proprietary or confidential information, including our trade secrets unlawfully. 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. Additionally, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no legal recourse to prevent them from using this information to compete with us. If any of our trade secrets, particularly unpatented know-how, were to be obtained or independently developed by a competitor, our competitive position would be harmed. We operate in the biotechnology sector and rely heavily on information technology. Any interruption, malfunction, or lapse related to that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively. We rely on both internal information technology systems and those of third parties to process and store sensitive data, including confidential research, business plans, financial information, intellectual property and personal data that may be subject to legal protection, and ensure the continuity of the Company's operations. As of the date of that the financial statements included in this Annual Report on Form 10-K, though the Company and our service providers have experienced certain cybersecurity incidents, we are issued not aware of any previous cybersecurity incidents that have materially affected or are reasonably likely to materially affect the Company. Any such cybersecurity incidents could result in a material compromise of our systems or the systems of our third-party vendors, and the information stored there could be accessed, publicly disclosed, lost, stolen, corrupted or rendered, permanently or temporarily, inaccessible. Furthermore, the Company or its service providers may not promptly discover a system intrusion. Cybersecurity incidents could have a material impact on our business, operations or financial results. Any access, disclosure or other loss of information, including Company data being compromised within the systems of our third-party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information or personal health information, disrupt our operations and damage our reputation, which could adversely affect our business. We also may need to make a material ransom payment to unencrypt, re-access, or preserve the confidentiality of our data or systems. We could be

required to spend significant financial and other resources to respond to and remedy the damage caused by such an incident, including the costs to recover data or to repair or replace networks and information technology systems, increased cybersecurity protection costs and increased insurance premiums. If our information technology systems or data, or those of third parties upon whom we rely or interact, are or were compromised, we could experience material adverse consequences resulting from such compromise. In the ordinary course of our business, we and the third parties we rely on collect, receive, store, use, transfer, make accessible, dispose of, transmit, disclose or otherwise process proprietary, confidential and sensitive information, personal information, personal health information, participant-study- health- related data, proprietary information, intellectual property, and trade secrets (collectively, "sensitive data"). In addition, we rely on service providers to establish and maintain appropriate information technology and data security protections to operate critical business systems (such as cloud- based infrastructure and systems, personnel email, as well as data storage and Management-management systems). However, except for contractual protections, which may prove ineffective, we have limited ability to control the safeguards implemented and actions taken by such third parties. These service providers may not maintain adequate information security measures. We may share or receive sensitive data with or from third parties whose information security measures may not be adequate. The risk of cybersecurity incidents may be heightened as a result of our some of our employees utilizing a remote working environment, which may be less secure and more susceptible to cybersecurity incidents. Additionally, the prevalent use of mobile devices that access our sensitive data increases the risk of data breaches. Advances in computer capabilities, discoveries in the field of artificial intelligence, cryptography, inadequate facility security or other developments may result in a compromise or breach of the technology we use to safeguard sensitive information. Our information technology systems, including in our remote work environment, and those of parties upon which we rely, are vulnerable to evolving threats. These threats are prevalent, continue to increase and come from a variety of sources such as hackers; external or internal bad actors; personnel (such as through theft, error and misuse); sophisticated nation- states and nation- state- supported actors; and others. These threats include, but are not limited to, outages, social- engineering attacks, malicious code or intrusions, malware, denial- of- service attacks, personnel misconduct or errors, ransomware attacks, supply- chain attacks, software bugs, computer viruses, server malfunctions, software and hardware failures, misdirected wire transfers, theft or loss of data and other information technology assets, adware, natural disasters, terrorism, war, as well as telecommunication and electrical failures. In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant disruptions to operations, loss of data and income, reputational harm and diversion of funds. If we were to experience such an attack, ransom payments might alleviate some of the negative impacts of a ransomware attack but we might be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Any of these threats may result in unauthorized, unlawful or accidental loss, corruption, access, modification, destruction, alteration, acquisition or disclosure of sensitive data (including without limitation clinical trial data). The costs to us to attempt to protect against such cybersecurity incidents and breaches are significant and could potentially require us to modify our business (including without limitation non- clinical and clinical trial activities). While we have implemented security measures designed to protect our information technology systems and to identify and remediate potential vulnerabilities, such measures may not be successful. We may not be able to detect vulnerabilities in our information technology systems because such threats and techniques used by threat actors change frequently, are sophisticated in nature and may not be detected until after a security incident has occurred. In addition, we may not have adequate insurance coverage to remediate or provide compensation for any losses associated with such events. If we or our third- party partners upon whom we rely experience or are perceived to have experienced a breach, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits and inspections), interruptions in our operations (including disruptions to our clinical trials), interruptions or restrictions on processing sensitive data (which could result in delays in obtaining, or our inability to obtain, regulatory approvals and significantly increase our costs to recover or reproduce the sensitive data), reputational harm, litigation (including class- action claims), indemnification obligations, monetary fund diversions, financial loss and other harms. In addition, such a breach may require notification of the breach to relevant stakeholders, certain state agencies or the media. Such disclosures are costly and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Many of our contracts with relevant stakeholders include obligations relating to safeguarding sensitive data and a breach or other cybersecurity incident could lead to claims against us by such stakeholders. There can be no assurance that the limitations of liability or other protections in our contracts would be enforceable or adequate or would otherwise protect us from liabilities, damages or claims relating to our data privacy and security obligations. In addition, failure to maintain effective internal accounting controls related to data security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and could subject us to regulatory and private party scrutiny. We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to material adverse consequences. In the ordinary course of business, we process personal data and other sensitive data (including proprietary and confidential business information, trade secrets, intellectual property, clinical trial data, and other sensitive third- party data). We are subject to or affected by numerous data privacy and security obligations such as various federal, state, local and foreign laws, regulations, and guidance; industry standards; external and internal privacy and security notices and policies; contracts; and other obligations governing the processing of personal data by us and on our behalf. These obligations may change, are subject to differing interpretations and may be inconsistent across jurisdictions. The global data protection landscape is rapidly evolving and implementation standards and enforcement practices are likely to

remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect us or our collaborators', service providers' and others' ability to operate in certain jurisdictions or to collect, store, transfer (including across jurisdictional borders), use, share, and otherwise process personal data, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these obligations is high and is likely to increase in the future. These obligations may necessitate changes to our information technologies, systems and practices and to those of any service providers that process personal data on our behalf. In addition, these obligations may require us to change our business plans. Outside the U. S., an increasing number of laws, regulations and industry standards apply to data privacy and security. For example, the E. U.'s GDPR, imposes strict requirements on the processing of personal data. Under the E. U. GDPR, government regulators may impose temporary or definitive bans on personal data processing as well as fines of up to 20 million Euros or 4 % of the annual global revenues of the noncompliant company, whichever is greater. Additionally, the Personal Information Protection Law ("PIPL") of the People's Republic of China may apply to certain personal data processed by us, our collaborators or others on our behalf. Similar to the E. U. GDPR, PIPL imposes strict requirements on the processing of personal data and allows for statutory fines and penalties. Certain jurisdictions, including the U. K., E. U., and China have enacted data localization laws and cross-border personal data transfer laws which make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the U. K. or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. The processing of sensitive personal data, such as physical health conditions, is a topic of active interest among regulators. As we expand into countries and jurisdictions outside the U. S., we will be subject to additional laws and regulations that may affect how we conduct business in relation to the personal data or personal health information we or our third-party partners process. For example, in relation to cross-border personal data laws, if we cannot maintain a valid compliance mechanism for cross-border personal data transfers, we may face increased exposure to regulatory actions, fines and injunctions against the transferring of personal data from the U. K., Europe, China and elsewhere. We may have to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense. Likewise, we expect that there will continue to be new laws, regulations and industry standards relating to data privacy and security in the U. S. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (the "CCPA"), imposes obligations on business to which it applies. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to \$ 7, 500 per violation). While the CCPA contains limited exceptions for clinical trial data, the CCPA's implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. In addition, the CCPA establishes a new California Privacy Protection Agency to implement and enforce the CCPA which could increase the risk of an enforcement action. Other states (such as Colorado, Virginia, Delaware, Texas and others) have also enacted data privacy laws. If we become subject to new data privacy laws, the risk of enforcement actions or class-action litigation brought against us could increase because we may become subject to additional obligations and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state agencies). Further, there are regulations related to data privacy and security that are specific to our industry. For example, the U. S. Department of Health and Human Services has issued rules governing the use, disclosure, and security of protected health information, and the FDA has issued further guidance concerning cybersecurity for medical devices. HIPAA, as amended by HITECH, and their respective implementing regulations impose significant obligations on covered entities and business associates to safeguard the privacy, security, and integrity of individually identifiable health information, also known as protected health information. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our personnel or third parties we rely on fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a service provider to comply with applicable data privacy and security obligations could result in adverse effects, including inability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e. g., investigations, fines, penalties, audits, inspections and similar activities); litigation (including class-related claims); additional reporting requirements and oversight; bans on processing personal data; orders to destroy or not use personal data; individual, media or agency notifications, including without limitation notice to the Department of Health and Human Services; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to comply as well as to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. Moreover, trial participants or research subjects as well as the providers who share their information with us, may contractually limit our ability to use and disclose the information, and we may face significant liability for failing to abide by such limitations. Risks Related to Operations Our future success depends on our ability to retain our Co- Chief Executive Officers, Chief Operating Officer and other key executives. We are highly dependent on the principal members of our executive and scientific teams, including Mr. Robert W. Duggan and Dr. Mahkam Zanganeh, our Co- Chief Executive Officers, and Mr. Manmeet Soni, our Chief Operating Officer and Chief

Financial Officer, all of whom are at- will employees. They may terminate their employment with us at any time. Mr. Duggan and Dr. Zanganeh have also been married since December 18, 2024. We do not maintain “ key person ” insurance on any of our executive officers. The unplanned loss of the services of any of these persons could materially impact the achievement of our research, development and commercialization objectives. We or the third parties we rely on may be adversely affected by social unrest or terrorism. Social instability, disruption, or widespread destruction in areas where we operate or in significant markets could have a negative impact on our business. Events, including war, terrorism, riot, civil insurrection or social unrest, regardless of cause, could result in material adverse effects on our ability to operate, the ability of our suppliers to operate, and macroeconomic conditions. Such negative impacts may adversely affect the Company’ s business, results of operations and financial condition. We or the third parties we rely on may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. The changing nature, frequency, and severity of natural disasters and extreme weather events such as tornadoes, hurricanes flooding, extreme heat, and wildfires pose a risk to Company facilities, assets, and programs, as well as those of third parties on whom we rely. Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, or other event occurred that prevented us from using all or a significant portion of our offices or prevented a third party on whom we rely from using its facilities, or if a disaster damaged critical infrastructure that we and third parties rely upon, or if a disaster otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for extended periods period of time. In addition to operational impacts, natural disasters could significantly affect clinical trial participants, institutions, doctors, and supporting staff. For participants, a disruption in trial operations could delay access to investigational therapies, compromise ongoing treatment regimens, or create uncertainty about trial continuity. Institutions and medical personnel and staff could face logistical challenges, including damage to clinical trial sites, limited availability of resources, and interrupted communication channels. Key staff may be unable to perform their duties due to displacement, injury, or other disaster- related issues, leading to trial delays and operational challenges. Such disruptions may result in increased costs, delays in regulatory submissions, and reputational harm. Our existing disaster recovery and business continuity plans may not fully mitigate these risks, and unanticipated gaps in communication during emergencies may hinder our decision making and response efforts. We may incur substantial expenses to address and recover from such disruptions, which could further strain our financial and operational resources. Widespread health concerns, pandemics or epidemics, and other outbreaks of illness may negatively affect the Company’ s ability to maintain operations and execute its business plan. Widespread health concerns, pandemics, epidemics and other outbreaks of illness can have evolving and uncertain impacts on our business. As a result of any widespread health concern, pandemic, or other outbreaks of illness, including the COVID- 19 pandemic, the Company has in the past and may experience disruptions that severely impact our business, commercialization, third party vendor operations, including foreign and domestic supply chains, or delays in clinical trial activities, including:

- delays or difficulties in initiating clinical trial sites;
- disruption to and delays in preclinical research and analysis activities due to an extended temporary closure of contract lab facilities;
- disruptions in supply, logistics or other activities related to the procurement of materials, which could have a negative impact on the Company’ s ability to conduct preclinical studies, initiate or complete clinical trials or commercialize product candidates;
- diversion of healthcare resources away from conducting clinical trials;
- interruption of key preclinical studies and clinical trial activities, due to limitations on travel imposed or recommended by federal, state, provincial or municipal governments, employers and others;
- limitations in resources that would otherwise be focused on the conduct of the Company’ s business or current or planned preclinical studies or clinical trials, including due to sickness, restrictions on travel, prolonged stay- at- home or shelter- in- place orders and other pandemic related concerns;
- slowed enrollment in and delayed execution of clinical trials due to hospital closures to clinical trials or patient hesitation to enroll in clinical trials;
- impact of infection of patients on the outcomes of clinical trials; and
- changes in regulations as part of a response to the future pandemic or epidemic may require the Company to change the ways in which the preclinical studies and clinical trials are conducted and incur unexpected costs, or requires the Company to discontinue our preclinical research or clinical trials altogether.

Our employees may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation. We may be exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA or Office of Inspector General regulations or similar regulations of comparable non- U. S. regulatory authorities, provide accurate information to the FDA or comparable non- U. S. regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non- U. S. regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, or a request for the reimbursement of expenses that were not incurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines and other sanctions. Key personnel have been, and may continue to be, difficult to attract and retain. Our ability to maintain and grow our business is

directly related to the service of our employees in each area of our business, as we consider talent to be a key asset. Our performance is directly tied to our ability to hire, train, motivate and retain qualified personnel, including highly skilled technical, operational and program managerial, clinical, medical, analytical and legal or financial personnel. There is significant competition for personnel in the clinical sciences marketplace, particularly in certain geographies where we are located, including but not limited to the United States, where we plan to expand our physical presence, as well as Europe. Also, employees in our industry are increasingly able to work remotely, which could increase employee mobility and turnover, making it more difficult for us to attract and retain employees. In addition, many of our clinical development, operational and program management positions, require deep technical expertise, and it can be particularly challenging to identify and attract candidates and retain employees possessing such expertise. We have experienced, and may continue to experience, attrition in certain key positions. If we are unable to hire sufficient numbers of qualified employees or retain and motivate existing employees, our business and operating results would be harmed. Additionally, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Risks Related to Owning Our Common Stock Our principal stockholder and Co- Chief Executive Officer maintains the ability to control or significantly influence all matters submitted to stockholders for approval. As of December 31, 2024, Mr. Duggan beneficially owned, in the aggregate, shares of common stock representing over 70 % of our outstanding capital stock. Mr. Duggan is able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, Mr. Duggan is able to control or influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. As a member of the board of directors, Mr. Duggan will adhere to the corporate governance standards adopted by the company. As a “ controlled company ” under the listing requirements of the Nasdaq Stock Market, we have an exemption from certain corporate governance requirements, which could adversely affect our stockholders by denying them certain rights and protections. Mr. Duggan owns more than a majority of the voting power of our outstanding shares of common stock. Under the Nasdaq Stock Market listing requirements, a company of which more than 50 % of the voting power is held by an individual, group, or another company is a “ controlled company ”. We have in the past, and we expect in the future, to rely on the “ controlled company ” exemptions under the Nasdaq Stock Market listing requirements. For example, in the past, a majority of the members of our board of directors were not independent directors, and our compensation and nominating and corporate governance committees did not consist entirely of independent directors. Accordingly, during the period we remain a controlled company and during any transition period following a time when we are no longer a controlled company, you may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the Nasdaq Stock Market. The price of our shares of common stock have in the past, and may continue to be volatile and fluctuate substantially, which could result in substantial losses for our stockholders. The market prices of our shares of common stock on the Nasdaq Global Market have in the past and may continue to be volatile and fluctuate substantially. The stock market in general and the market for smaller pharmaceutical and biotechnology 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, stockholders may not be able to sell their shares of common stock at or above the price at which they were purchased. The market price for our shares of common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of ivonescimab and any other product candidate that we develop;
- results of clinical trials of product candidates of our competitors;
- the acquisition activity and licensing and collaboration efforts of our competitors and large biopharmaceutical companies;
- changes or developments in laws or regulations applicable to ivonescimab and any other product candidates that we develop;
- our entry into, and the success of, any collaboration agreements with third parties;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in- license additional product candidates, products or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the biotechnology and pharmaceutical sectors;
- regulatory or legal developments in the United States and other countries;
- the societal and economic impact of public health epidemics and pandemics, and government efforts to slow their spread;
- general economic, industry and market conditions;
- the trading volume of the shares on the Nasdaq Global Market; and
- the other factors described in this “ Risk Factors ” section.

Additionally, the stock market historically has experienced significant price and volume fluctuations. These fluctuations are often unrelated to the operating performance of particular companies. These broad market fluctuations may cause declines in the trading price and market value of our common stock. Substantial future sales of our shares of common stock in the public market, or the perception that these matters sales could occur, could cause the price of the shares to decline significantly, even if our business is doing well. Sales of a substantial number of our shares of common stock in the public market could occur at any time. These sales, or the perception in the market that these sales could occur, could cause the market price of the shares to decline. Following the domestication, all of our outstanding shares of common stock were freely tradeable in the public market without restriction, unless held by our affiliates. Our principal stockholder and Co- Chief Executive

Officer, Mr. Duggan, holds a substantial number of shares. Mr. Duggan's shares have been registered for resale pursuant to an effective registration statement on Form S-3. If he sells, or indicates an intention to sell, substantial amounts of shares in the public market, the trading price of our shares could decline. We are a "large accelerated filer" and the reduced disclosure requirements applicable to "non-accelerated filers," and, starting in the first fiscal quarter of 2025, "smaller reporting companies" previously available to us no longer apply. As of June 30, 2024, the market value of our common stock that was held by non-affiliates exceeded \$700 million, and as a result, we now qualify as a "large accelerated filer." As such, we incur significant additional expenses in complying with the Sarbanes-Oxley Act of 2002 and rules implemented by the SEC. As a large accelerated filer, we are subject to certain disclosure requirements that are applicable to other public companies that were not applicable to us as a "non-accelerated filer" and "smaller reporting company." We have incurred and will continue to incur significant legal, accounting and other expenses that we did not previously incur. In addition, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the Nasdaq Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including raising the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. Additionally, if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional capital-financial and management resources. Additionally, we expect that our loss of "non-accelerated filer" and "smaller reporting company" status will require additional attention from management and will result in increased costs to us, which could include higher legal fees, accounting fees and fees associated with investor relations activities, among others. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our shares of common stock. Effective internal controls over financial reporting are described in Item 2—Liquidity necessary for us to provide reliable financial reports and Capital Resources—Sources, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of Liquidity of the Sarbanes-Oxley Act, or Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements included or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our shares of common stock. We are required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management is required to assess the effectiveness of these controls annually. Now that we have transitioned from a "non-accelerated filer" and "smaller reporting company" to a "large accelerated filer," our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. Pursuant to Section 404 (a) of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal controls over financial reporting. In order to comply with Section 404 (a) of the Sarbanes-Oxley Act, we expect to incur additional expenses and devote increased management effort including documenting and evaluating our internal controls over financial reporting. In this regard Annual Report on Form 10-K. However, we cannot guarantee will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the U. S. as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees. Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be able to obtain the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: • any derivative action or proceeding brought on or our sufficient additional funding behalf; • any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders; • any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law ("DGCL") or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or • any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent

jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U. S. shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. While the Delaware courts have determined that such funding-choice of forum provisions are facially valid, if available a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be obtainable-enforced by a court in those other jurisdictions. These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find the either exclusive forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could materially adversely affect our business, financial condition and operating results. Because we do not anticipate paying any cash dividends on terms satisfactory our shares of common stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders. We have never declared or paid cash dividends on our shares of common stock. We currently intend to retain all of our future earnings to fund the development and expansion of our business. Any determination to pay dividends in the future will be at the discretion of our board of directors. As a result, capital appreciation of our shares of common stock, if any, will be the sole source of gain for our stockholders for the foreseeable future. If equity research analysts stop publishing research or reports about our business or if they issue unfavorable commentary or downgrade our shares of common stock, the price of the shares could decline. The trading market for our shares of common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our shares of common stock could decline if one or more equity research analysts downgrades such securities or if analysts issue other unfavorable commentary about us or our business. In addition, if one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading prices and trading volumes of our shares of common stock to decline. We are exposed to risks related to currency exchange rates. We conduct a portion of our operations in the U. K and rely on third parties across the globe. Exchange rate fluctuations between local currencies and the U. S. dollar create risk in several ways, including the following: weakening of the U. S. dollar may increase the U. S. dollar cost of overseas research and development expenses and the cost of sourced product components outside the United Kingdom; strengthening of the U. S. dollar may decrease the value of our revenues denominated in other currencies; the exchange rates on non-dollar transactions and cash deposits can distort our financial results; and commercial pricing and profit margins are affected by currency fluctuations. We have broad discretion in the use of our cash and cash equivalents and may not use them effectively. Our management has broad discretion in the use of our cash and cash equivalents and could spend our cash in ways that do not improve our results of operations or enhance the value of our shares of common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the market price of our shares of common stock to decline and delay the development of our product candidates. We may complete a future acquisition that may not achieve intended results or could increase the number of our outstanding shares or amount of outstanding debt or result in a change of control. In addition to the License Agreement and the transactions contemplated thereby, we may pursue business development opportunities to expand or enhance our pipeline of drug candidates, including without limitation, through potential acquisitions of and / or collaborations with other entities. Any such transaction could happen at any time, could be material to our business and could take any number of forms, including, for example, an acquisition, merger or a collaboration with other entities. Evaluating potential transactions and integrating completed ones may divert the attention of our management from ordinary operating matters. The success of these potential transactions will depend, in part, on our ability to realize the anticipated growth opportunities through the successful integration of the businesses we acquire with our existing business, as well as the success of the underlying business or intellectual property that we acquire or otherwise obtain rights to. Even if we are successful in integrating the acquired businesses, these integrations may not result in the realization of the full benefit of any anticipated growth opportunities or these benefits may not be realized within the expected time frames. In addition, acquired businesses may have unanticipated liabilities or contingencies. If we complete an acquisition cannot continue as a going concern, our stockholders would likely lose most or all of their investment or other strategic transaction, we may require additional financing that could result in us an increase in the number of our outstanding shares or the aggregate amount of our debt