You should carefully consider, in addition to other information contained in this document, the risks and uncertainties below before* [REDACTED] *in our H Shares. Any of the risks and uncertainties listed below could have a material adverse effect on our business, results of operations, financial condition, or on the* [REDACTED] *of our H Shares and could cause you to lose all or part of your* [REDACTED]. *Additional risks and uncertainties not presently known to us or that we currently deem immaterial could also harm our business, results of operations, financial condition, or on the* [REDACTED] *of our H Shares. Past performance is no guarantee of future results.

Our operations are subject to a number of risks. Many of these risks are beyond our control and can be categorized into: (i) risks relating to our business and industry; (ii) risks relating to our financial position and need for additional capital; (iii) other risks relating to our operations; (iv) risks relating to conducting business in the jurisdiction where we operate; and (v) risks relating to the [**REDACTED**].

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to the Development of Our Drug Candidates and Regulatory Approval

The regulatory approval process of the NMPA and other comparable regulatory authorities for our product candidates is lengthy and the result is unpredictable. We may not achieve favorable results for our drug candidates in clinical trials, and cannot give any assurance that any of our drug candidates currently in development will receive regulatory approval. Any failure to timely obtain these regulatory approvals could adversely affect our business prospects and profitability.

We are subject to risks associated with obtaining regulatory approvals. New pharmaceutical products must be approved by the NMPA or other comparable regulatory authorities before they can be marketed and sold. The time required to obtain approvals from the relevant regulatory authorities in different jurisdictions is unpredictable, typically taking years following the commencement of pre-clinical studies and clinical trials, and depends on numerous factors, including the substantial discretion of the regulatory authorities. Significant time, efforts and financial resources are required to bring our product candidates to market in compliance with the regulatory processes, and we cannot assure you that we will be able to meet all regulatory requirements or that our product candidates will be eventually approved for sale. Obtaining regulatory approvals may take longer than expected, or such approvals may be subject to limitations on the indicated uses for which we intend to market the relevant product, therefore restricting its market size and adversely affecting our business, results of operations and growth prospects.

We may fail to receive regulatory approvals from the NMPA or other comparable regulatory authorities for our product candidates due to a number of reasons, including:

- disagreement in the design or implementation of our clinical trials;
- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- insufficient or suboptimal data collected from the clinical trials, or failure of our clinical trial results to meet the level of statistical and medical significance required for approvals;
- failure of our clinical trial process to pass the GCP inspections;

- unexpected changes in regulations, testing requirements, or approval policies that render our pre-clinical and clinical data insufficient for approvals;
- failure of our drug candidates to pass GMP inspections during the regulatory review process or across the production cycle of our drugs;
- failure of our clinical sites to pass audits carried out by the NMPA or other comparable regulatory authorities, resulting in a potential invalidation of our research data; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

In addition, the NMPA or other comparable regulatory authorities may require more information to support approval, including additional pre-clinical or clinical data, which may result in delay in or denial of regulatory approval. Furthermore, clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions, and regulatory approval in one jurisdiction does not mean that regulatory approval will be obtained in any other jurisdiction. Approval procedures vary among jurisdictions and can involve additional product testing and validation and additional administrative review periods. We cannot assure you that we will be able to meet regulatory requirements of different jurisdictions or that our product candidates will be approved for sale in those jurisdictions. Additional time, efforts and expenses may be required to bring our product candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes.

Failure to obtain regulatory approvals in a timely manner, or at all, or failure to obtain regulatory approvals with an intended scope of indications, could have a negative impact on the commercial prospects of our product candidates, and may cause reputational damage to us. Consequently, we would not be able to realize any revenue on such product candidate and we may need to incur additional expenses, which could materially and adversely affect our business, financial condition, results of operations and prospects.

Furthermore, regulatory authorities may revoke approval, approve our drug candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of post-marketing clinical trials, or may approve a drug candidate with a label narrower than what we desire. The NMPA and other comparable regulatory authorities have 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 pre-clinical, clinical or other studies. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

We cannot assure you that any of our drug candidates will successfully progress through the drug development process or become a commercially viable drug and any such failure could have a material adverse effect on our business, prospects, financial condition and results of operations.

We had not experienced any delay in the clinical development or regulatory approval process of our drug candidates as of the Latest Practicable Date, nor do we anticipate experiencing such delay.

The development process of innovative pharmaceutical products is typically lengthy, costly, and with uncertain outcome, and we may be unable to achieve the clinical development results of our drug candidates as we expect, or at all.

Clinical trials are expensive, difficult to design and implement, and can take years to complete, with uncertainty as to the outcomes. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including but not limited to:

- regulators may require that we or our investigators suspend or terminate clinical research for various reasons such as non-compliance with regulatory requirements;

- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;

- our drug candidates may lack meaningful clinical responses, which may expose the participants to unacceptable health and safety risks;

- our drug candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials;

- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;

- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;

- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- the costs of clinical trials of our drug candidates may be substantially higher than anticipated; and

- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, or if we are unable to successfully complete clinical trials of our drug candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may be delayed in obtaining regulatory approval for our drug candidates or not obtain regulatory approval at all, or obtain approval for proposed indications that are not as broad as intended. Our drugs could be required to be removed from the market after approval, or become subject to additional post-marketing testing requirements and/or restrictions on how they are to be distributed or used. Any of these events could have a material adverse effect on our business performance and prospects.

The pharmaceutical industry in China is highly regulated and such regulations are subject to change, which may affect approval and commercialization of our drug candidates.

We conduct our operations in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. For details on the current regulatory framework applicable to our current and planned business in China, please see "Regulatory Overview." In particular, to conduct clinical trials in China, we must apply for and obtain the NMPA's approval. The Center for Drug Evaluation ("**CDE**") under the NMPA reviews clinical trial applications, and may issue negative feedbacks or questions on such applications, which could result in the delay or denial of the NMPA's approval.

Moreover, the regulatory framework in China regarding the pharmaceutical industry has been under continuous reform. For example, in recent years, PRC regulatory authorities have been introducing new policies and measures with respect to the review, approval and regulation of pharmaceutical products, raising the standards for the review of each stage of the development of new drugs. Furthermore, rules and policies of the NMPA may be subject to amendments in the future, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. Any such changes or amendments may result in

increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the benefits we believe are available to us from developing and manufacturing drugs in China.

We may encounter various delays in the pre-clinical programs, clinical development and regulatory approval process, which may result in delays in, or suspension of, the commercialization of our drug candidates.

We may experience delays in completing our pre-clinical or clinical trials, and numerous unforeseen events could arise during, or as a result of, future clinical trials, which could delay or prevent us from receiving regulatory approval, including:

- we may encounter difficulties in enrolling sufficient participants for our clinical trials, enrollment may be slower than we anticipate, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate;

- our drug candidates may have undesirable side effects or unexpected characteristics, causing us or our investigators, regulators, institutional review boards ("**IRBs**") or ethics committees to suspend or terminate the trials, or reports may arise from pre-clinical testing or clinical trials of other drugs or therapies that raise safety or efficacy concerns about our drug candidates;

- our third parties including collaborators may not successfully carry out their contractual duties or meet expected deadlines;

- regulators, IRBs or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;

- we may experience delays in reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites, CROs, principal investigators ("**PIs**") or hospitals who conduct clinical trials on our behalf, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites, PIs and hospitals;

- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon drug development programs;

- third-party contractors used in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;

- the ability to conduct a companion diagnostic test to identify subjects who are likely to benefit from our drug candidates;

- we may elect to, or regulators, IRBs or ethics committees may require that we suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks; and

- the cost of clinical trials of our drug candidates may be greater than we anticipate.

Our drug development costs will also increase if we experience delays in testing or regulatory approvals, and we may run out of funding before a trial is complete, which could result in us having to delay or suspend the trial until sufficient funding is procured, or we would have to abandon developing the drug candidate completely. In addition, if we are required to delay clinical trials for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our products non-competitive. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant pre-clinical study or clinical trial delays also could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates. If we fail to achieve product development milestones as disclosed in this document, our business prospects might be adversely affected. Any of the above negative developments could have a material adverse effect on our business, financial condition and results of operations.

Results of earlier studies and clinical trials may not be predictive of results of later-stage clinical trials.

The results of pre-clinical studies and early clinical trials may not be predictive of the success of later phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily predict successful final results. Our drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits.

In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and demographics of the patient populations, including genetic differences, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. As drug candidates are developed through pre-clinical and clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Differences in the number of clinical trial sites and countries involved may also lead to variability between earlier and later-phase clinical trials. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives. In addition, our future clinical trial results may differ from earlier trials and may not be favorable. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. If so, we would have expended a significant amount of capital to progress the relevant drug candidates to that stage, and would not realize any revenue on such drug candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially and adversely affect our business, financial condition, results of operations and prospects.

A number of companies in the pharmaceutical industry have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in pre-clinical testing or early-stage clinical trials. Accordingly, results from completed pre-clinical studies and early-stage clinical trials of our drug candidates may not be indicative of the results that we may obtain in later stage trials, where such drugs may fail to show the desired safety and efficacy traits. Such variability in safety and/or efficacy results may be caused by numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Results may also differ from earlier trials due to the larger number of clinical trial sites and potentially different countries and populations involved in such trials.

Furthermore, data collected from pre-clinical studies and clinical trials involving one of our drug candidates may not be sufficient to support a conclusion of receiving regulatory approval from the NMPA or other comparable regulatory authorities required to market and distribute the drug.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that are currently contemplated, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates, if at all;
- ultimately obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements;
- encounter difficulties in obtaining, or be unable to obtain, reimbursement for use of certain drugs;
- be subject to restrictions on the distribution and/or commercialization of drugs; and/or
- have the drug removed from the market after obtaining regulatory approval.

Any of the above developments could result in a material adverse effect on our business, financial condition and results of operations.

Our drug candidates may cause undesirable adverse events.

Undesirable adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA and other comparable regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our clinical trials could be suspended or terminated and the NMPA and other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Drug-related adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims. Any of these occurrences may harm our reputation, business, financial condition, results of operations and prospects significantly.

In addition, if one or more of our drug candidates receive regulatory approval, and we or others later identify undesirable side effects caused by such drugs, it could result in a number of potentially significant negative consequences, including but not limited to, the following situations whereby:

- we may be forced to suspend marketing of the drug;
- regulatory authorities may withdraw approvals for the commercial sales of the drug;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop risk evaluation and mitigation measures for the drug or, if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under the risk evaluation and mitigation measures;
- we may be required to conduct post-market studies;

- we could be required to recall our products and be sued and held liable for harm caused to subjects or patients; and

- our reputation may suffer.

If our drug candidates prove to cause severe adverse effects before or after they are approved for sale, NMPA and other comparable regulatory authorities may require that we include black box warnings or contraindications in their package inserts, which could have an adverse impact on the commercialization of the relevant drugs.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

We may not be able to fully realize the potential of Pumecitinib and our other drug candidates as we planned.

Our Core Product, PG-011 (Pumecitinib), is currently focused on mild-to-moderate atopic dermatitis and seasonal allergic rhinitis. As of the Latest Practicable Date, we had completed the Phase IIb/III clinical trial of Pumecitinib gel for the indication of mild to moderate atopic dermatitis in adults and adolescents aged 12 to 17 years, and we also completed the final dosing in the Phase IIb/III clinical trial of Pumecitinib nasal spray for the indication of moderate-to-severe seasonal allergic rhinitis in adults. We are also planning to conduct research on the clinical development of indications for Pumecitinib such as prurigo nodularis and non-segmental vitiligo. In addition to our Core Product, we are also developing a number of other drug candidates, including PG-033 (for the indication of pruritus), PG-018 (for the indication of autoimmune kidney diseases), PG-040 (for the indication of glaucoma), and PG-312 (for the indication of urticaria).

We cannot ensure that our drug candidates will obtain approval for marketing as we planned. Should the pharmaceutical products approved for marketing fail to gain recognition from physicians, patients and relevant parties in the medical field, our product commercialization and business operations will be adversely affected.

We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

As we have limited financial and managerial resources, we focus our product pipeline on research programs and drug candidates that we identify for selected indications. For the year ended December 31, 2024 and 2025 and the four months ended April 30, 2025 and 2026, we incurred research and development expenses for Pumecitinib (including clinical trials of PG-011-AD, PG-011-AR, PG-011-NSV and PG-011-PN) of RMB88.7 million, RMB84.0 million, RMB22.0 million and RMB38.5 million, respectively, representing 60.7%, 65.4%, 60.6% and 70.6% of our total research and development expenses for the same period, respectively. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. Accordingly, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we cannot accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug 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 drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a collaboration arrangement.

If the research and development progress of our other products under development is not smooth, we may face the risk of reliance on limited number of products.

As of the Latest Practicable date, our Core Product, Pumecitinib gel, had completed Phase IIb/III clinical trial for the indication of mild-to-moderate atopic dermatitis in adults and adolescents aged 12 to 17, and we also completed the final dosing in the Phase IIb/III clinical trial of Pumecitinib nasal spray for the indication of moderate-to-severe seasonal allergic rhinitis in adults. Our other drug candidates under development may require extended periods of time before they enter into the NDA stage.

If the development and clinical trials of our other drug candidates do not develop as expected, we will rely on revenues generated from our Pumecitinib products after they are approved for sale. We cannot assure you that we will be able to generate revenue from these limited number of products at a satisfactory level, or at all. As such, our financial condition, results of operations and prospects may be materially and adversely affected.

Risks Relating to the Commercialization of Our Drug Candidates

We have no track record in launching and marketing drug candidates. If we are unable to further develop our marketing and sales capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not be able to generate revenue from our drug candidates.

We have not yet demonstrated the ability to launch and commercialize any of our drug candidates. As a result, our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer and cost more than it would if we were a company with experience launching and marketing drug candidates.

We compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing, and commercial distribution capabilities for any or all of our drug candidates, we will likely pursue collaborative arrangements regarding the sales and marketing of our drug candidates. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will provide us with effective sales forces for such drug candidates. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates.

There can be no assurance that we will be able to further develop and successfully maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaboration partners to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue, etc., which would materially adversely affect our business, financial condition, results of operations and prospects.

We had not experienced any delay in the commercialization of our drug candidates as of the Latest Practicable Date, nor do we anticipate experiencing such delay.

If our competitors develop therapies that are similar, more advanced, or more effective than ours, or launch innovative products and therapies ahead of us, our financial condition and results of operations and our ability to successfully commercialize our drug candidates could be materially and adversely affected.

The pharmaceutical industry is characterized by rapid technological change, and the development and commercialization of innovative drugs is highly competitive. We face competition from other pharmaceutical companies worldwide. There may be other pharmaceutical and

biopharmaceutical companies that are pursuing the development of drugs for the treatment of the same indications for which we are developing our drug candidates. Our competitors may have significantly greater financial, development, manufacturing, marketing, sales and supply resources or experience than we do. Our commercial opportunity and success will be reduced or eliminated, if any competing products become available that are more effective or cost-efficient than ours.

In particular, we face intense competition from existing products and product candidates under development for the treatment of atopic dermatitis, allergic rhinitis, and other diseases or symptoms that our drug candidates are intended for. For example, as of the Latest Practicable Date, there were four innovative topical drugs approved in China for the treatment of atopic dermatitis, and there are more than ten companies in China that are developing innovative topical drugs for atopic dermatitis; as of the same date, there were approximately 25 drug candidates under development in China for the indication of allergic rhinitis. As there are a number of other drug candidates currently in clinical trials in China and globally targeting the same or similar indications as our drug candidates, our development and commercialization of JAK inhibitor drugs may be adversely affected by some or all of such product candidates that receive regulatory approvals prior to or after we do.

If we cannot maintain or develop clinical collaborations and relationships with our principal investigators, key opinion leaders, physicians and experts, our results of operations and prospects could be adversely affected.

Our relationships with PIs, key opinion leaders ("**KOLs**"), physicians and experts play an important role in our research and development and marketing activities. We have established extensive interaction channels with PIs, KOLs, physicians and experts to gain first-hand knowledge of unmet clinical needs and clinical practice trends, which is critical to our ability to develop new market-responsive drugs. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with our PIs, KOLs, physicians and experts, or that our efforts to maintain or strengthen such relationships will yield the successful development and marketing of new products. These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. Moreover, we cannot assure you that our academic promotion and marketing strategy will continue to serve as an effective marketing strategy. Industry participants may no longer want to collaborate with us or attend our conferences, and our marketing strategy may no longer be able to yield results that are commensurate to our efforts spent. If we are unable to develop new drugs or generate returns from our relationships with industry participants as anticipated, or at all, our business, financial condition and results of operations may be materially and adversely affected.

We operate in a highly competitive environment, and we may not be able to compete effectively against current and future competitors, which could adversely affect our revenue and profitability.

We operate in a highly competitive environment. Failure to compete effectively could result in decrease in sales, lower prices and loss of market share, any of which could have a material adverse effect on our financial condition, results of operations and prospects. Our products are expected to compete primarily in terms of efficacy, safety, price and general market acceptance. Our competitors include large domestic and international pharmaceutical companies, as well as smaller emerging pharmaceutical and biotechnology companies. There are a number of potential competitors that currently market and sell drugs or are pursuing the development of drugs for the treatment of the same indications as our product candidates. In particular, we may face intense competition in the development of innovative drugs. Some of these competitors have better resources and expertise than us. The competitive landscape of our target market is constantly evolving with the introduction of next-generation treatments and advanced technologies, which could provide more effective or convenient treatment options. In light of the intense competition, we may not be able to compete effectively and obtain substantial market share. We anticipate that we will face increasing competition as new drugs enter the market and advanced technologies become available.

Our commercial opportunity could be significantly reduced or even eliminated if our competitors develop and commercialize drugs that are safer, more effective, more convenient, or less expensive than the drugs we may develop or commercialize. Our competitors also may obtain approval from the NMPA or other comparable regulatory authorities for their drugs 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. They may render our product candidates obsolete or non-competitive before we can recover expenses of developing and commercializing any of our product candidates.

Our products may also face increased competition from substitute products. To the extent that our competitors' substitute products are, or are perceived to be, more clinically or cost effective than ours, or otherwise gain wider market acceptance than any of our pharmaceutical products, this could adversely affect our sales volumes and pricing levels for the relevant products. If pharmaceutical products manufactured overseas are perceived more favorably than products manufactured domestically in the PRC, it could erode our market share and have a material adverse impact on our results of operations and prospects.

Successful sales and marketing are crucial for us to enhance our competitiveness, including our ability to increase the market penetration of our existing products, expand our coverage of hospitals and other medical institutions and promote new products. If we are unable to increase or maintain the effectiveness and efficiency of our sales and marketing activities, our sales volume and business prospects could be adversely affected.

In addition, there may also be significant consolidation in the pharmaceutical industry among our competitors, or alliances developed among competitors that may rapidly acquire significant market share. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative or licensing arrangements with large and established companies. If we fail to effectively compete with our competitors or adjust to structural changes in the pharmaceutical industry, our revenue and profitability may be materially and adversely affected.

Negative results from off-label use of our future approved products and counterfeit pharmaceutical products could materially harm our business reputation, product brand image and financial condition and expose us to liability.

If we successfully commercialize any of our candidates, such approved products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a formulation that is not in accordance with regulatory approved usage and labeling. Even though the NMPA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our drug candidate, upon regulatory approval, may be subject to off-label use and is prescribed in a patient population, dosage or formulation that has not been approved by competent authorities. This occurrence may render our drug candidate less effective or entirely ineffective and/or may cause unexpected adverse drug reactions. Any of these occurrences could create negative publicity and significantly harm our reputation, brand image, business operations, financial condition, results of operations and prospects. These occurrences may also expose us to liability and cause a delay in the progress of our clinical trials and may also ultimately result in delay in or failure to obtain regulatory approval for our drug candidates.

In addition, certain drug products distributed or sold may be manufactured without proper licenses or approvals or be fraudulently mislabeled with respect to their contents or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. As counterfeit pharmaceutical products in many cases resemble the authentic pharmaceutical products yet are generally sold at lower prices, any counterfeiting of our future approved drug could reduce their market demand if not timely prevented by relevant government authorities. In addition, counterfeit

pharmaceutical products are unlikely to meet our or our rigorous manufacturing and testing standards, and may even cause health damage to patients. Our reputation, business operations, financial condition, results of operations and document could suffer as a result of counterfeit pharmaceutical products.

If our products are not included in or are removed from national, provincial or other government sponsored medical insurance programs, our business, financial condition, results of operations and prospects could be materially and adversely affected.

The successful commercialization of our drugs after they are approved depends in part on the extent to which reimbursement for these drugs and related treatments will be available from relevant health administrative authorities, private health insurers and other organizations. The regulations that govern reimbursement for new therapeutic drugs vary substantially from country to country. In China, the *National Reimbursement Drug List* ("**NRDL**") and *Provincial Reimbursement Drug Lists* ("**PRDL**") include drugs under the *National Medical Insurance Catalogue*, which affect the amounts reimbursable to program participants for those drugs. There can be no assurance that Pumecitinib or any of our drug products will be included in the NRDL or the PRDL after approval for commercial sale. Compared to generic and essential drugs, innovative drugs, such as our drug products, may be subject to limitations on their inclusion in the NRDL or the PRDL due to cost constraints. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL or the PRDL, our revenue from commercial sales would be highly dependent on patient self-payment, which can make our products less competitive.

Government authorities and third-party payers, such as private health insurers and healthcare organizations, decide which medications they will pay for and stipulate reimbursement levels. With the trend of cost containment in the global healthcare industry, government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. There are an increasing number of third-party payers requiring companies to provide them with predetermined discounts from list prices and challenging the prices charged for medical products. There can be no assurance as to whether or to what extent reimbursement will be available for Pumecitinib or any drug we commercialize in the future. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approvals. Obtaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a doctor. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize Pumecitinib or any drug candidate that we have developed.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the indications and purposes for which the drug candidates are approved by the NMPA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may be subject to change. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for drugs with lower cost that have been covered in reimbursement policies, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by governmental healthcare programs or private payers and by any future lift or relaxation of laws and regulations that presently restrict imports of drugs from countries where they may be sold at lower prices than in the jurisdictions in which we operate or have a presence. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, financial condition, results of operations and prospects.

The pricing of our products may be subject to pressure from procurement practice of national or other third-party reimbursement programs, healthcare reform initiatives or unfavorable pricing regulations, which could harm our business.

In China, the pricing of prescription pharmaceutical products is subject to continuing governmental supervision. For example, centralized procurement in China has strong bargaining power over pricing of pharmaceutical products. The price of our products, after they are commercialized, may be affected by the centralized procurement process. Our products may also become subject to reimbursement practices, healthcare reform initiatives, or unfavorable price regulations after they are commercialized. Adverse pricing limitations may hinder our ability to recoup our investment in our product candidates.

Relevant government authorities in China have implemented policies that aim to further increase the affordability of pharmaceutical products. In the future, the relevant authorities may continue to implement policies which limit the prices that hospitals, clinics, and other medical practitioners can charge for our products, which in turn would limit the prices that we can charge them and adversely affect our profitability. There may also be other reform measures on the tender process for pharmaceutical products or other policies affecting pharmaceutical prices, which may result in downward adjustments to the prices of our commercialized products, and may in turn adversely affect our revenue, and profitability. As China's healthcare system as a whole has undergone continuous reform in recent years in respect of insurance coverage, access to medical products and services, and the role of the private sector in product development, we cannot predict if or when the relevant authorities will amend the policies regarding prices of pharmaceutical products, or if additional pharmaceutical products may become subject to price limits and/or more stringent insurance reimbursement limits. Any negative developments in respect of the above could have a material adverse effect on our business, financial condition, and results of operations.

The market opportunities for our drug candidates may be smaller than we anticipate, which could render some drug candidates ultimately unprofitable.

We estimate the incidence and prevalence of target patient populations for particular diseases based on various third-party sources, such as scientific literature, surveys of clinics, patient foundations or market research, as well as internally generated analyses, and we use such estimates in making decisions regarding our drug development strategy, including determining which candidates to focus our limited resources on in pre-clinical or clinical trials. These estimates may be inaccurate or based on imprecise data. The total addressable market opportunity will depend on, among other things, acceptance of the drug by the medical community and patient access, drug pricing, reimbursement and the availability of alternative treatments. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or access.

Furthermore, new studies may change the prevailing estimate of incidence or prevalence of diseases, and the number of addressable patients for our drug candidates in any case may turn out to be lower than expected. In such cases, we may never achieve profitability without obtaining regulatory approval for additional indications. Any of the above unfavorable developments could have a material adverse effect on our business, financial condition and results of operations.

We may not be successful in our efforts to identify, discover or license-in new drug candidates to build or maintain our product pipeline, or license-out our existing drug candidates.

We may fail to identify, discover or license-in new drug candidates for clinical development for a number of reasons. For example, with respect to identifying and discovering new drug candidates for development in-house, our research methodology may be unsuccessful in identifying potential drug candidates or those we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Research programs to pursue the development of our drug candidates for additional indications and to

identify new drug candidates and disease targets require substantial technical, financial and human resources whether or not we ultimately are successful. We may consider licensing-in promising drug candidates to add to our pipeline in the future. Regardless of whether we develop new drug candidates in-house or license-in, our R&D efforts may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including:

- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or

- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our drug candidates, develop suitable potential drug candidates through internal research programs, or successfully license-in drug candidates at favorable commercial terms or at all, any of which could materially adversely affect our future growth and prospects. Even if we are able to identify, discover or license-in the drug candidates that we target, we cannot assure you that the product will be successfully commercialized. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

Furthermore, we may license-out our existing drug candidates to other drug developers, or otherwise collaborate with third parties on our existing drug candidates. We cannot assure you that when we license-out drug candidates, we will successfully be able to do so, or that any such partner will be able to successfully promote or commercialize products licensed from us, which in turn could adversely affect the benefits that we may achieve from such arrangement. If we are unable to successfully identify a licensee partner for a particular drug candidate and are not able to further develop such drug candidate in-house, we may not be able to recover our investment in that product.

Even after we successfully license-in or license-out drug candidates, we cannot assure you that our licensors or licensees will not breach the relevant license agreements, whether inadvertently or otherwise. Alternatively, our licensors or licensees might conclude that we have materially breached our license agreements. In either case, the license agreements may be terminated, thereby stopping us from developing and commercializing the drug candidates we licensed-in or generate licensing fees and royalties from the drug candidates we licensed out.

Risks Relating to Our Intellectual Property Rights

We depend on patents, trade secrets and other forms of intellectual property protections, but these protections may not be adequate.

We rely on a combination of patent, trade secret and other intellectual property laws in China to protect our intellectual property. However, intellectual property right protections may not prove meaningful against competitive offerings or otherwise be commercially valuable and, as such, our patents may be challenged in courts and patent offices. Such challenges may result in the relevant patents being narrowed in scope, invalidated, or held unenforceable, in whole or in part, which could limit the ability of us or our licensors to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration for the patent protection of the relevant technology and product candidate.

Obtaining and maintaining patents require the payment of fees such as annual fees and various other governmental fees in several stages over the lifetime of a patent, and compliance with a number of procedural, documentary, and other similar provisions during the patent application

process. We may rely on our outside counsel to help us comply with these requirements. There are situations in which non-compliance can result in abandonment, loss of priority, or lapse of the patent or patent application, resulting in partial or complete loss of patent rights.

As a result of actual or threatened patent infringement claims, we could also be prevented from entering into licenses on commercially acceptable terms or at all. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, *inter partes* review, derivation or post-grant proceedings regarding intellectual property rights with respect to our current or future products. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights. This could have a material adverse effect on our business, financial condition, and results of operations. Moreover, successful patents may not issue in a form that will provide us with any meaningful protection against competitors who may be able to circumvent our patents by developing similar or alternative technologies or product candidates in a non-infringing manner.

In addition, we cannot assure you that we will be successful in obtaining additional intellectual property or enforcing our intellectual property rights against unauthorized users. We also rely on unregistered proprietary rights, including know-how and trade secrets related to development, manufacturing, and distribution of our products and product candidates. Agreements entered into between us and our employees and other third parties prohibiting them from disclosing proprietary information or technology may not provide meaningful protection, and may not effectively prevent leakage or unauthorized disclosure of trade secrets and other proprietary information. Furthermore, third parties who are not party to our confidentiality agreements may obtain access to our trade secrets or know-how, and others may independently develop similar or equivalent trade secrets or know-how. The disclosure or use of our intellectual properties or technologies by others, including our competitors, could reduce or eliminate any competitive advantage we have developed, cause us to lose sales opportunities or otherwise harm our competitive position, which could have a material adverse effect on our business, financial condition, and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annual fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA in several stages over the lifetime of a patent. The CNIPA also requires compliance with a number of procedural, documentary, and other similar provisions during the patent application process. We may rely on our outside counsel to help us comply with these requirements. There are situations in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Third parties could be able to circumvent our patents by developing similar or alternative products and technologies in a non-infringing manner, and our ability to successfully commercialize any product or technology would be materially adversely affected.

Our drug candidates face competition from other medications. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, we may not be able to realize the full potential of the relevant drug candidate in an exclusive manner, which would have a material adverse effect on our future revenue and profit from that drug.

Patent terms may not be adequate to protect our competitive position on our drug candidates in the absence of patent linkage, patent term extensions and other exclusivities. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed. Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.

The life of a patent and the protection it affords is limited. For example, the expiration of a patent is generally 20 years for invention in China. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates. For the expiration dates of our issued patents for our drug candidates, please see "Business — Intellectual Property."

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected. There can be no assurance that the applicable authorities will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business could be harmed.

Our patent rights relating to our drug candidates could be found invalid or unenforceable if challenged.

Our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the CNIPA or the applicable foreign counterpart, or made a misleading statement, during prosecution. There is no assurance that we may always prevail in legal assertions of invalidity and unenforceability.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a drug candidate. Our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The court may decide not to grant an injunction against further infringing activities and instead award only monetary damages, which may not be an adequate remedy. In addition, if the breadth or strength of protection provided by our owned patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Any loss of patent protection could have a material adverse impact on one or more of our drug candidates and our business.

If we are unable to protect the confidentiality of our trade secrets and confidential information, our business and competitive position could be harmed.

In addition to our issued patents and pending patent applications, we rely on our trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaboration partners, outside scientific collaboration partners, sponsored researchers, contract manufacturers, consultants, advisors and other third parties that have access to them.

However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements may breach the terms of any such agreements and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be adversely affected.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, or claims asserting ownership of what we regard as our own intellectual property.

Our employees, consultants and advisors, including our senior management, may currently be, or were previously employed at other pharmaceutical companies or research institutions, including our competitors or potential competitors. Some of these employees, consultants, and advisors, including each member of our senior management, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we, our employees, consultants and advisors, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Litigation could result in substantial costs and be a distraction to our employees and management.

We may be unsuccessful in executing the agreements assigning intellectual property to us with our employees, consultants and contractors who in fact develop intellectual property that we regard as our own. Furthermore, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights.

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar drug candidates or technology, without payment to us, or could limit the duration of the patent protection covering our drug candidates and technology. Such challenges may also result in our inability to develop, manufacture or commercialize our drug candidates without infringing third-party patent rights. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Intellectual property and other laws and regulations are developing, which could diminish the value of our intellectual property and impair the intellectual property protection of our drug candidates.

Our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity and is costly, time-consuming and inherently uncertain. Developments in either the patent laws or their interpretation in different jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights. Our existing patent rights and future patent applications may face certain potential influence.

We may from time to time be involved in legal proceedings and disputes to protect or enforce our intellectual property rights, or defend against infringement and other claims alleged by third parties, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our intellectual property rights. To counter infringement, misappropriation, or any other unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we have infringed, misappropriated, or otherwise violated their intellectual property rights. We may not be able to prevent third parties from infringing upon, misappropriating, or otherwise violating our intellectual property rights. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at the risk of being invalidated, held unenforceable, or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our trade secret or other confidential information could be compromised by disclosure

during this type of litigation. Any failure by us to prevent the misappropriation or disclosure of our proprietary information could materially and adversely affect our business, financial condition, results of operations and prospects.

If we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties or engaging in unfair competition, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Defending ourselves against third parties' intellectual right infringement allegations, meritorious or not, would be expensive and time consuming, and would be a substantial diversion of our resources and our management team's attention. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

In the event that third parties assert infringement claims against us, there is no assurance that the outcome would be in our favor. If we were found by courts or other competent authorities to have infringed on the patent or other intellectual property rights of third parties, we may be subject to injunctive or other court order or judgement, which could prevent us from developing and commercializing our drug candidates, or at least delay the development or commercialization process. Our involvement in such proceedings may attract publicity, thereby having a substantial adverse effect on our reputation and brand name, which could have a substantial adverse effect on the [**REDACTED**] of our shares. Such litigation or proceedings could also substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In the event of a successful claim against us of infringement, misappropriation, or other violation of intellectual property, or a settlement by us of any such claims, we may have to pay substantial damages. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. Any such license might not be available on reasonable terms or at all. A license could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly.

Our brand name has not been registered as trademark in China and therefore may not be adequately protected. This could adversely affect our ability to build brand recognition in our intended market, and our reputation and business could be adversely affected.

We conduct our business under the brand name of "普祺醫藥." As of the Latest Practicable Date, 普祺醫藥 had not been registered as trademark in China. As a result, we may be unable to prevent others from using the same or similar brand name in their business activities, including on products similar to ours. Furthermore, the Chinese expression of 普祺 has been registered as a trademark by an Independent Third Party in China on product types similar to ours. As such, we could be prevented from using our desired brand name on our own products or in our own business activities, which could materially adversely affect our ability to build brand recognition in our intended market, and, as a result, our business and prospects. As our drug candidates mature and obtain regulatory approval in the future, we expect the importance of our brand name will further increase in order to differentiate us from our competitors. If we are unable to use our desired brand name on our products after they are approved, our business and prospects could be materially adversely affected.

Risks Relating to Our Reliance on Third Parties

We work with various third parties to develop our drug candidates, such as those who help us conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.

As is common practice in the industry, we have worked with and plan to continue to work with third-party collaborators, such as CROs and CMOs, to generate, monitor, and manage data for our ongoing pre-clinical and clinical programs and to manufacture the drug samples used in pre-clinical studies and clinical trials. As our relationship with CROs and CMOs is contractual in nature, we may have limited control over their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements, and scientific standards, and our collaboration with the CROs and CMOs does not relieve us of our regulatory responsibilities. We, our CROs and CMOs for our pre-clinical and clinical programs, and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the NMPA and other comparable regulatory authorities for all of our drugs in clinical development. If we or any of our CROs, CMOs or clinical investigators fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with products produced under GMP regulations. Failure to comply with these regulations by us or our CMOs may require us to repeat clinical trials, which would delay the regulatory approval process.

If our relationships with our third-party collaborators terminate, we may not be able to enter into arrangements with alternative replacements or do so on commercially reasonable terms. In addition, our third-party collaborators are not our employees, and except for remedies available to us under our agreements with such CROs and CMOs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. If our third-party collaborators do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality of our drug samples or the accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or sourcing new third-party collaborators involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business. In light of the foregoing, any failure of our third-party collaborators to carry out their contractual duties or meet expected deadlines could materially adversely affect our business, financial condition, results of operations and prospects.

We may rely on third parties to manufacture our drug candidates. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

We currently rely on third parties to manufacture our drug candidates for their development and clinical trials. Reliance on third-party manufacturers would expose us to additional risks, including:

- we may have little control over the manufacturing process and quality control over such third-party manufacturers;

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and GMP-compliance inspections by the NMPA or other comparable regulatory authorities;

- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs;

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;

- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- manufacturers may infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;

- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and

- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or materially adversely impact commercialization of our future approved drug candidates. In addition, we may rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on us until deficiencies are remedied.

We have a limited number of suppliers for major purchases during the Track Record Period and the loss of one or more key suppliers could disrupt our operations.

For the year ended December 31, 2024 and 2025 and the four months ended April 30, 2026, purchases from our five largest suppliers for each year in the Track Record Period accounted for 30.6%, 27.1% and 19.8% of our total purchases, respectively, and purchases from our largest supplier accounted for 11.0%, 7.7% and 5.9% of our total purchases, respectively. See "Business — Our Suppliers" for further details. We believe that we have stable relationships with our existing suppliers. However, the stability of operations and business strategies of our suppliers are beyond our control, and we cannot assure you that we will be able to secure a stable relationship with such suppliers. If any of our major suppliers terminates its business relationship with us, we may encounter difficulty in finding a replacement that can provide alternative products and on terms acceptable to us. If this occurs, our business, financial condition, and results of operations may be adversely affected.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We incurred net losses during the Track Record Period and we may continue to incur losses in the near future and may not achieve or maintain profitability. **[REDACTED]** ***are at risk of losing substantially all of their*** **[REDACTED]** ***in our H Shares.***

[REDACTED] in pharmaceutical drug development is highly risky. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We continue to incur operating loss related to our ongoing operations. We have incurred losses in each period since our inception. See "Financial Information." Potential **[REDACTED]** may lose substantially all their **[REDACTED]** in us given the high risks involved in our business.

As of the Latest Practicable Date, none of our drug candidates had been approved for marketing and sale in any jurisdiction. We have not generated any revenue from the sale of pharmaceutical products, and we will continue to incur significant R&D and other expenses related to our on-going operations. We expect to continue to incur losses in the foreseeable future. Typically, it takes many years to develop a new drug from the time it is discovered to when it is available for treating patients. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved drug candidates, our ability to generate revenue and the timing and amount of milestones and other payments we make or receive with or through arrangements with third parties. If any of our drug candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance and commercialization, we may never become profitable. Our failure to become and remain profitable may affect **[REDACTED]** perception of our potential value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. Any decline in our value could also cause you to lose all or part of your **[REDACTED]**.

We had net cash outflow from operating activities throughout the Track Record Period and we will likely need substantial additional funding for our drug development and commercialization efforts, which may not be available on acceptable terms, or at all.

Our operations have consumed substantial amounts of cash since our inception. Due to our negative operating cash flow, we have needed external financing throughout our operating history, which we have financed primarily through private placements.

Our expenses may increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our various clinical stage drug candidates, continue research and development of our pre-clinical stage drug candidates, initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates and expand our manufacturing capability. Our future capital requirements will depend on many factors, including:

- the number and development requirements of the drug candidates we pursue;
- the scope, progress, timing, results and costs of researching and developing our drug candidates, and conducting pre-clinical and clinical trials;
- the cost, timing and outcome of regulatory review of our drug candidates;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive regulatory approval;

- any cash received from commercial sales of any drug candidates for which we receive regulatory approval;
- our ability to establish and maintain strategic partnerships, collaboration, licensing or other arrangements and the financial terms of such agreements;
- the cost, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or license other drug candidates and technologies; and
- our headcount growth and associated costs.

Moreover, as we obtain regulatory approval for our clinical stage drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In particular, the costs required for the manufacture of any drug candidate that receives regulatory approval may be substantial as we would have to undertake substantial expansion plans for our manufacturing facilities. Our current manufacturing expansion plans will require substantial capital investments, which we intend to finance primarily through additional bank loans and cash generated from operations. However, financing may be unavailable in amounts or on terms acceptable to us. If we are unable to raise capital when needed or on acceptable terms, we could incur losses and be forced to delay, reduce or terminate our research and development programs or any future commercialization efforts, which could have a material adverse effect on our business, financial condition and results of operations. Furthermore, the sale of additional equity or equity-linked securities could result in dilution to the Shares held by our Shareholders. The incurrence of indebtedness would result in increased debt service obligations and could result in operating and financing covenants restricting our operations or our ability to pay dividends, which in turn could have a material adverse effect on our business, financial condition and results of operations.

We have historically received government grants, subsidies and other preferential policies for our R&D and other activities and enjoyed preferential tax treatment during the Track Record Period. Expiration of, or changes to, these incentives or policies or our failure to satisfy any condition for these incentives would have an adverse effect on our results of operations.

In the past, local governments in China granted certain financial incentives from time to time to us as part of their efforts to encourage research and development activities, and we recognized government grants of RMB9.9 million, RMB35.5 million, RMB0.5 million and RMB3.9 million, respectively, for the year ended December 31, 2024 and 2025 and the four months ended April 30, 2025 and 2026, respectively. The timing, amount and criteria of government financial incentives are subject to the discretion relevant government authorities and cannot be predicted with certainty. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives in the future. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

Our ability to generate revenue from sales of drug products and become profitable depends significantly on our success in a number of factors that affect the sales volume, pricing levels and profit margins of such drug products, such as competition or change in market environment.

Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including but not limited to:

- obtaining regulatory approvals and marketing authorizations for drug candidates for which we complete clinical trials;
- launching and commercializing Pumecitinib and other drug candidates for which we obtain regulatory approvals and marketing authorizations;
- completing research regarding, and nonclinical and clinical development of, our drug candidates;
- developing a sustainable and scalable manufacturing process for Pumecitinib and other drug candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing facilities;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new drug candidates, intellectual property and technologies;
- collaborating with business development partners and their ability to successfully promote and market our products;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trademarks, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

We cannot guarantee that we will be able to obtain regulatory approvals for any of our drug candidates in a timely manner, or at all. Substantial investments may be incurred before and after we generate any revenue from product sales. Even though we have received the regulatory approval or if our drug candidates are approved for commercial sale, we expect to continue incurring significant costs associated with the manufacturing and the commercial launch of the drug products. Moreover, our expenses could increase beyond expectations if we are required by the NMPA or other applicable authorities to perform studies in addition to those that we currently anticipate.

Considering the regulatory approval for Pumecitinib and the potential approval to market one or more of our drug candidates in the future, our revenue will depend on factors that affect the sales volume, pricing level or profitability of such approved products. Factors that could adversely affect the sales volumes, pricing levels and profitability of the products we sell include: exclusion from, or reduced coverage under, the national, provincial or other government-sponsored medical insurance programs, the impact of government pricing regulations, sales of substitute products by competitors, interruptions in the supply of raw materials, increases in the cost of raw materials, issues with product quality or side effects, intellectual property infringements, adverse changes in our sales and distribution network, and unfavorable policy, regulatory or enforcement changes. Many of these factors are outside of our control, and any factor adversely affecting the sales volumes, pricing levels and profit margins of our products could adversely affect our operations, revenue and profitability.

OTHER RISKS RELATING TO OUR OPERATIONS

Any failure to obtain, maintain, or renew various licenses and permits or to comply with applicable laws and regulations and industry standards, or any change to the applicable laws, regulations or industry standards could harm our reputation and business, results of operations and prospects.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or impose fines and penalties which could materially and adversely affect our business, financial condition and results of operations. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change in the future, and there can be no assurance that we will be able to meet new criteria that may be imposed. If the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect our business, results of operations and prospects.

We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.

We routinely obtain and manage clinical trial related-data through clinical research organizations, who apply de-identification methods such as coding and replacing full names with initials before transmitting these data to us. As such, we are subject to the relevant national and international data protection and privacy laws, directives, regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officers and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects' private or medical records without their consent, they will be held liable for damage caused thereby. The personal information of patients or subjects for our clinical trials is highly sensitive and we are subject to strict requirements under the applicable privacy protection regulations in the relevant jurisdictions. Whilst we have adopted security policies and measures to protect our proprietary data and patients' privacy, privacy leakage incidents might not be avoided due to hacking activities, human error, employee misconduct or negligence or system breakdown.

Furthermore, our clinical trials also frequently involve professionals from third-party institutions working onsite with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. We also cooperate with third parties including CROs/SMOs, principal investigators, hospitals and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure.

In addition, any development in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could have a material adverse effect on our business, financial condition and results of operations.

Our business depends on our senior management members and other key personnel. If we fail to retain our key senior management members and other key personnel, or to attract, retain and train qualified personnel, our business prospects could be adversely affected

Our success depends heavily upon the continued services of our senior management members, key R&D personnel and key sales and marketing personnel. In particular, the industry experience, management expertise and contributions of our Directors and other members of our senior management are crucial to our success. They play a crucial role in the development and commercialization of our products and realization of the potential benefits of our intellectual property. In addition, the future success in the sale of our products depends on the dedication and skills of our sales and marketing personnel. Accordingly, our ability to attract and retain key personnel is a critical factor in our competitiveness.

Our employment agreements with senior management members do not prevent our executives from terminating their employment with us at any time. We do not maintain any key person insurance. If we lose the services of any key personnel, we may be unable to recruit a suitable or qualified replacement and may incur additional expense to recruit and train new personnel, which could disrupt our business and growth. In addition, if any of our key personnel joins a competitor or forms a competing business, we may lose know-how, trade secrets and customers.

Furthermore, as we expect to continue expanding our operations and product portfolio, recruiting, retaining and training qualified R&D, manufacturing and quality management, and sales and marketing personnel will be critical to our success. We will need to continue attracting and retaining personnel with extensive experience and industrial knowledge. We may also need to hire, train and manage individuals with expertise that is separate, supplemental or different from expertise that we currently have. Competition for these individuals in the pharmaceutical industry is intense and could cause us to offer higher compensation and other benefits in order to attract and retain them, thereby increasing our operating costs and in turn, materially and adversely affecting our financial condition and results of operations. If we are unable to attract, motivate, train and retain these key personnel required to achieve our business objectives, our business prospects could be adversely affected.

We may encounter difficulties in successfully managing our growth and expanding our operations.

Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage our growth. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

As our development and commercialization plans and strategies evolve, we must hire additional managerial, operational, manufacturing, financial and other personnel. Our recent growth and any future growth will impose significant additional responsibilities on our management, including but not limited to:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- continuing to innovate and develop advanced technologies in the highly competitive pharmaceutical industry;
- managing our relationships with third parties, including suppliers and collaboration partners;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and business partners as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals. Our failure to do so could materially and adversely affect our business, financial condition, results of operations and prospects.

We may be subject to product liability lawsuits that could cause us to incur substantial liabilities and adversely affect our business, financial condition, results of operations and reputation.

We face an inherent risk of product and professional liability as a result of the clinical testing and any future commercialization of our product candidates inside and outside China. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against the claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- adverse effect on our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulatory authorities;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;

- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any approved product candidate; and
- a decline in the [**REDACTED**] of our H Shares.

To cover such liability claims arising from clinical trials, we purchase clinical trial insurance to cover adverse events in our clinical trials. It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If we are unable to defend ourselves against such claims, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our products are found to be defective. In addition, we may be required to recall the relevant products, suspend sales or cease sales. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

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 materially adversely affect 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 may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may produce hazardous waste products. We may 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, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

In addition, we may be required to incur substantial costs 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. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

We are subject to comprehensive construction project approval, acceptance and filing requirements, and may be exposed to compliance costs, rectification obligations and/or potential liabilities.

Under PRC laws and regulations, construction projects are subject to a broad range of approvals, filings and acceptance procedures before commencement and before the relevant facilities are put into use. Our current research facility, which is located in one of our leased properties in Beijing, did not fully comply with the applicable approval or acceptance requirements during its renovation in 2019. Such historical non-compliance primarily include failure to obtain the construction permit and to conduct the completion acceptance procedure. Failure to obtain such permits or conduct such acceptance procedure may give rise to administrative actions by the relevant local authorities, including fines and mandatory remedial actions.

We cannot assure you that the competent authorities will not impose penalties, require remedial measures or impose operational restrictions on us as a result of such non-compliance. There is also no assurance that additional or more stringent approval, acceptance or safety requirements will not be imposed in the future, or that we will be able to fully comply with all such requirements in a timely manner.

Failure to comply with the labor and social insurance-related laws and regulations may adversely affect our business, financial condition, and results of operations

The PRC government has issued various labor-related regulations to further protect the rights of employees. Companies operating in China are required to complete related registration with the competent authorities and contribute to the government-sponsored employee benefits plans in amounts equal to certain percentages of salaries, including bonuses and allowances, of employees up to a maximum amount specified by the local government from time to time at locations where our employees are based. We provide social security insurance as required by relevant rules and regulations in China, including but not limited to general care and work-related injury insurance, for our employees.

The interpretation and implementation of the Labor Contract Law, Social Insurance Law, and related regulations in China are continually changing. These changes make it difficult to predict compliance outcomes. We cannot guarantee that authorities won't demand settlement of shortfall amounts within a deadline or impose penalties. Non-compliance could result in fines, charges, or other regulatory actions, adversely impacting our business and financial condition.

Our insurance coverage may not completely cover the risks related to our business and operations, which could expose us to significant costs and business interruptions.

Our operations are subject to hazards and risks associated with our research and development, as well as other aspects of our operations, which may cause significant harm to persons or damage to properties. We maintain different types of insurance policies, including social insurance for our employees and personal accident insurance. However, there is no assurance that our insurance policies will be adequate to cover all losses incurred. Losses incurred and associated liabilities may have a material adverse effect on our results of operation if such losses or liabilities are not covered by our insurance policies.

Currently, we maintain insurance coverage against liabilities arising from adverse events in clinical trials. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our drug candidates and drugs if there were a catastrophic event or failure of our manufacturing facilities or processes. Any of the foregoing would materially adversely affect our business, financial condition, results of operations and prospects.

We may be subject to disasters, health epidemics, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Natural disasters, acts of war, terrorism or other force majeure events beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the jurisdictions where we conduct our business. Our operations, and those of our collaboration partners, suppliers and other third parties, may be under the threat of natural disasters such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, force majeure events such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or potential wars or terrorist attacks. The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments could materially disrupt our business and operations.

There also could occur serious natural disasters, which may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, disaster, epidemics, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. As we rely on third parties on various services and supplies, the occurrence of any of the foregoing events could seriously harm ability to obtain services or supplies if such third parties are affected by disasters, epidemics, business interruptions and other force majeure events. In addition, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. Acts of war or terrorism may also injure our employees, disrupt our business network and destroy our markets. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition, results of operations and prospects.

We are subject to risks associated with leasing space.

As of the Latest Practicable Date, we leased seven real properties for business operation, which are mainly used as our office, research and development facilities and future manufacturing facility. We may not always be able to renew our leases upon their expiration, either on commercially acceptable terms or at all, which could compel us to relocate. Our inability to enter into new leases or renew existing leases on terms acceptable to us could cause material disruption to our business operations, thereby materially and adversely affecting our business, financial condition and results of operations.

In addition, as of the Latest Practicable Date, we had not registered one of our property leases as required by applicable PRC laws. As registration of the lease agreement will require the cooperation of the landlord, there is no assurance that we can complete the registration of such lease agreement in a timely manner or at all. Our PRC Legal Advisor advised us that the failure to register the lease agreement for our leased property in the PRC will not affect the validity of this lease agreement, but if we fail to complete the registration within the prescribed time frame as required by competent municipal land and real estate administration departments in the PRC, a penalty ranging from RMB1,000 to RMB10,000 may be imposed against us for each unregistered lease. If we are demanded to complete any such registration and fail to do so, we may be subject to fines.

Our Controlling Shareholders have significant influence over us and their interests may not always be aligned with the interest of our other Shareholders.

Prior to and immediately following the completion of the [**REDACTED**], our Controlling Shareholders will remain having substantial control over our Company. Subject to the Articles of Association and the PRC Company Law, the Controlling Shareholders will be able to exercise significant control and exert significant influence over our business or otherwise on matters of significance to us and other Shareholders by voting at the shareholders' meeting and at Board meetings. The interest of the Controlling Shareholders may differ from the interests of other Shareholders and they are free to exercise their votes according to their interests. To the extent that the interests of the Controlling Shareholders conflict with the interests of other Shareholders, the interests of other Shareholders can be disadvantaged and harmed.

RISKS RELATING TO CONDUCTING BUSINESS IN THE JURISDICTION WHERE WE OPERATE

We are subject to political, economic and social developments as well as the laws, rules, regulations and licensing requirements in China, and any disruptions in these respects may materially affect us.

Our businesses, assets and operations are located in or derived from our activities in the PRC, and as a result, our business, financial condition and results of operations are subject, to a significant degree, to the economic, political, social and regulatory environment in the PRC. We are unable to accurately predict the precise nature of all the risks and uncertainties that we face and many of these risks are beyond our control.

In recent years, the PRC government has implemented measures emphasizing the utilization of market forces in economic reform and the establishment of sound corporate governance practices in business enterprises. These economic reform measures may be adaptively adjusted from industry to industry or across different regions of the country. Changes in China's business environment and changes in the business environment in jurisdictions we may operate in the future could have a material impact on our business, results of operations and financial condition.

Our performance will continue to be affected by the PRC economy, which in turn is influenced by the global economy. Trade wars among major economies may affect the availability and cost of various imported goods, including potentially equipment and materials which we rely on in our operations. Most notably, the United States government has made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs which have led to other countries, including China and members of the EU, imposing tariffs against the United States in response. These trade wars may escalate going forward and may result in certain types of goods, such as advanced R&D equipment and materials, becoming significantly more expensive for us to procure from overseas suppliers or even becoming illegal to export.

Any of the above factors may materially and adversely affect our business, financial condition and results of operations.

There might be uncertainties in effecting service of legal process and enforcing foreign judgments or bringing actions against us and our management.

Currently, all of our assets are located in the PRC. As a result, it may be difficult for the investors to directly effect service of process upon us in the PRC.

On January 18, 2019, the Supreme People's Court and the government of the Hong Kong Special Administrative Region entered into the *Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region* (關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排) (the "**Arrangement**"), which establishes a mechanism with further clarification on and certainty for reciprocal recognition and enforcement of judgments in a wider range of civil and commercial matters between Chinese mainland and Hong Kong. The Arrangement has come into effect on January 29, 2024. Pursuant to the Arrangement, a judgment rendered by a Hong Kong court can generally be recognized and enforced in the PRC even if the parties in the dispute do not enter into a choice of court agreement in writing. However, we cannot guarantee that all judgments made by Hong Kong courts will be recognized and enforced in the PRC, as whether a specific judgment will be recognized and enforced is still subject to a case-by-case examination by the relevant court in accordance with the New Arrangement.

We may face risks from transferring scientific data.

Enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term state secret is not clearly defined, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad or to any foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the applicable requirements, we may be subject to fines and other administrative penalties imposed by those government authorities.

Holders of H Shares and dividends on the H Shares may be subject to PRC income taxes.

Under the current PRC tax laws and regulations, non-PRC resident individuals and non-PRC resident enterprises are subject to different tax obligations with respect to the dividends paid to them by us and the gains realized upon the sale or other disposition of H Shares.

Non-PRC resident individuals are required to pay PRC individual income tax at a 20% rate for the income derived in China under the *PRC Individual Income Tax Law* (the "**IIT Law**") and its implementation guidelines. Accordingly, we are required to withhold such tax from dividend payments, unless applicable tax treaties between China and the jurisdiction in which the foreign individual resides reduce or provide an exemption for the relevant tax obligations. However, the income gained by individual foreigners from dividends and distributions of enterprises with foreign investment is exempted from individual income tax for the time being. In addition, under the IIT Law and its implementation regulations, non-PRC resident individual holders of H shares are subject to individual income tax at a rate of 20% on gains realized upon the sale or other disposition of H shares. However, the income of individuals from the transfer of the shares of listed enterprises is exempted from individual income tax. However, there is no assurance that these practices will not evolve, which could result in levying income tax on non-PRC resident individual holders on gains from the sale of H shares.

For non-PRC resident enterprises that do not have establishments or premises in China, and for those that have establishments or premises in China but whose income is not related to such establishments or premises, under the PRC Enterprise Income Tax Law and its implementation regulations, dividends paid by us and gains realized by such foreign enterprises upon the sale or other disposition of H Shares are subject to PRC enterprise income tax at a 10% rate. The withholding tax rate for dividends payable to non-PRC resident enterprise holders of H Shares will be 10% and we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including [**REDACTED**]). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty or arrangement will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be subject to the PRC tax authorities' approval.

The interpretation and application of applicable PRC tax laws and regulations by the competent tax authorities shall be in accordance with the then effective laws and regulations, and new taxes may be imposed which may materially and adversely affect the value of our H Shares.

RISKS RELATING TO THE [REDACTED]

No* [REDACTED] *currently exists for our H Shares, and an active* [REDACTED] *for our H Shares may not develop, especially taking into account that certain of our existing shareholders may be subject to a lock-up period.

No [**REDACTED**] currently exists for our Shares. The initial [**REDACTED**] for our Shares to the [**REDACTED**] will be the result of negotiations between our Company and the [**REDACTED**] (on behalf of the [**REDACTED**]), and the [**REDACTED**] may differ significantly from the [**REDACTED**] of the Shares following the [**REDACTED**]. We have applied to the Stock Exchange for the [**REDACTED**] of, and permission to [**REDACTED**] in, the Shares. A [**REDACTED**] on the Stock Exchange, however, does not guarantee that an active and [**REDACTED**] market for our Shares will develop, or if it does develop, that it will be sustained following the [**REDACTED**], or that the [**REDACTED**] of the Shares will not decline following the [**REDACTED**].

***The* [REDACTED] *of our H Shares may be volatile, which could lead to substantial losses to* [REDACTED].**

The [**REDACTED**] of our H Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the [**REDACTED**] of the shares of other companies engaging in similar business may affect the price and [**REDACTED**] of our H Shares. In addition to market and industry factors, the [**REDACTED**] of our H Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our drug candidates, the results of our applications for approval of our drug candidates, regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our H Shares may be subject to [**REDACTED**] not directly related to our performance.

Future sales or perceived sales of our H Shares in the* [REDACTED] *by major Shareholders following the* [REDACTED] *could materially and adversely affect the* [REDACTED] *of our H Shares.

Prior to the [**REDACTED**], there has not been a [**REDACTED**] for our H Shares. Future sales or perceived sales by our existing Shareholders of our H Shares after the [**REDACTED**] could result in a significant decrease in the prevailing [**REDACTED**] of our H Shares. Only a limited number of the H Shares currently outstanding will be [**REDACTED**] immediately after the [**REDACTED**] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our H Shares in the [**REDACTED**] or the perception that these sales may occur could significantly decrease the prevailing [**REDACTED**] of our H Shares and our ability to raise equity capital in the future.

***Should the* [REDACTED] *be higher than the net tangible book value per Share, subject to* [REDACTED]*, you may experience an immediate* [REDACTED] *in the book value of the* [REDACTED] *you* [REDACTED] *in the* [REDACTED].**

As the [**REDACTED**] of our H Shares is higher than the net tangible assets per Share immediately prior to the [**REDACTED**], [**REDACTED**] of our H Shares in the [**REDACTED**] may experience an immediate [**REDACTED**]. Our existing Shareholders will experience an increase in the [**REDACTED**] adjusted net tangible asset value per Share of their Shares. In addition, holders of our H Shares may experience further [**REDACTED**] of their interest if we [**REDACTED**] additional H Shares in the future to raise additional capital.

Raising additional capital may cause* [REDACTED] *to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may finance our future cash needs through public or private offerings, debt financings, collaboration arrangements and licensing arrangements or other funding sources. Our Shareholders may experience [**REDACTED**] in their holdings if we [**REDACTED**] more securities in the future. New shares or share-linked securities [**REDACTED**] by us may also confer rights and privileges that take priority over those conferred by the H Shares.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be [**REDACTED**], and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our H Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the [**REDACTED**] of our H Shares to decline.

Because we do not expect to pay dividends in the foreseeable future after the* [REDACTED]*, return on an* [REDACTED] *in our H Shares will depend on the* [REDACTED] *of our H Shares.

We currently intend to retain most, if not all, of our available funds and any future earnings after the [**REDACTED**] to fund the development and commercialization of our pipeline drug candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an [**REDACTED**] in our H Shares as a source for any future dividend income.

Our Board has complete discretion as to whether to distribute dividends. The timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, [**REDACTED**] in our H Shares will likely depend entirely upon any [**REDACTED**] of our H Shares. There is no guarantee that our H Shares will [**REDACTED**] after the [**REDACTED**] or even maintain the price at which you [**REDACTED**] the H Shares. You may not realize [**REDACTED**] in our H Shares and you may even lose your entire [**REDACTED**] in our H Shares.

***Regulations on currency conversion and remittance of Renminbi into and out of the PRC may limit our ability to pay dividends and other obligations and affect the value of your* [REDACTED].**

Conversion of Renminbi into foreign currencies and the remittance of foreign currency out of the PRC are subject to regulation by relevant PRC authorities. A substantial majority of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends, or otherwise satisfy foreign currency denominated obligations.

Under existing PRC foreign exchange regulations, payments of current account items, including the payment of dividends, interest payments and expenditures from the transaction, can be made in foreign currencies without prior approval from the SAFE by complying with certain procedural requirements. However, approval from appropriate governmental authorities is required where Renminbi is to be converted into foreign currency and remitted out of the PRC to pay capital expenses such as the repayment of bank loans denominated in foreign currencies. Further, the PRC government may also restrict access to foreign currencies for current account transactions. If the

foreign exchange control system prevents us from obtaining sufficient foreign currency to satisfy our currency demands, we may not be able to pay certain of our expenses as they come due or to pay dividends in foreign currencies.

Any possible conversion of our Domestic Shares into H Shares in the future could increase the number of our H Shares* [REDACTED] *and negatively impact the* [REDACTED] *of our H Shares.

According to the stipulations by the State Council's securities regulatory authority and the Articles of Association, our Domestic Shares may be converted into H Shares and such converted H Shares may be listed or traded on an overseas stock exchange, provided that prior to the conversion and trading of such converted shares, the requisite internal approval processes (but without the necessity of Shareholders' approval by class) have been duly completed and the approval from the relevant PRC regulatory authorities, including the CSRC, have been obtained. In addition, such conversion, trading and [**REDACTED**] must comply with the regulations prescribed by the State Council's securities regulatory authorities and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. We can apply for the [**REDACTED**] of all or any portion of our Domestic Shares on the Stock Exchange as H Shares in advance of any proposed conversion to ensure that the conversion process can be completed promptly upon notice to the Stock Exchange and delivery of shares for entry on the H Share register. This could increase the supply of H Shares [**REDACTED**], and future sales, or perceived sales, of the converted H Shares may adversely affect the [**REDACTED**] price of H Shares.

We cannot make fundamental changes to our business without the consent of the Stock Exchange.

On April 30, 2018, the Stock Exchange adopted rules under Chapter 18A of the Listing Rules. Under these rules, without the prior consent of the Stock Exchange, we will not be able to effect any acquisition, disposal or other transaction or arrangement or a series of acquisitions, disposals or other transactions or arrangements, which would result in a fundamental change in our principal business activities as set forth in this document. As a result, we may be unable to take advantage of certain strategic transactions that we might otherwise choose to pursue in the absence of Chapter 18A. Were any of our competitors that are not listed on the Stock Exchange to take advantage of such opportunities in our place, we may be placed at a competitive disadvantage, which could have a material adverse effect on our business, financial condition and results of operations.

Facts, forecasts and statistics in this document obtained from official government sources relating to the pharmaceutical industry may not be fully reliable.

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government sources. However, neither we, the [**REDACTED**], the Joint Sponsors, the [**REDACTED**] nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics official government sources, or ascertained the underlying economic assumptions relied upon in the relevant forecasts from such sources. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from official government sources, and you should not place undue reliance on them.

Forward-looking information in this document is subject to risks and uncertainties.

This document contains certain future plans and forward-looking statements about us that are made based on the information currently available to our management. The forward-looking information contained in this document is subject to certain risk and uncertainties. Whether we implement those plans, or whether we can achieve the objectives described in this document, will depend on various factors including the market conditions, our business prospects, actions by our competitors and the global financial situations.

***You should read the entire document carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the* [REDACTED].**

Subsequent to the date of this document but prior to the completion of the [**REDACTED**], there may be press and media coverage regarding us and the [**REDACTED**], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [**REDACTED**]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. You should rely solely upon the information contained in this document, the [**REDACTED**] and any formal announcements made by us in making your [**REDACTED**] decision regarding our H Shares. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective [**REDACTED**] are cautioned to make their [**REDACTED**] decisions on the basis of the information contained in this document only and should not rely on any other information.