

RISK FACTORS

An [REDACTED] in our H Shares involves various risks. You should carefully consider all the information in this Document and in particular the risks and uncertainties described below before making an [REDACTED] in our H Shares. In particular, we are a biopharmaceutical company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. Our operations and the biopharmaceutical industry involve certain risks and uncertainties, some of which are beyond our control and may cause you to lose all your [REDACTED] in our H Shares. The occurrence of any of the following events could materially and adversely affect our business, financial condition, results of operations or prospects. If any of these events occurs, the [REDACTED] of our H Shares could decline, and you may lose all or part of your [REDACTED]. Additional risks and uncertainties not presently known to us, or not expressed or implied below, or that we deem immaterial, could also harm our business, financial condition and results of operations.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-looking Statements” in this Document. You should seek professional advice from your relevant advisers regarding your prospective [REDACTED] in the context of your particular circumstances.

RISKS RELATING TO THE DEVELOPMENT, CLINICAL TRIALS AND REGULATORY APPROVAL OF OUR PIPELINE PRODUCTS

We face competition from existing drugs and drug candidates under development.

We face competition from existing drugs and drug candidates under development in the global innovative drug market. Competition in therapeutic areas such as oncology autoimmune diseases, and metabolic disorders, to which our Core Products and many other pipeline assets belong, is intense given the abundance of existing competing oncology therapy options, approved drugs and drug candidates that continue to increase.

Our commercial opportunities may be adversely impacted if our competitors develop and commercialize drugs that are safer, more effective, more convenient, or less expensive than any of the drugs that we may develop or commercialize. Our competitors also may obtain approval from the regulatory authorities for their drugs more quickly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market. This may render our pipeline products obsolete or less competitive before we can recover the expenses of developing and commercializing our pipeline products. Additionally, our drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial, technical and human resources and expertise in R&D, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Additional mergers and acquisitions in the pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

RISK FACTORS

Our business and financial prospects depend substantially on the success of our pipeline products. If we are not able to successfully complete clinical development, obtain regulatory approval and commercialize our pipeline products, including our Core Products, or experience delays in doing so, our business prospects could be adversely affected.

As of the Latest Practicable Date, several of our drug candidates had not been approved for commercialization. We believe our future revenue and profitability will substantially depend on our ability to complete the development of our drug candidates, obtain requisite regulatory approvals and successfully manufacture and commercialize our drug candidates. We have invested a significant portion of our efforts and capital resources in the development of our existing drug candidates, and we expect to incur substantial and increasing expenditures for the development and commercialization of our drug candidates in the future. However, development of new drugs, including developing our Core Products taragarestrant (D-0502) and D-2570 in China and overseas markets, can be time-consuming and costly, and the outcome may be uncertain. The success of our drug candidates will depend on several factors, including: successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies; favorable safety and efficacy data from our clinical trials and other studies; receipt of regulatory approvals for planned clinical trials, future clinical trials or drug registrations, manufacturing and commercialization; establishing sufficient manufacturing capabilities to ensure supply for clinical use and future commercialization, either by making arrangements with third-party manufacturers or building facilities ourselves; our ability to effectively and simultaneously design, manage and supervise a number and range of clinical trials in multiple jurisdictions; our ability to reach agreements on acceptable terms with prospective third-party service providers, such as CROs, and trial sites, the terms of which can be subject to negotiation and may vary among different third-party service providers and trial sites; the performance by contract research organizations, or CROs, or other third parties we may retain of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data; obtaining and maintaining patent, trade secret and other intellectual property (“IP”) protection and regulatory exclusivity; ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other IP rights of third parties; successfully launching our drug candidates, if and when approved; obtaining favorable reimbursement from third-party payors for drugs, if and when approved; competition with other products and drug candidates; continued acceptable safety profile following regulatory approval; and obtaining sufficient supplies of any drug products that may be necessary for use in clinical trials for evaluation of our drug candidates in combination with such drug products.

Furthermore, due to the novelty of our therapeutics, a substantial amount of education and training may need to be provided to patients and medical personnel in the future, which may potentially increase our sales and marketing expenses.

Clinical development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results.

Clinical development is capital-intensive and may demand years of effort to complete, while its outcomes are inherently uncertain and may not be favorable. We may encounter unexpected difficulties while executing our clinical development plans for our drug candidates. Failure can occur at any time during the clinical development process. Furthermore, the results of preclinical 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 indicate the success of final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy profiles. Many companies in the biopharmaceutical industry have experienced significant setbacks in advanced clinical trials due to unsatisfactory efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. It is also common that various aspects of the development programs, such as manufacturing and formulation, are altered along the entire R&D stage in an effort to optimize processes and results, and there can be no assurance that such alterations would help achieve the intended objectives.

RISK FACTORS

There may be significant variability in safety or efficacy results among different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in size and demographics of the enrolled patients (such as genetic differences and patient adherence to the dosage regimen) and the dropout rate among enrolled patients in clinical trials. Differences in the number of clinical trial sites and countries involved may also lead to variability among clinical trials. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and deviate from our expectation, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates.

The regulatory approval processes for pharmaceutical products are time consuming and depend on numerous factors, and if we are ultimately unable to obtain regulatory approval for our pipeline products, our business could be substantially harmed.

The regulatory approval processes of pharmaceutical products depend on numerous factors, some of which may be outside our control. Generally, such approvals take years to be obtained following the commencement of preclinical studies and clinical trials. Approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate’s clinical development and may vary among jurisdictions. We may not obtain marketing approval for befotertinib (BPI-D0316) and garsorasib (D-1553) outside China, and we cannot guarantee that we will be able to obtain regulatory approvals for our other existing drug candidates or any drug candidates we may discover in the future.

Our pipeline products could fail to receive the regulatory approval for many reasons, including: disagreement with the design or implementation of our clinical trials; failure to demonstrate that a drug candidate is safe and effective and potent for its proposed indication; failure of our clinical trial results to meet the level of statistical significance required for approval; failure of our clinical trial process to pass relevant Good Clinical Practice (“GCP”) inspections; disagreement with our interpretation of data from preclinical studies or clinical trials; insufficient data collected from the clinical trials of our drug candidates to support the submission and filing of an NDA or other submissions or to obtain regulatory approval; failure of the manufacturer of our drug candidates to pass Good Manufacturing Practice (“GMP”) inspections during the regulatory review process or across the production cycle of our drug candidates; failure of our clinical sites to pass audits carried out by the regulatory authorities, resulting in a potential invalidation of our research data; changes in approval policies or regulations that render our preclinical and clinical data insufficient for obtaining approvals; failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations; or clinical sites, investigators or other participants in our clinical trials deviating from the trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

If clinical trials of our drug candidates fail to demonstrate safety and efficacy profiles to the satisfaction of regulatory authorities, or if adverse events, serious adverse events or other safety concerns arise, we may incur additional costs, experience delays or ultimately be unable to complete the development and commercialization of our drug candidates.

We may experience unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to obtain regulatory approval or commercialize our drug candidates. Such events may include, among others, failure by regulators, institutional review boards or ethics committees to authorize or permit clinical trials; manufacturing, supply or quality issues; failure by our third-party contractors to comply with applicable regulatory requirements or contractual obligations; negative, inconclusive or insufficiently positive clinical trial results; and the suspension or termination of clinical trials due to safety concerns, lack of clinical benefit or other unexpected findings.

Adverse events, serious adverse events, including patient deaths, occurring during clinical trials or after completion of clinical trials or a patient’s discontinuation or withdrawal from a study, whether or not related to our drug candidates, could cause us, clinical investigators or regulatory authorities to interrupt, delay, suspend or terminate clinical trials. Such events may also result in additional

RISK FACTORS

clinical investigations, modifications to clinical protocols, narrower indications, more restrictive labeling, delays or denial of regulatory approvals, or changes to our development plans. In addition, such events could adversely affect patient recruitment and retention, result in potential product liability claims, damage our reputation and the perception of our drug candidates, and adversely impact our ability to obtain regulatory approvals or successfully commercialize our drug candidates.

Development of product candidates in combination with other therapies could expose us to additional risks.

In addition to monotherapies, we are developing certain pipeline products with other commercialized therapies as combination therapies to achieve potential synergistic effects and improved efficacy profile. For instance, we are investigating the safety and efficacy of our Core Product, taragarestrant (D-0502), in combination with palbociclib for the treatment of advanced or metastatic ER-positive and HER2-negative breast cancer in China and the U.S. However, development of such combination therapies could expose us to additional risks. For instance, we may be unable to successfully develop or market our pipeline products or may experience significant regulatory delays, if safety, efficacy or other issues arise from any pharmaceutical product or medical treatment used, or intended to be used, in combination with our drug candidates. Additionally, as combination therapies may increase the rate of serious or unexpected AEs, which could result in a clinical hold as well as pre-approval and post-approval restrictions by the regulatory authorities on the proposed combination therapy, including narrowing of the indication, warnings, additional safety data collection and monitoring procedures.

Even if any of our product candidates were approved for use in combination with other existing approved therapies, we would continue to be subject to multiple risks, such as the possibility that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment, which could adversely affect the market perception and acceptance of the combination therapy. In such scenarios, we may need to identify other potential combination therapies for our product candidates and conduct additional preclinical and clinical studies before these alternative therapies receive regulatory approvals for marketing. Additionally, components of the combination therapies, other than our product candidates, may not be under our control, and it is possible that we may encounter difficulties in obtaining sufficient quantities for clinical trials or, when commercialized, patients may not have adequate access to such components for their treatment regimes. In any of aforementioned scenarios, the development efforts and commercialization prospects regarding our product candidates would be impaired.

If we encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll enough participants who remain in the trial until its conclusion. We may experience difficulties in participant enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the clinical trial protocol, the resources we have to facilitate timely subject enrollment in our clinical trials, the efforts made by trial execution personnel including our CROs to screen and recruit eligible subjects, the ability to obtain and maintain informed consents, epidemics, and the proximity and availability of clinical trial sites for prospective subjects, among others.

In addition, our clinical trials may compete with other clinical trials for drug candidates in the same therapeutic area as ours. Such competition will likely reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead enroll in a trial conducted by our competitors. Delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could delay or prevent the completion of these trials and adversely affect our ability to advance the development of our drug candidates.

RISK FACTORS

Interim and/or preliminary data derived from our clinical trials that we announce or publish from time to time may change as more valid data becomes available and are subject to verification procedures that could result in material changes in the final results.

From time to time, we may publish interim and/or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary data also remain subject to verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly affect our business prospects and may cause the [REDACTED] of H Shares to fluctuate significantly after the [REDACTED].

Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these drug candidates on a timely basis or at all, which would have an adverse effect on our business.

Many of our product candidates are still in the preclinical development stage, and the risk of failure of preclinical programs is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies to obtain regulatory clearance to initiate human clinical trials. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for the contemplated clinical development of our preclinical drug candidates on the timelines we expect, if at all, and we cannot be sure that submission of IND applications or similar applications will result in the regulatory authorities allowing clinical trials to begin.

We may allocate our limited resources to pursue particular drug candidates or indications 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. 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. Furthermore, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through licensing, collaboration or royalty arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights 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 partnering arrangement.

We may fail to sufficiently and promptly respond to rapid scientific and technological changes, clinical demand and market changes in the pharmaceutical industry, and we may be unable to maintain or enhance our market share in this industry for a variety of reasons.

The global pharmaceutical industry is characterized by rapid advances in science and technology and the continuous emergence of new treatment options. Our future success partially depends on our ability to launch new products that meet evolving market demands, in particular, new drugs that are effective in treating oncology, metabolic and autoimmune diseases. We cannot assure you that we will be able to respond to emerging or evolving trends by improving our product portfolio in a timely manner, or at all.

In addition, clinical demand for pharmaceutical products may change rapidly and significantly. Our success depends on our ability to anticipate product offering lead-time and demand, identify preferences of patients and physicians and adapt our products to these preferences.

RISK FACTORS

We may need to adjust our R&D plan, production scale and schedule, product portfolio, and inventory levels based on market demand, sales trends and other market conditions. There can be no assurance that we will be able to sufficiently and promptly respond to changes in clinical demand and purchasing patterns in the future.

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 principal investigators (“PIs”), key opinion leaders (“KOLs”), physicians and experts play an important role in our R&D and future marketing activities. We have established extensive interaction channels with PIs, KOLs, physicians and experts to gain first-hand knowledge of 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 and 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. Also, their market insights and perceptions, which we take into account in our R&D process, may be inaccurate and lead us to develop products that do not have significant market potential. 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 and our marketing strategy may no longer be able to yield results that are commensurate to our efforts spent.

All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated.

All jurisdictions in which we intend to conduct our biopharmaceutical industry activities regulate the pharmaceutical industry. In doing so they employ extensive regulations governing the development, approval, manufacturing, marketing, sales and distribution of pharmaceutical products. Differences in regulatory regimes across jurisdictions may lead to a higher compliance burden.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires spending of substantial time and financial resources. Any recently enacted and future legislation may increase the difficulty and cost of us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain. Changes in government regulations or in practices relating to the pharmaceutical industry, such as a relaxation in regulatory requirements; the introduction of simplified approval procedures, which would lower the entry barrier for potential competitors; or an increase in regulatory requirements, which may increase the difficulty for us to satisfy such requirements.

RISKS RELATING TO DEPENDENCE ON THIRD PARTIES

We rely on our current and future collaborators’ willingness and ability to devote resources to the development and commercialization of some of our pipeline products and to otherwise support our business as contemplated in our collaboration agreements.

We rely on our current and future collaborators to support our business, including clinical development, regulatory filings, manufacturing and/or commercialization of certain of our pipeline products. For example, we have granted Betta exclusive rights to develop, manufacture and commercialize befotertinib (BPI-D0316) in Chinese Mainland, Hong Kong, and Taiwan. Befotertinib (BPI-D0316) obtained the regulatory approval from the NMPA in 2023. Also, we granted CTTQ an exclusive license to develop, register, manufacture and commercialize garsorasib (D-1553) in Chinese Mainland. Garsorasib (D-1553) obtained the regulatory approval from the NMPA in 2024. Therefore, our future financial position will partly depend on the commercialization efforts of Betta and CTTQ.

RISK FACTORS

However, as we may have little or no control over the marketing and sales efforts beyond the contractual terms, the actual revenue generated from the commercialization of befotertinib (BPI-D0316) and garsorasib (D-1553) may be lower than anticipated, and we may not realize the contemplated benefits from these collaborations. There is also no assurance that our collaborators will not seek to change the terms of the collaboration agreements with the effect of diminishing benefits to us. We also cannot assure you that our existing or future collaborations will not be terminated prior to the expiry of contemplated terms. Such terminations could significantly impact the development and commercialization of our pipeline products and impact our financial results and future prospects.

We may continue to receive from certain of our current and future collaborators with information about the status, progress and results of clinical trials and regulatory processes that they are conducting, sponsoring or pursuing with respect to our partnered product candidates. We may not have direct access to the underlying data or direct communications with the relevant regulators. In addition, our collaboration with our current and future collaborators could subject us to a number of additional risks, including: our collaborators have significant discretion regarding whether and when to pursue planned activities; we cannot control the quantity and nature of the resources our collaborators may devote to the development, commercialization, marketing and distribution of products or product candidates; disputes between us and our collaborators may delay or terminate the research, development or commercialization of the applicable pipeline products or result in costly litigation or arbitration that diverts management’s attention and resources; we may not receive stipulated milestone payments from our collaborators, at the expected time or at all, if our collaborators do not achieve future milestones or if we and our collaborators disagree about whether a milestone has been reached; with respect to collaborations, partnerships or other arrangements under which we have an active role, we and our collaborators may have differing opinions or priorities, or we may encounter challenges in joint decision making, which may delay or terminate the research, development or commercialization of the applicable products and product candidates; our collaborators may not properly maintain or defend relevant IP rights, or may infringe the IP rights of third parties, or may use our or third parties’ proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation; and business combinations, financial difficulties or significant changes in a collaborator’s business strategy may adversely affect that collaborator’s willingness or ability to continue to pursue our products or product candidates.

We may not receive some or all of the potential milestone and/or royalty payments from our collaboration and licensing agreements.

From time to time, we may enter into collaboration and licensing agreements that include clauses regarding potential development and commercial milestone payments and/or royalties. The milestone payments will only be payable to us upon the achievement of certain milestones based on clinical development progress and achievement of specified amounts of annual net sales of the licensed products. We may also receive tiered royalties tied to the net sales amount of the licensed products. There is a risk that any or all of the milestone events under these various agreements might not be achieved, that our licensees may not achieve sales that would entitle us to royalty payments, and that any or all of the consideration tied to the achievement of the milestone events and royalties might not be received. For example, pursuant to our agreements with Betta and CTTQ, Betta and CTTQ shall be solely responsible for commercializing befotertinib (BPI-D0316) and garsorasib (D-1553) in China, respectively, and we are entitled to certain royalties and commercial milestone payments that are keyed to the annual net sales of befotertinib (BPI-D0316) and garsorasib (D-1553), respectively, in addition to other enumerated upfront and milestone payments. For example, we are entitled to receive RMB180.0 million from Betta under our collaboration agreement, and we have received RMB80.0 million milestone payment from Betta on December 26, 2025. We have not formally asserted a breach or initiated any enforcement or termination actions under the collaboration agreement, and we continue to evaluate our rights and options taking into account commercial

RISK FACTORS

considerations and the overall relationship with our partner. We are in active discussion with Betta on the settlement of the balance milestone payments and aim to resolve this matter through amicable negotiation under the framework of the our collaboration agreement.

We work with various third-party service providers to develop our pipeline products. If these third parties fail to duly perform their contractual obligations or meet expected timelines, we may be unable to obtain regulatory approvals for, or commercialize, our pipeline products, and our business, financial condition and results of operations could be materially and adversely affected.

We have worked with and may continue to work with third-party service providers on our ongoing preclinical and clinical programs. For example, we seek assistance from CROs, clinical trial sites, consultants and other third parties to monitor, support and/or conduct preclinical studies and clinical trials of our drug candidates. During the Track Record Period, we engaged seven CROs to support our clinical trials for our Core Products. We work with these parties to execute our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocols, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by the regulatory authorities for all of our drug candidates in clinical development. If any of our CROs or clinical investigators fail to comply with the applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the 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. Furthermore, due to the involvement of third parties, the data we gather in our R&D may be affected by factors unrelated to our drug candidates or out of our control, which could adversely affect the reliability of results derived from our R&D activities.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. If CROs fail to duly perform their contractual obligations or meet expected timelines, if they need to be replaced or if the quality or 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 approvals for, or successfully commercialize, our drug candidates. Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines.

We depend on third parties to provide a stable and adequate supply of investigational drugs for our research and development efforts and supply of APIs for commercial sales. Any disruptions of, quality issues or significant price increases in such supply could adversely affect our business.

We have limited experience in manufacturing biopharmaceutical products, which is a complex process requiring significant expertise and capital investment, in part due to strict regulatory requirements. During the Track Record Period, we did not have in-house manufacturing facility and we outsourced manufacturing activities to reputable third-party manufacturing service providers. For manufacturing of our product candidates, we currently outsource such production to a number of CDMOs. Going forward, we may continue to engage third-party CDMOs to manufacture a portion of our pipeline products for R&D activities and commercial sales. For instance, we engage third-party manufacturing service providers to provide the APIs. Our engagement with third-party CDMOs exposes us to certain risks, including: we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the regulatory authorities must

RISK FACTORS

evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates, which could require new testing and GMP-compliance inspections by the 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; manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately, or may otherwise fail to perform as agreed; manufacturers are subject to ongoing periodic unannounced inspection by the regulatory authorities to ensure strict compliance with GMP and other government regulations. We do not have control over third-party manufacturers’ compliance with these regulations and requirements; manufacturers may not properly obtain, protect, maintain, defend or enforce our IP rights or may use our IP or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our IP or proprietary information or expose us to potential liability; manufacturers may infringe, misappropriate or otherwise violate the IP rights of third parties; manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, unstable political environments, natural or man-made disasters, or other events beyond control, which may lead to interruption of the manufacturing process; we may be unable to detect or cure quality defects in drug products manufactured by the third-party service providers with our established quality control and quality assurance procedures; contaminants may be discovered in the manufacturing facilities of the third-party service providers, which could lead to close of such manufacturing facilities for an extended period of time to investigate and remedy the contamination.

In the event that our suppliers are unable to provide adequate supplies of products or services to us, our operations, including in-house CMC functions and the R&D of our pipeline products, may be adversely affected. We may also be exposed to the possibility of increased costs, which we may not be able to pass on to purchasers of our pipeline products and as a result, lower our profitability. Any delay or interruption in the provision of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs, and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely. The risks discussed above could also jeopardize our ability to provide any future approved drug candidates for commercial sale.

In addition, any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, result in gaps in the audit of our processes, jeopardize any GMP certifications we may have in the future and/or harm our market reputation and relationship with business collaborators.

The stability of operations and business strategies of our service providers and collaborators are beyond our control, and we cannot assure you that we will be able to secure a stable relationship and high-quality outsourced services or materials. If any of our large manufacturing service providers or collaborators terminates its business relationship with us, we may encounter difficulty in finding a replacement that can provide services or materials of equal quality at a similar price.

We may face difficulties in forming additional collaboration and strategic alliances in the future.

We have formed and may in the future form or seek strategic alliances, create collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our other drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration, partnership, licenses or other arrangement will depend, among other things, upon our assessment of the collaborator’s resources and expertise, the terms and conditions of the proposed collaboration, partnership, licenses or other arrangement and the proposed collaborator’s evaluation

RISK FACTORS

of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to its ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. Moreover, we may not be successful in our efforts to establishing or maintaining our collaborations, partnerships, licenses or other arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial potential. If and when we collaborate with a third party for the development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party.

RISKS RELATING TO COMMERCIALIZATION AND MANUFACTURING OF OUR PIPELINE PRODUCTS

We have limited experience in launching and marketing drug products and may not be able to successfully do so in the future.

Our collaborators Betta and CTTQ will be solely responsible for the commercialization of our approved products befotertinib (BPI-D0316) and garsorasib (D-1553), respectively. Since none of our other pipeline products has reached the commercialization stage, we have not yet demonstrated an ability to launch and commercialize drug products. Given our lack of experience, we may require a longer time frame or be less cost-efficient in the commercialization process than a company with more experience launching and marketing drug products. This inexperience may subject our business operations to greater risk.

Furthermore, if we do not 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 pipeline products. 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 have effective sales forces. If we choose to pursue this path, we may have little or no control over the marketing and sales efforts of such third parties beyond contractual terms, 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. We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel and any revenue we receive will depend upon the efforts of such third parties. Therefore, we cannot assure you that we will be able to establish or maintain relationships with third-party partners to successfully commercialize any product. As a result, we may not be able to generate the anticipated product sales revenue.

The size of the actual markets for our pipeline products may be smaller than our estimates and our pipeline products may not be able to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for their commercial success.

Our projections of the number of patients who may benefit from treatment with our pipeline products are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be fewer than expected. As a result, the potentially addressable patient population and market size for our pipeline products may be smaller than our estimates.

Furthermore, there is no guarantee that any of our pipeline products would be approved for the line of therapy we ultimately aim for. For example, oncology therapies may be characterized as first line, second line or later line therapy depending on options for treatment and prior treatments

RISK FACTORS

received. For indications with well-established standard of care therapies, the regulatory authorities may approve new therapies initially only for second or later lines of therapy. There is no guarantee that our pipeline products will be approved as an early-line therapy for certain indications. As a result, we may not achieve the anticipated market size and revenue unless such market approval is for the intended lines of therapy or for additional indications.

Additionally, our pipeline products may not be able to gain sufficient market acceptance in the medical community and physicians, patients or third-party payers may prefer other products to ours. If our pipeline products do not achieve an adequate level of acceptance, we may not realize sufficient income from sales that turns us profitable. The degree of market acceptance of our pipeline products, once approved for commercial sale, will depend on: the clinical indications for which our pipeline products are approved; physicians, hospitals, medical treatment centers and patients considering our pipeline products; efficacy and safety profile of our pipeline products; the potential and perceived advantages of our pipeline products over alternative treatments; the prevalence and severity of any side effects; limitations or warnings contained in the labeling approved by regulatory authorities; the timing of market introduction of our pipeline products as well as competitive drugs; the cost of treatment in relation to alternative treatments; the availability of adequate coverage, reimbursement and pricing by third-party payers and government authorities; price control or downward adjustment by the government authorities or other pricing pressure; relative convenience and ease of administration, including as compared to alternative treatments; the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities; and the effectiveness of sales and marketing efforts regarding our pipeline products and competing drug products. The market acceptance for our products, if any, may not be maintained over time if new drug products or technologies are introduced that are more favorably perceived than our pipeline products, have better safety and efficacy profiles or render our drug candidates obsolete.

Inability to conduct effective sales and marketing activities either by ourselves or through third parties would negatively affect the sales volume of our pipeline products after they are approved for commercialization, and our operations, revenue, profitability and business prospects could be adversely affected.

Sales and marketing efforts regarding our pipeline products will consist of raising awareness and knowledge of our products and product candidates among medical professionals, hospitals, other medical institutions and pharmacies. Therefore, the sales and marketing force must possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication skills. If we or our commercialization collaborators are unable to effectively train the sales representatives, sales and marketing of our pipeline products may be less successful than desired. Moreover, the ability to attract, motivate and retain a sufficient number of qualified sales professionals, either by us or by our collaborators, is important. Competition for experienced marketing, promotion and sales personnel is intense. If we or our collaborators are unable to attract, motivate and retain a sufficient number of marketing, promotion and sales professionals, sales volume of our products may be adversely affected, and we may be unable to expand our hospital coverage or increase our market penetration as contemplated.

The commercialization of our pipeline products, if approved, may be subject to uncertainties from national, provincial or other third-party drug reimbursement practices and unfavorable drug pricing policies or regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from jurisdiction to jurisdiction. In China and some other markets, the pricing of drug products remains subject to continuing governmental control even after initial approval, and the pricing negotiations can take considerable time. As a result, the commercial launch of our drug candidates, once approved, can be delayed due to price regulation, which will negatively impact our revenues. The ability to commercialize any approved drug candidates

RISK FACTORS

successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.

A primary trend in the global healthcare industry is cost containment. Government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payers are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any commercialized pipeline products and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved products. Obtaining or maintaining reimbursement for our future approved products may be difficult. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidates.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the approved indications. For instance, in the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payers. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effectiveness data for the use of our approved pipeline products on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

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 not be made permanent. 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 lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drug candidates or any new drugs that we develop could have a material adverse effect on our business, our results of operation, and our overall financial condition.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

Our patent rights may be challenged and invalidated.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the U.S., the EU and other jurisdictions. We may be involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or interference proceedings challenging our patent rights or the patent rights of others. If we are unsuccessful in any interference proceedings or other priority or validity disputes to which our IPs are subject, we may lose valuable IP rights through the loss of one or more patents or our patent claims may be narrowed, invalidated, or held unenforceable. In addition, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our drug candidates. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical drug products.

RISK FACTORS

Also, we may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other IP as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. In addition, former employees may become employed by competitors who develop similar technology, and could assist the competitor in designing around our patents. We may be unsuccessful in executing an IP assignment agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable IP rights, such as exclusive ownership of, or right to use, IP important to our product candidates. Further, litigation could result in substantial costs and be a distraction to management and other employees.

Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated due to noncompliance.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration (the “CNIPA”), the United States Patent and Trademark Office (the “USPTO”) and other applicable patent agencies in several stages over the lifetime of a patent. These patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Certain non-compliance events can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Such events 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 might be able to enter the market, which would have a material adverse effect on our business.

If our patent terms expire before or soon after our drug candidates are approved, our business may be materially harmed.

Patents have a limited duration. Depending on the jurisdiction, various extensions may be available, but the life of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for inventions in China and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the U.S. Once the patent life has expired, we may be open to competition from competitive medications. Upon expiration of our issued patents or patents that may issue from our 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. 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.

In addition, some of our patents and patent applications may, in the future, be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. Besides this, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

RISK FACTORS

Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.

In the U.S., the Federal Food, Drug, and Cosmetic Act, as amended by the law generally referred to as the “Hatch-Waxman Amendments,” provides the opportunity for patent-term restoration of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. The Hatch-Waxman Amendments also have a process for patent linkage, pursuant to which FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Finally, the Hatch-Waxman Amendments provide for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity (as defined) and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where FDA designates the product candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after FDA grants marketing approval for the innovative product.

In China, the amendment to the PRC Patent Law which was promulgated in October 2020 introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the patent owner to submit applications for a patent term extension of up to a maximum length of five years, and after the new drug is approved for marketing, the total effective term of the patent shall not exceed 14 years. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements.

There can be no assurance that the relevant governmental authorities will agree with our assessment of eligible patent extensions, and such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we requested. In such instances, a lower-cost generic drug can emerge onto the market much more quickly, leading to early generic competition that may have a material and adverse effect on our financial position and business prospect.

We may not be able to protect our IP rights or prevent unfair competition by third parties.

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our IP rights in some countries can have a different scope and strength than do those in some other countries. In addition, the laws of certain countries do not protect IP rights to the same extent as the laws of certain other countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing drugs made using our inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may be able to circumvent our patents by developing similar or alternative products and technologies in a non-infringing manner, or may export otherwise infringing drugs to certain jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in certain other countries. These drugs may compete with our drug candidates and our IP rights may not be effective or adequate to prevent them from competing.

RISK FACTORS

We may become subject to IP infringement claims, which could expose us to substantial liability, harm our reputation, limit our research and development or other business activities and/or impair our ability to commercialize our product candidates.

Our commercial success depends significantly on our ability to develop, manufacture, market and sell pharmaceutical products and use our proprietary technologies without infringing the IP rights of third parties. The pharmaceutical industry is characterized by extensive litigation regarding patents and other IP rights. Defending against claims of patent infringement, misappropriation of trade secrets or other violations of IP rights could be costly and time-consuming.

The publication of discoveries in scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and invention patent applications are filed. We may not know with certainty whether any third party may have filed a patent application without our knowledge while we are still developing or producing that product or other relevant technology.

Third parties may assert infringement claims against us based on patents or other IP rights they hold. There is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. We are not currently involved in any material patent litigations. In the past, we have been involved in certain IP-related litigations in the PRC and the U.S. These proceedings concerned alleged infringement of technical or commercial secrets or patent-related matters, none of which involved our product candidates, and all of which were ultimately resolved in our favor through successful defense, dismissal by the courts, or withdrawal of claims by the plaintiffs, without resulting in any material adverse impact on our business, financial condition or results of operations.

Whether a product infringes a patent involves an analysis of complex legal and factual issues, the determination of which is often uncertain, and the burden of proof required to successfully challenge a third-party patent may be high. Such legal proceedings could lead to considerable legal costs and be a distraction to our management. If we are found to infringe on a third party’s IPs, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, one or more of the following may occur: we may have to reformulate the affected product(s) so that it does not infringe the IP rights of others, which may not be possible or could be very costly and time-consuming; we may be forced to discontinue production and sales of the affected product(s) or cease developing and commercializing the affected product candidate(s); we may be prevented from commercializing our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court; and we may be required to obtain royalty-bearing licenses from such third party to such patents, which may not be available on commercially reasonable terms, or at all, and such licenses could be non-exclusive, thereby giving our competitors and other third parties’ access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments.

Furthermore, potential disputes with our business partners may arise if we are unable to agree on whether the product candidates under collaboration involve freedom-to-operate concerns. In addition, some of our competitors are larger than we are and have substantially greater resources than we do. They are, therefore, likely to be able to sustain the costs of complex IP litigation longer than we could. The uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research projects, in-license needed technologies, or enter into strategic partnerships that would help us bring our product candidates to market.

RISK FACTORS

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We own registered trademarks in Chinese Mainland. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. Competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other IP may be ineffective and could result in substantial costs and diversion of resources.

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

In addition to patents, we rely on trade secret protection to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to trade secrets, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CDMOs, clinical research coordinators, consultants and advisers. However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether our protection measures will be effective. Any of the parties with whom we enter into confidentiality agreements may breach the agreement terms and improperly disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach. As a result, 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. 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.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our pipeline products.

The laws and regulations governing patents could be revised from time to time that would affect our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Such changes may impact the value of our patent rights or other IP rights. For instance, the U.S. has enacted wide-ranging patent reform legislation. The U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained.

IP rights do not necessarily protect us from all potential threats.

IP rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: others may be able to make products that are similar to any candidates we may develop while our candidates are not protected by our IP rights; we or our current or future collaborators might not have been the first to develop drug candidates covered by the issued patent that we license or may own in the future; we or our current or future collaborators might not have been the first to file patent applications covering certain of our, or their, candidates; others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed IP

RISK FACTORS

rights; our pending patent applications or those that we may file in the future may not lead to issued patents; issued patents that we hold rights to may not provide us with a competitive advantage; we may obtain patents for certain technologies many years before we commercialize candidates leveraging such technologies, and because patents have a limited life, which may begin to run prior to the commercial sale of the related candidates, the commercial value of our patents may be limited; our competitors or other third parties might conduct R&D activities in jurisdictions where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; we may not develop additional proprietary technologies that are patentable; and we may choose not to file a patent for certain trade secrets, and a third party may subsequently file a patent covering such IP.

RISKS RELATING TO OUR FINANCIAL POSITION

We have incurred significant operating losses since inception, and we anticipate that we will continue to incur operating losses and may fail to achieve or maintain profitability in the future. As a result, you may lose substantially all of your [REDACTED] in us.

[REDACTED] in the development of innovative biopharmaceutical products can be highly speculative as it entails substantial upfront expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we continue to incur significant R&D costs and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred operating losses since our inception. In 2024 and 2025 and for the six months ended June 30, 2025 and 2026, our total loss for the year/period were RMB240.2 million, RMB316.9 million, RMB121.5 million and RMB137.1 million, respectively. As of June 30, 2026, our accumulated losses were RMB2,998.9 million. Substantially all of our operating losses during the Track Record Period resulted from costs and expenses incurred by our R&D activities, including those in relation to our preclinical studies and clinical trials, which exceeded the revenue we recognized in the same periods. Our ability to generate revenue and achieve profitability depends significantly on our success in obtaining regulatory approvals for each drug candidate, which we may not be able to do in a timely manner or at all.

We expect to continue to incur losses in the near future and that these net losses may increase as we continue to carry out certain activities relating to our development, including: continue to advance the clinical trials and preclinical studies of our pipeline products; seek regulatory approvals for our pipeline products and commence commercialization; identify additional drug candidates with significant market potential; respond to scientific advancements, new technologies and market developments; maintain, protect and expand our IP portfolio; and enter into additional strategic collaborations to maximize the value of our pipeline products.

Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our operating losses have had, and will continue to have, an adverse effect on our working capital and shareholders' equity. Our inability to become and remain profitable may affect [REDACTED] perception of our potential value and could impair our ability to raise additional capital, expand our business or continue our operations. Failure to become and remain profitable may also adversely affect the [REDACTED] of our H Shares. A decline in the [REDACTED] of our H Shares could cause potential [REDACTED] to lose all or part of their [REDACTED] in our business.

We had net operating cash outflows during the Track Record Period.

Since our inception, our operations have consumed substantial amounts of cash. We had net cash used in operating activities of RMB242.0 million in 2024, RMB155.4 million in 2025, RMB105.8 million for the six months ended June 30, 2025 and RMB188.2 million for the six months ended June 30, 2026. Additionally, we are exposed to credit risk on the cash and cash equivalents deposited in financial institutions. In the event that any of them becomes insolvent and is taken into receivership by the relevant government agencies, there will be uncertainty as to the timing and extent to which we will be able to recover our cash on deposit at such financial institution.

RISK FACTORS

We expect that we may experience net cash outflows from our operating activities for the foreseeable future. We may need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or other sources. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on reasonable terms, we could have to delay, limit, reduce or terminate our R&D programs or any future commercialization efforts. Our inability to obtain additional funding when we need it could seriously harm our business.

We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates.

During the Track Record Period, we financed our operations, including our preclinical studies and clinical trials, primarily through [REDACTED] from our financing activities. We expect to fund our future operations primarily with existing cash and cash equivalents, net [REDACTED] from the [REDACTED], payments received from our license and collaboration agreements, including royalties from the sales of befortertinib (BPI-D0316) and garsorasib (D-1553) in China, [REDACTED] from commercial loans, and future sales of our commercialized drug products. Changes in our ability to fund our operations may affect our cash flow and results of operations. Apart from this [REDACTED], we may nevertheless require substantial additional capital to meet our continued operating cash requirements, especially to fund our R&D activities, commercialization of our drug candidates and development of manufacturing capabilities. As our business continues to expand, we may seek additional funding through equity offerings, debt financings, license and collaboration arrangements and other sources, which may not be available on terms favorable or commercially reasonable to us or at all.

We face exposure to fair value change of financial assets at FVTPL and valuation uncertainty.

In 2024 and 2025 and for the six months ended June 30, 2025 and 2026, we recorded gain on fair value changes of financial assets at FVTPL of RMB1.3 million, RMB2.5 million, RMB0.9 million and RMB0.7 million, respectively. As of June 30, 2026, we had financial assets at FVTPL of RMB153.0 million, which consisted of wealth management products purchased from reputable banks and other financial institutions in the PRC. After [REDACTED], we may continue to purchase low-risk wealth management products with a short maturity period based on our operational needs. We therefore face exposure to fair value change of financial assets measured at FVTPL. We cannot assure you that we can recognize comparable fair value gains in the future, and we may on the contrary recognize fair value losses, which would affect our result of operations for future periods. As such, the valuation of financial assets at FVTPL has been, and will continue to be, subject to uncertainties in estimations, which may not reflect the actual fair value of these financial assets and result in fluctuations in profit or loss from year to year.

Share-based payments may have a material and adverse effect on our financial performance and cause shareholding dilution to our Shareholders.

We have granted share-based payments to, among others, attract and retain outstanding individuals to serve the Company. We believe the granting of share-based payment is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based payment to employees in the future. In 2024 and 2025 and for the six months ended June 30, 2025 and 2026, we incurred equity-settled share-based payment expenses of RMB47.0 million, RMB35.7 million, RMB21.3 million and RMB6.2 million, respectively. See Note 33 of the Accountants' Report set out in Appendix I to this Document. As a result, our expenses associated with share-based payment may increase, which may have an adverse effect on our results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the grants under our currently effective Restricted Share Incentive Schemes and

RISK FACTORS

any subsequently adopted share incentive schemes from time to time. If we choose to do so, we may experience substantial change in our share-based payment charges. In addition, such share-awards may dilute the shareholding percentage of our existing Shareholders and could result in a decline in the value of our H Shares.

We are subject to credit risk arising from trade receivables.

As of December 31, 2024 and 2025 and June 30, 2026, we had trade receivables (net of loss allowance) of RMB165.3 million, RMB84.7 million and RMB86.0 million, respectively, mainly consisted of an aggregate of RMB180.0 million, RMB100.0 million and RMB100.0 million from Betta as of December 31, 2024 and 2025 and June 30, 2026, respectively, which we are entitled to receive under our collaboration agreement. We have received RMB80.0 million milestone payment from Betta on December 26, 2025. We are in active discussion with Betta on the settlement of the balance milestone payments. Nevertheless, we may be exposed to credit risk with our counterparties and may not be able to collect all of such receivables due to a variety of factors that are outside of our control. If the relationship between us and any of our counterparties is terminated or deteriorated, or if our counterparties experience financial or operational difficulties, the recoverability of our trade receivables may be negatively affected, which may have a material and adverse effect on our business, financial condition and results of operations.

Certain of our subsidiaries currently enjoy, and other subsidiaries may in the future enjoy, preferential tax treatment, including reduced tax rates, and certain other preferential treatment or government grants. The expiration of, or changes to, any of these preferential treatments or subsidies could adversely affect our business, financial condition, and results of operations.

We have received preferential tax treatments and currently benefit from certain preferential tax treatments that reduce our overall tax obligations. These benefits include reduced tax rates, tax refunds, or other favorable tax policies provided by governmental authorities in certain jurisdictions where we operate. However, these preferential tax treatments are typically subject to review and renewal by the relevant tax authorities and are dependent on our compliance with applicable rules and regulations. There is no assurance that we will continue to qualify for such preferential tax treatment or that these benefits will be renewed upon expiration. In addition, changes to existing laws, regulations, or interpretations of tax policies could result in the reduction or elimination of these benefits. Furthermore, we have received government grants in the past, but we cannot guarantee that we will continue to receive such government grants or preferential tax treatment in the future. Any such change, non-renewal, or failure to qualify could significantly increase our tax obligations or reduce our income and adversely affect our business, financial condition, and results of operations.

Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses.

Fluctuations in exchange rates between the Renminbi and the U.S. dollar and other currencies may be affected by, among other things, trade tensions between the U.S. and China, as well as international economic and political developments. Due to the economic situation and financial market developments in the PRC and abroad, the PRC government has decided to proceed further with reform of the Renminbi exchange rate regime and to enhance the Renminbi exchange rate flexibility. Changes in exchange rates have in the past, and could in the future continue to, materially and adversely affect our financial conditions and results of operations.

RISKS RELATING TO OUR OPERATIONS

We may encounter difficulties in managing our anticipated growth or expand our operations successfully.

As we seek to advance our pipeline products through clinical trials and eventually achieve commercialization, we will need to expand our development, regulatory, manufacturing, sales and marketing capabilities or contract with third parties to provide these capabilities for us. In addition, we may need to manage additional relationships with various strategic partners, suppliers and other

RISK FACTORS

third parties. Future growth will impose significant additional responsibilities on our management. Our future financial performance and our ability to commercialize our pipeline products and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We cannot assure you that we will be able to successfully develop and commercialize our drug candidates and build suitable, or procure for external providers, manufacturing, sales, marketing and managerial functions to meet our growth targets.

Managing our growth and executing our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive global pharmaceutical market, effective coordination and integration of our teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, increased sales and marketing activities, effective quality control, and management of our suppliers and collaborators. If we are not able to effectively manage our growth or execute our growth strategies, our business, financial condition, results of operations and prospects could be adversely affected.

We, our management and directors may be involved in claims, disputes, litigation, arbitration or other legal proceedings in the ordinary course of business.

We, our management or directors may from time to time become party to litigations, legal disputes, claims or administrative proceedings arising in the ordinary course of our business. These may concern issues relating to product liability, environmental matters, breach of contract, employment or labor disputes. For example, we may be sued if our pipeline products 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, negligence, strict liability or a breach of warranties.

Involvement in legal disputes may distract our management's or directors' attention and consume our time and other resources. Furthermore, any legal disputes which are initially not of material importance may escalate due to the facts and circumstances of the cases, the likelihood of winning or losing, the monetary amount at stake and the parties concerned, and such factors may result in these cases becoming of material importance to us. If we cannot successfully defend ourselves against the claims, we may incur substantial liabilities or be required to limit commercialization of our pipeline products. Negative publicity arising from litigations, legal disputes, claims or administrative proceedings may damage our reputation and the image of our brands and products. In addition, if any verdict or award is rendered against us, we could be required to pay significant monetary damages, assume other liabilities, and suspend or terminate the related business ventures or projects.

Our future success depends in part on our ability to retain key executives and to attract, hire, retain and motivate other qualified and highly skilled personnel.

We depend on the continued contributions of our senior management, especially the executive officers listed in the section headed "Directors and Senior Management" in this Document, and other key employees, many of whom may be difficult to replace. Replacing executive officers, scientific employees, and other qualified personnel may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products like those we develop. The loss of the services of any of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives.

Our future success is dependent on our ability to attract qualified employees and retain existing key employees, especially our drug development and technology professionals. There is, and will continue to be, intense competition for highly skilled management, technical, sales and other personnel with experience in our industry in the cities where our offices are located. Our need to increase the number of our qualified employees and retain key employees may cause us to

RISK FACTORS

materially increase compensation-related costs, including stock-based compensation. We must provide competitive compensation packages and a high-quality work environment to hire, retain and motivate employees. To the extent we hire personnel from competitors, we also may be subject to allegations that they have been improperly solicited or divulged proprietary or other confidential information. If we are unable to retain and motivate our existing employees and attract qualified personnel for important positions, we may be unable to manage our business effectively, including the development, marketing and sale.

If our CROs, CDMOs or business partners fail to comply with environmental, health and safety laws and regulations, we could be subject to fines or penalties and other negative consequences that could have a material adverse effect on 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 materials, and may produce hazardous wastes. For additional information on our internal control measures with regard to compliance with environmental, health and safety laws, see “Business — Social, Health, Work Safety and Environmental Matters” and “Business — Risk Management and Internal Control.” We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from use of hazardous materials caused by our third-party research collaborators or other contractors or consultants, we could be held liable for any resulting damages, and any liability could exceed our resources. In addition, we may incur substantial costs to ensure compliance with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may affect our research, development or production efforts.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We maintain insurance policies required under the applicable laws and regulations as well as based on our assessment of our operational needs and industry practice. For more details, please see “Business — Insurance.” For example, we maintain insurance coverage for adverse events in our clinical trials, but this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations. Our insurance coverage may also be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

Our information technology systems, or those used by our partners or other contractors or consultants, may fail or suffer security breaches.

We make use of information technology systems to obtain, process, analyze and manage data. We use these systems to monitor the daily operations of our business, record R&D activities, maintain operating and financial data, as well as manage our quality control systems. Our information technology systems and those of our CROs, CDMOs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication and electrical failures. Any system damage or failure that interrupts data input, retrieval or transmission or increases service time could disrupt our normal operations. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed. There can be no assurance that we will be able to effectively handle a failure of our information systems, or that we will be able to restore our operational capacity in a timely manner to avoid disrupting our business. In addition, if the capacity of our information systems fails to meet the increasing needs of our expanding operations, our ability to expand may be constrained.

RISK FACTORS

Negative publicity on us or failure to maintain and enhance our recognition and reputation may materially and adversely affect our business.

Market awareness and recognition of our brand image, and the maintenance of a positive brand image, are crucial to the success of our business. We may not be successful in promoting our brands to remain competitive. In addition, we may engage various third parties, such as contract sales organizations, to expand our commercialization network and increase market access for our drugs, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties. Any negative publicity, including disputes concerning us, our business partners or our affiliates could adversely affect our reputation and prospects. If we are unable to maintain a good reputation, our ability to attract and retain key employees and business partners could be harmed.

Our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. Negative publicity about us, such as alleged misconduct or improper activities, can harm our business, financial condition, results of operations and prospects. Any regulatory inquiries or investigations against our operations or management, any perceived unethical, fraudulent, or inappropriate business conduct by us, our business partners or our affiliates, could harm our reputation and materially and adversely affect our business. Moreover, any negative media publicity about the pharmaceutical industry in general, including issues and allegations involving other companies, may negatively impact our reputation. If such negative publicity relates to our products and business, the adverse impact on our financial condition or results of operations might be more significant. Any such negative publicity may undermine the public confidence in our products, reputation, brand image, business prospects, and impair the development and commercialization of our pipeline products. Investigations and increasingly stringent regulations arising from such negative publicity, if any, may draw time and attention from our management team, which would have otherwise been devoted into our business operations, or may incur additional compliance expenses.

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.

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 regions where we conduct our business. Our operations, and those of our third-party collaborators, suppliers and other contractors and consultants, 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. For example, since the end of December 2019, the outbreaks of a novel strain of coronavirus COVID-19 have materially and adversely affected the global economy. Many countries and regions had been affected by the COVID-19 outbreaks. There is no assurance that such kind of health epidemic or even a more severe pandemic will not occur again in the future.

We may be exposed to the risks of conducting business in multiple jurisdictions.

We are exploring and plan to continue to explore market opportunities overseas, and we intend to continue to identify and collaborate with reputable local partners that have proven track record to maximize the global value of our pipeline products. We will also continue seeking licensing and co-development opportunities to expand our global clinical programs. However, such activities may subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including: efforts to enter into license and collaboration arrangements with third parties may increase our expenses or divert our management’s attention from the development of drug candidates; political and economic instability as well as geopolitical tensions, including the threat of war or terrorist attacks (notably the Russia-Ukraine conflicts and the reaction of the international community, the consequences of which on the financial markets and the global

RISK FACTORS

business climate remain uncertain); differing regulatory requirements for drug approvals and marketing internationally; potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment; difficulty of effective enforcement of contractual provisions in local jurisdictions; unexpected changes in regulatory requirements, and delays resulting from difficulty in obtaining export licenses; significant adverse changes in currency exchange rates; compliance with tax, employment, immigration and labor laws for employees traveling abroad; the effects of applicable foreign tax structures and potentially adverse tax consequences; and business interruptions resulting from natural disasters.

In addition, changes in international trade policies may also adversely affect various aspects of our business operations. For example, the U.S. government has made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies towards China. It remains unclear what additional actions, if any, will be taken by the U.S. or other governments with respect to international trade agreements, the imposition of tariffs on goods imported into the U.S., tax policy related to international commerce, or other trade matters. It is unknown whether new tariffs will be imposed, or whether new laws and regulations will be enacted, or the effect that any such actions would have on us or our industry. Any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the import or export of raw materials and disrupt our drug development and the manufacturing of our drug candidates. Such unfavorable policies may also negatively impact the hiring of scientists and other R&D personnel, the demand for and competitiveness of our drugs, or prevent us from selling our drugs in certain countries.

On December 18, 2025, the U.S. Senate passed the BIOSECURE Act as a part of the National Defense Authorization Act for Fiscal Year 2026, which was signed into law by the U.S. President. We are of the view that the BIOSECURE Act will not have a material and adverse impact on our business, primarily because we are not a recipient of any U.S. federal government contracts, loans, grants or funding and do not anticipate applying for such contracts, loans, grants or funding in the future. Furthermore, to our best knowledge, none of our licensing partners are using any services provided by us under the respective licensing arrangements in connection with any federal contracts, loans, grants or funding.

RISKS RELATING TO DOING BUSINESS IN JURISDICTIONS WHERE WE OPERATE

We will be concurrently subject to PRC and Hong Kong [REDACTED] and regulatory requirements.

As we are listed on the Shanghai Stock Exchange and will be [REDACTED] on the Main Board of the Hong Kong Stock Exchange, we will be required to comply with the listing rules (where applicable) and other regulatory regime of both jurisdictions, unless otherwise agreed by the relevant regulators. Accordingly, we may incur additional costs and consume additional resources in complying with the requirements of both jurisdictions.

Our A Shares are listed on the Shanghai Stock Exchange, and the characteristics of the A Share and H Share markets may differ.

Our A Shares are listed on the Shanghai Stock Exchange. Following the [REDACTED], our A Shares will continue to be traded on the Shanghai Stock Exchange and our H Shares will be [REDACTED] on the Hong Kong Stock Exchange. Under current PRC laws and regulations, without the approval from the relevant regulatory authorities, our H Shares and A Shares are neither interchangeable nor fungible, and there is no [REDACTED] or settlement between the H Share and A Share markets. With different [REDACTED] characteristics, the H Share and A Share markets have divergent [REDACTED] volumes, [REDACTED] and [REDACTED] bases, as well as different levels of retail and institutional [REDACTED] participation. As a result, the [REDACTED] performance of our H Shares and A Shares may not be comparable. Nonetheless, fluctuations in the price of our A Shares may adversely affect the [REDACTED] of our H Shares, and vice versa. Furthermore, due to the different characteristics of the H Share and A Share markets, the historical prices of our A Shares may not be indicative of the performance of our H Shares. You should therefore not place undue reliance on the [REDACTED] history of our A Shares when evaluating the [REDACTED] decision in our H Shares.

RISK FACTORS

We are subject to privacy laws and information security policies related to data privacy and security, and we may be exposed to risks relating to personal or other sensitive information.

We and the CROs we engage may routinely receive, collect, generate, process, store, transmit and maintain medical data treatment records and other personal details or sensitive information of subjects enrolled in our clinical trials. As a result, we are subject to a wide range of data protection and privacy laws, regulations, directives, and standards at the local, national, and international levels, as well as contractual obligations governing the collection, use, retention, protection, disclosure, and transfer of personal data across the jurisdictions in which we operate. The legislative and regulatory landscape for privacy, data protection and information security continues to evolve in jurisdictions worldwide, and there has been an increasing focus on these issues with the potential to affect our business. Our ongoing efforts to comply with evolving laws and regulations may be costly and require ongoing modifications to our policies, procedures and systems.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, PRC Cyber Security Law (《中華人民共和國網絡安全法》), which became effective in June 2017, created China’s first national-level data protection for “network operators”, which may include all organizations in China that provide services over the internet or another information network. On June 10, 2021, the Standing Committee of the National People’s Congress (NPCSC) promulgated the PRC Data Security Law (《中華人民共和國數據安全法》), effective on September 1, 2021, which imposes data security and privacy protection obligations on entities and individuals which carry out data activities, and introduces a data classification and hierarchical protection system. On August 20, 2021, the NPCSC promulgated the PRC Personal Information Protection Law (《中華人民共和國個人信息保護法》), effective on November 1, 2021, which further detailed the general rules and principles on personal information processing and further increased the potential liability of personal information processor. See “Regulatory Overview — Laws and Regulations on Information Security and Data Privacy.” Compliance with newly enacted laws and regulations may significantly increase our operational costs or necessitate changes to our business practices that could materially and adversely affect our operations.

Such 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. We and our third-party collaboration parties such as clinical research centers have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization, and setting internal rules requiring employees to maintain the confidentiality of our subjects’ medical records. However, these measures may not always be effective. For example, our and our collaboration partner’s information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, our clinical trials involve multi-party collaboration, we cannot guarantee that our collaboration partners or their personnel will consistently adhere to our or their data privacy management standards.

Furthermore, any change 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. For laws and regulations related to the privacy and security of personal information in China, see “Regulatory Overview — Laws and Regulations on Information Security and Data Privacy.”

Laws in all 50 U.S. states require businesses to provide notice under certain circumstances generally to governmental authorities and affected individuals in connection with certain breaches of personal information, and, in the future, we may be required to notify applicable governmental authorities and affected individuals in the event of a data breach or other data security incident. In addition to data breach notification laws, some states have enacted statutes and rules requiring

RISK FACTORS

businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. Other states also have enacted laws and regulations relating to privacy and information security and comprehensive privacy laws. The laws are not consistent, as certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international, or other state laws, and such laws may differ from each other, which may complicate compliance efforts. These laws may apply directly to our business or indirectly by contract when we enter into collaboration arrangements to other companies. If we become subject to these new or additional privacy laws, the risk of enforcement actions against us could increase.

In addition, the European Union’s General Data Protection Regulation (EU) 2016/679, or GDPR, went into effect on May 25, 2018 in respect of processing operations carried out in the context of the activities of an establishment in the European Economic Area, or EEA, and any processing relating to the offering of goods or services to individuals in the EEA and/or the monitoring of their behavior in the EEA. The GDPR provides that EEA member states may make their own further laws and regulations to introduce specific requirements in certain areas, including related to the processing of “special categories of personal data,” including personal data related to health and genetic data. This may lead to greater divergence among the laws and regulations that apply to the processing of personal data across the EEA and United Kingdom, compliance with which, as and where applicable, may increase our costs and could increase our overall compliance risk. Such laws and regulations could also limit our ability to collect, use, share and otherwise process personal data in the context of our EEA and/or UK establishments (regardless of where any such processing occurs), and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business, and harming our business and financial condition.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “**Scientific Data Measures**”), which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, 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, if and to the extent our R&D of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our R&D of drug candidates may be hindered, which may materially and adversely affect our business, financial condition, results of operations and prospects. In addition, according to the Administration of Human Genetic Resources (《人類遺傳資源管理條例》) promulgated in March 2024 and the PRC Biosecurity Law (《生物安全法》) promulgated in April 2024, if any scientific data falls within the scope of Chinese human genetic resources, any transfer of such data outside of China will be subject to the prior approval of the PRC Ministry of Science and Technology. There can be no assurance that we will be able to obtain such approval in a timely manner, or at all.

The data collected by us mainly includes personal information of patients participating in clinical trials and clinical trial data, and the relevant data are processed in accordance with the informed consent forms agreed by the patients. To the best of our knowledge, we believe that all the personal information of patients generated in our clinical trials has been de-identified to the extent necessary. According to the cooperation agreements entered into with our overseas collaboration partners, we provide online access of certain clinical data to them.

RISK FACTORS

According to Article 22 of the Administration of the Management of Human Genetic Resources, an approval is not required where clinical institutions, in order to obtain the marketing licenses of relevant drugs and medical devices in China, carry out international cooperation in clinical trials by utilization of China’s human genetic resources by the clinical institutions but not involving the export of physical materials of human genetic resources. However, the two cooperating parties shall, before conducting such clinical trials, submit the types, quantities and uses of the human genetic resources to be used to the health department of the State Council for filing. We transfer clinical trial data to our collaboration partners online, which does not involve the export of physical materials of human genetic resources, and have filed with the Human Genetic Resource Administration of China certain reports regarding the use of human genetic materials in clinical studies.

In addition, our transfer of the clinical trial data to our overseas collaboration partners does not involve data export security assessment under the Measures for the Security Assessment of Cross-Border Data Transmission, because we are not critical information infrastructure operator, we do not process personal information of more than 1 million people, and we do not provide personal information of more than 100,000 people or sensitive personal information of more than 10,000 people to our overseas collaboration partners.

We may be directly or indirectly subject to applicable anti-kickback, false claims laws, doctor payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, which could expose us to increased compliance costs and diminished future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which our drug products, for which marketing approvals are obtained, are marketed, sold and distributed. For instance, the marketing and sales activities of befotertinib (BPI-D0316), garsorasib (D-1553) and our other pipeline products, once they are approved by the NMPA, will be subject to various PRC fraud and abuse laws, including the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》) and the PRC Criminal Law (《中華人民共和國刑法》). After receiving marketing approvals from the FDA, our operations will be subject to federal and state fraud and abuse laws of the U.S., including the federal Anti-Kickback Statute and the False Claims Act, as well as physician payment transparency laws and regulations, including the Physician Payments Sunshine Act.

Furthermore, we are subject to anti-bribery laws in China and overseas that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing other improper advantages. In addition, we are subject to the Foreign Corrupt Practices Act of the U.S., which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and regulations, and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws or regulations. If any regulatory actions are instituted against us, they could result in substantial costs and be a distraction to management and our specific personnel.

We are also exposed to the risk that our independent contractors, consultants, commercial collaborators, principal investigators, CROs, CDMOs, suppliers and vendors may engage in misconduct or other improper activities. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials,

RISK FACTORS

which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties. Those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

There might be uncertainties in effecting service of legal process and enforcing foreign judgments against us and our management in the PRC.

We are a company incorporated under the laws of the PRC, and a significant portion of our assets and the majority of our Directors and senior management are located in the PRC. As a result, it may be difficult for the [REDACTED] to directly effect service of process outside the PRC upon us or most of our Directors and senior management in the PRC.

On July 14, 2006, the Supreme People’s Court of the PRC 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 Courts of the Mainland and the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “**Arrangement**”). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case pursuant to a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A judgment rendered by a Hong Kong court may not be enforced in Chinese Mainland if the parties in dispute have not agreed to enter into a choice of court agreement in writing.

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 “**New Arrangement**”), which seeks to establish 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 New Arrangement does not include the requirements for a choice of court agreement in writing by the parties. The New Arrangement has come into effect on January 29, 2024 and superseded the Arrangement. After the New Arrangement became effective, 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.

Required procedures on the remittance of Renminbi into and out of the PRC may affect our ability to pay dividends and other obligations and affect the value of your [REDACTED].

Procedures on the remittance of Renminbi into and out of the PRC are required under the relevant PRC laws and regulations. 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 H Shares. Shortages in the availability of foreign currency may affect our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations. Under the relevant PRC laws and regulations, foreign exchange transactions under the current account conducted by us do not require advance approval from China’s State Administration of Foreign Exchange (“SAFE”), but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies.

RISK FACTORS

Holders of 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, pursuant to the Circular on Certain Policy Questions Concerning Individual Income Tax (《財政部、國家稅務總局關於個人所得稅若干政策問題的通知》) (Cai Shui Zi [1994] No. 020) issued by the MOF and SAT on May 13, 1994, the income gained by individual foreigners from dividends and bonuses of enterprises with foreign investment are 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, pursuant to the Circular of Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) (Cai Shui Zi [1998] No. 61) issued by the MOF and the SAT on March 30, 1998, from January 1, 1997, the income of individuals from the transfer of the shares of [REDACTED] enterprises continues to be exempted from individual income tax.

As of the Latest Practicable Date, no aforesaid provisions had expressly provided that individual income tax shall be levied on non-PRC resident individual holders on the transfer of shares in PRC resident enterprises [REDACTED] on overseas stock exchanges, and to our knowledge, no such individual income tax was levied by PRC tax authorities in practice. However, there is no assurance that the PRC tax authorities will not change these practices 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. In accordance with the Circular on Issues Relating to Withholding of Enterprise Income Tax by PRC Resident Enterprises on Dividends Paid to Overseas Non-PRC Resident Enterprise Shareholders of H Shares (《關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》) (Guo Shui Han [2008] No. 897) issued by SAT on November 6, 2008, 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.

Despite the arrangements mentioned above, 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 your [REDACTED] in our H Shares.

RISK FACTORS

We are subject to risks in relation to our social insurance and housing provident fund contributions.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to the social insurance plans and the housing provident fund under the relevant PRC laws and regulations for our employees. As of the Latest Practicable Date, we did not make full social security insurance contributions for two employees who are not PRC citizens, in accordance to their own preference, which we estimate to be approximately RMB0.7 million during the Track Record Period. We also engaged a third-party human resources agency to pay social insurance premium and housing provident funds for 12 employees. Pursuant to the agreement entered into between such third-party human resources agency and us, the third-party human resources agency would pay social insurance premium and housing provident funds for such employee on behalf of us. If the relevant governmental authorities determine the use of the third-party agency to pay social insurance premium and housing provident funds to be non-compliant in the future or such human resources agency fails to pay the social insurance premium or housing provident funds for our employee as required by applicable PRC laws and regulations, or if the relevant government authorities require us to pay social insurance premium for employees who are not PRC citizens despite their own preference not having us make such payments, we may be subject to additional contribution, late payment fee and/or penalties imposed by the relevant PRC authorities for failing to discharge our obligations in relation to payment of social insurance premium and housing provident funds as an employer or be ordered to rectify. This in turn may adversely affect our financial condition and results of operations.

We are subject to risks associated with our leased properties.

We have leased certain properties in China as our offices and laboratories. Pursuant to Interpretation of Supreme People’s Court on Several Issues Concerning the Specific Application of Law in the Trial of Cases Involving Disputes over Contracts for Lease of Urban Houses (《最高人民法院關於審理城鎮房屋租賃合同糾紛案件具體應用法律若干問題的解釋》) promulgated by the Supreme People’s Court of the PRC, lessee’s request to continue performance of the lease contract may not be enforceable in the event the property is foreclosed by the mortgagee where the property is mortgaged before leased to the lessee. As of the Latest Practicable Date, we have leased 2 properties in Shanghai after such properties were mortgaged. We may not be able to exercise rights of the lessee if the mortgagee forecloses on the property. In addition, pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, we had not registered 5 lease agreements as tenant, which were primarily used as offices and laboratories. We may be subject to fines if we fail to rectify such non-compliance within the prescribed time frame after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of lease agreements. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfill the registration requirements, which may increase our costs in the future. In addition, as our leases expire, we may face difficulties renewing them, either on commercially acceptable terms or at all. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

RISK FACTORS

RISKS RELATING TO THE [REDACTED]

There has been no [REDACTED] for our H Shares. An active [REDACTED] for our H Shares may not develop or be sustained, and their [REDACTED] and [REDACTED] maybe volatile, which could lead to substantial losses to [REDACTED].

Prior to the [REDACTED], there was no [REDACTED] for our H Shares. We cannot assure you that a [REDACTED] for our H Shares with adequate [REDACTED] will develop and be sustained following the completion of [REDACTED]. The [REDACTED] for our H Shares to the [REDACTED] is the result of negotiations between us and the Overall Coordinators (for themselves and on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the [REDACTED] of the H Shares following the [REDACTED].

We have applied to the Hong Kong Stock Exchange for the [REDACTED] of, and permission to [REDACTED] in, the H Shares (including any H Shares which may be issued pursuant to the exercise of the [REDACTED]). A [REDACTED] on the Hong Kong Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] for the H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the H Shares will not decline following the [REDACTED]. If an active [REDACTED] for our H Shares does not develop following the completion of the [REDACTED], the [REDACTED] and [REDACTED] of our H Shares could be materially and adversely affected.

Furthermore, the [REDACTED] and [REDACTED] of our H Shares may be volatile. The following factors, among others, may affect the [REDACTED] and [REDACTED] at which our H Shares will [REDACTED]: variations in our revenue, earnings and cash flow; announcement of new investments, business collaborations, strategic alliances or acquisitions; any unexpected business interruptions resulting from epidemics, natural disasters or power shortages; any major changes in our Directors, senior management or other key personnel; our inability to obtain or maintain regulatory approval for our operations; our inability to compete with our competitors effectively; political, economic, financial and social developments; or fluctuations in market prices for our products or raw materials. Moreover, shares of other companies listed on the Hong Kong Stock Exchange with operations and assets in China have experienced significant price volatility in the past. It is possible that our H Shares may be subject to changes in [REDACTED] not directly related to our performance and as a result, [REDACTED] in our H Shares may suffer substantial losses.

Our Single Largest Group of Shareholders have substantial influence over our Company and their interests may not be aligned with the interests of our other Shareholders.

Immediately upon the completion of the [REDACTED], without taking into account any H Shares which may be issued pursuant to the exercise of the [REDACTED] and further Shares may be issued under the Restricted Share Incentive Schemes, our Single Largest Group of Shareholders will collectively control approximately [REDACTED]% of the voting power at our Shareholders' meetings. Our Single Largest Group of Shareholders will thus have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional Shares or other equity securities, timing and amount of dividend payments, and our management. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their H Shares as part of a sale of our Company and might reduce the [REDACTED] of our H Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interests of our Single Largest Group of Shareholders may differ from the interests of our other Shareholders. We cannot assure you that our Single Largest Group of Shareholders will not exercise their substantial influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

RISK FACTORS

Future sales or perceived sales or conversion of significant amounts of our H Shares in the [REDACTED] following the [REDACTED] could materially and adversely affect the [REDACTED] of our H Shares.

The [REDACTED] of our H Shares could decline as a result of future sales of a substantial number of our H Shares or other securities relating to our H Shares in the [REDACTED], or the issuance of new shares or other securities, or the perception that such sales or issuances may occur. Future sales, or anticipated sales, of substantial amounts of our securities, including any future offerings, could also materially and adversely affect our ability to raise capital at a specific time and on terms favorable to us. In addition, our Shareholders may experience dilution in their holdings if we issue more securities in the future. New Shares or Shares-linked securities issued by us may also confer rights and privileges that take priority over those conferred by the H Shares.

In addition, while [REDACTED] shares in the [REDACTED] are not subject to any restrictions on the disposal of the H Shares they subscribed (except otherwise disclosed in this Document), they may have existing arrangements or agreement to dispose part or all of the H Shares they hold immediately or within certain period upon completion of the [REDACTED] for legal and regulatory, business and market, or other reasons. Such disposal may occur within a short period or any time or period after the [REDACTED]. Any [REDACTED] of the H Shares [REDACTED] by such [REDACTED] pursuant to such arrangement or agreement could adversely affect the [REDACTED] of our H Shares and any sizeable sale could have a material adverse effect on the [REDACTED] of our H Shares and could cause substantial volatility in the [REDACTED] of our H Shares.

Purchasers of our H Shares in the [REDACTED] may experience immediate dilution upon such purchases. Further, you may experience further dilution if we issue additional Shares or equity securities in the future.

The [REDACTED] of the H Shares is higher than the net tangible asset value per H Share immediately prior to the [REDACTED]. Therefore, [REDACTED] of the H Shares in the [REDACTED] will experience an immediate dilution, while our existing Shareholders will receive an increase in the [REDACTED] adjusted consolidated net tangible asset value per Share of their Shares. In order to support the growth and expansion of our business, we may consider [REDACTED] and issuing additional Shares in the future. To the extent that such additional Shares are issued at a [REDACTED] lower than the net tangible asset value per Share at that time, purchasers of the H Shares may experience dilution in the net tangible asset value per Share of their Shares. In addition, we may issue Shares pursuant to employee incentive or share-based incentive schemes in accordance with applicable laws and regulations, which may have a dilutive effect on Shareholders’ interests in our Company.

Payment of dividends is subject to restrictions under the PRC law and there is no assurance whether and when we will pay dividends.

Under PRC law and the constitutional documents of our Company and our PRC operating subsidiaries, dividends may be paid only out of distributable profits, which refer to after-tax profits as determined under PRC GAAP less any recovery of accumulated losses and required allocations to statutory capital reserve funds. Any distributable profits that are not distributed in a given year are retained and become available for distribution in subsequent years. As a result, our Company and our PRC operating subsidiaries may not be able to pay a dividend in a given year if our Company or our PRC operating subsidiaries do not have distributable profits as determined under PRC GAAP even if they have profits as determined under IFRS. During the Track Record Period, no dividend had been paid or declared by us. See “Financial Information — Dividends” for further details of our dividend policy.

There can be no assurance that future dividends will be declared or paid. The declaration, payment and amount of any future dividends are subject to the discretion of our Directors, after taking into account our results of operations, financial condition, cash requirements and availability and other factors as they may deem relevant, and subject to the approval at Shareholders’ meeting. We may not have sufficient or any profits to enable us to make dividend distributions to our

RISK FACTORS

Shareholders in the future, even if our financial statements indicate that our operations have been profitable. For restrictions on the remittance of Renminbi out of the PRC, see “Risk Factors, Risk Factors Relating to Doing Business in Jurisdictions Where We Operate — Required procedures on the remittance of Renminbi into and out of the PRC may affect our ability to pay dividends and other obligations and affect the value of your [REDACTED].”

You should not place any reliance on any information released by us in connection with the listing of our A Shares on the Shanghai Stock Exchange.

As our A Shares are listed on the Shanghai Stock Exchange, we have been subject to periodic reporting and other information disclosure requirements in the PRC. As a result, from time to time, we publicly release information relating to us on the Shanghai Stock Exchange or other media outlets designated by the CSRC. However, the information announced by us in connection with our A Shares listing is based on regulatory requirements of the securities authorities, industry standards and market practices in the PRC, which are different from those applicable to the [REDACTED]. The presentation of financial and operational information for the Track Record Period disclosed on the Shanghai Stock Exchange or other media outlets may not be directly comparable to the financial and operational information contained in this document. Therefore, prospective [REDACTED] in our H Shares should be reminded that, in making their [REDACTED] decisions as to whether to [REDACTED] in our H Shares, should rely only on the financial, operating and other information included in this document. By applying to [REDACTED] our H Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and any formal announcements made by us in Hong Kong with respect to the [REDACTED].

Certain facts, forecasts and statistics in this Document relating to the biopharmaceutical industry are derived from various official government sources and have not been independently verified by us.

Certain statistics, information and data contained in this Document relating to China and elsewhere in the world, and the industry in which we operate have been derived from various official government publications. We believe that the sources of the information are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. However, information and statistics from official government sources have not been independently verified by us or any other parties involved in the [REDACTED] and no representation is given as to their accuracy. Due to possibly flawed or ineffective collection methods and analysis or discrepancies between published information and market practice, such statistics, information and data from official government sources in this Document may be inaccurate or may not be comparable to statistics, information and data produced with respect to other economies. There is no assurance that they are stated or compiled on the same basis or with the same degree of accuracy as the case may be in other jurisdictions. [REDACTED] should give consideration as to how much weight or importance they should attach to or place on such facts.

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].

Prior to the publication of this Document, there has been coverage in the media regarding us and the [REDACTED], which contained 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 any responsibility for the accuracy or completeness of such media coverage or forward-looking statements. We make no representation as to the appropriateness, accuracy, completeness or reliability of any information disseminated in the media. We disclaim any information in the media to the extent that such information is inconsistent or conflicts with the information contained in this Document. 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.