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An investment in our Shares involves significant risks. You should carefully consider all of the information in this prospectus, including the risks and uncertainties described below, before making an investment in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In any such case, the market price of our Shares could decline, and you may lose all or part of your investment. In particular, we are a biotechnology company seeking to list on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. There are unique challenges, risks and uncertainties associated with investing in companies such as ours, which may cause you to lose all or part of your investment.

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 prospectus.

RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR DRUG CANDIDATES

Our business and financial prospects depend substantially on the success of our clinical-stage and preclinical-stage drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and competitive position could be materially and adversely affected.

Our business and financial prospects depend substantially 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 financial resources in the development of our existing drug candidates, and expect to incur substantial and increasing expenditures for the development and commercialization of our drug candidates in the future.

The success of our drug candidates will depend on a number of factors, including:

- favorable safety and efficacy data from our preclinical studies and clinical trials;
- sufficient resources to acquire or discover additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- successful enrollment of patients in, and completion of, clinical trials as well as completion of preclinical studies;

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- sufficient supplies of drug products that are either used in combination or in comparison with our drug candidates in clinical trials;
- the performance by CROs or other third parties we engage to conduct clinical trials and their compliance with our protocols and applicable laws without damaging or compromising integrity of the resulting data;
- the capabilities and competence of our collaborators;
- receipt of regulatory approvals;
- commercial manufacturing capabilities;
- successful launch of commercial sales of our drug candidates, if and when approved;
- the obtaining and maintenance of favorable reimbursement from third-party payers for drugs, if and when approved;
- competition with other drug candidates and drugs;
- the obtaining, maintenance and enforcement of patents, trademarks, trade secrets and other intellectual property protections and regulatory exclusivity for our drug candidates;
- successful defense against any claims brought by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party; and
- the continued acceptable safety profile of our drug candidates following regulatory approval.

Some of our drug candidates represent a novel approach to therapeutic needs compared with more commonly used medical methods, and therefore carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. Any modification to the protocols related to the demonstration of safety or efficacy of our drug candidates may delay the clinical program, regulatory approvals or commercialization, and we may be required to supplement, modify, or withdraw and refile our applications for regulatory approvals. In addition, potential patients and their doctors may be inclined to use conventional standard-of-care treatments rather than any novel approach. Given the novelty of our drug candidates, a substantial amount of education and training may need to be provided to patients and medical personnel. This may have a material adverse effect on potential revenue generated from our drug candidates, which in turn may materially and adversely affect our competitive position, business, financial condition and results of operations.

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As of the Latest Practicable Date, all of our existing drug candidates were in various phases of preclinical and clinical development. If we do not achieve one or more of the aforementioned factors as expected, in a timely manner or at all, we could experience significant delays or difficulties in obtaining approvals for and commercializing our drug candidates, which would have a material adverse effect on our business, financial condition and results of operations.

Clinical drug development involves a costly and time-consuming process with an uncertain outcome, and we may encounter unexpected difficulties executing our clinical trials. Results of earlier studies and trials may not be predictive of future trial results.

Clinical trials are capital-intensive and may demand years of effort to complete, while their outcomes are inherently uncertain and may not be favorable. We may encounter unexpected difficulties during our clinical trials, such as delays in regulatory approvals, complexities of analytical testing technology, shortages of material supplies and outbreaks of epidemics, which may result in changes to our current clinical development plans. Failure can occur at any time or stage during the clinical trial process, which would result in a material and adverse effect on our business, financial condition and results of operations.

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 traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. It is common that various aspects of the development programs, such as manufacturing and formulation, are altered along the entire research and development stage in an effort to optimize processes and results, and there can be no assurance that such alterations would help achieve the intended objectives.

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 between earlier and later-phase clinical trials. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and other than as predicted, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates.

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If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.

RNA therapeutics are considered as emerging and relatively novel therapeutics. Their mechanisms of action have yet to be thoroughly understood, and AEs or side effects have been observed in preclinical studies and clinical trials in connection with their usage in patients with cancers.

Before obtaining regulatory approvals for the commercialization of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. If the results of the clinical trials of our drug candidates are not positive or only modestly positive for proposed indications, or if they raise safety concerns, any or some of the following would occur:

- Regulatory approvals for our drug candidates would be delayed or denied.
- We may be required to conduct additional clinical trials or other testing of our drug candidates beyond our current development plan.
- We may be required to add labeling statements, such as a “boxed” warning or a contraindication.
- We may be required to create a medication guide outlining the risks of the side effects for distribution to patients.
- We may be required to implement a risk evaluation and mitigation strategy program, including medication guides, doctor communication plans and other risk management tools with restricted distribution methods and patient registries.
- We may not be able to obtain regulatory approvals for all the proposed indications as intended.
- We may be subject to restrictions on how the drug is distributed or used.
- We may be sued or held liable for injury caused to individuals exposed to or taking our drug candidates.
- We may be unable to obtain reimbursement for use of the drug.
- Conditional regulatory approval of our drug candidates may require us to conduct confirmatory studies to verify the predicted clinical benefit and additional safety studies. The results from such studies may not support the clinical benefit, which would result in the approval being withdrawn.

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Having expended a significant amount of capital to progress our drug candidates, if such drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would not be able to realize any revenue on such drug candidates if they then or ultimately fail to receive regulatory approvals due to unsatisfactory clinical trial results, thereby materially and adversely affecting our business, financial condition, results of operations and prospects.

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

The successful and timely completion of clinical trials in accordance with their protocols depends on, among others, our ability to enroll a sufficient number of patients who opt to participate and remain in the clinical trials until the end of the trial. We may experience difficulties in patient enrollment for our clinical trials for a variety of reasons, including:

- the design of the trial;
- the size and demographics of the patient population;
- the size of the study population required for analysis of the trial's primary endpoints;
- the patient eligibility criteria defined in the protocol;
- our ability to obtain and maintain patient consents;
- patients' and clinicians' perceptions of the potential advantages and side effects of the drug candidate being studied compared with other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- the availability of approved therapies that are similar in mechanism to our drug candidates;
- the outbreak of epidemics or pandemics, such as COVID-19. See “– We may be subject to disasters, health epidemics such as COVID-19, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition and results of operations”;
- the proximity of patients to trial sites; and
- our ability to recruit clinical trial investigators with the appropriate competencies and experience.

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In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead choose to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct certain clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients available for our clinical trials at such clinical trial sites. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, thereby hindering the completion of these trials and adversely affecting our ability to advance the development of our drug candidates.

We may not be able to enhance our proprietary delivery platforms or develop new delivery platforms as expected to advance the development of innovative therapeutic modalities.

Our goal is to unlock the full potential of RNA therapeutics to silence gene targets by improving on and moving beyond the successes of conventional GalNAc RNAi delivery platforms to hepatocytes in the liver, in order to specifically reach a broader range of tissue and cell types. However, we may not be able to continually enhance our proprietary delivery platforms or develop new delivery platforms as expected. As a result, we may not be able to further expand the reach of our product pipeline and enhance the efficacy of our product candidates as expected, which may materially and adversely affect our business, results of operations and prospects.

We may be unable to identify, discover, develop or in-license new drug candidates, or to identify additional therapeutic opportunities for our drug candidates, to expand or maintain our product pipeline.

Although we mainly focus on the continued clinical testing, potential approvals and commercialization of our existing product candidates, the success of our business depends in part upon our ability to identify, discover, develop or in-license additional product candidates. There can be no assurance that we will be successful in identifying potential drug candidates. Drug candidates that we identify may be shown to have side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. Some drug candidates may be technically challenging to develop and manufacture. We have also pursued collaboration with third parties in the discovery and development of potential drug candidates. We have a strong track record of collaboration with biopharmaceutical and biotechnology companies as well as academic research institutions in China and the U.S. We are collaborating with Innovent and Shanghai Junshi on the development of combination therapies using STP705 and immune checkpoint inhibitors. We entered an agreement with Walvax to co-develop anti-influenza therapeutics, which includes an out-license for certain rights in mainland China, Hong Kong, Macau and Taiwan. However, there can be no assurance that such collaboration will be able to deliver the expected results.

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Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets require substantial technical, financial and human resources. Our research programs may show promising results in identifying potential indications and/or drug candidates at an initial stage yet fail to yield favorable results for clinical development.

We may fail to identify, discover, develop or in-license new drug candidates for clinical development and commercialization for a number of reasons, including the following:

- the research methodology used may not be effective in identifying potential indications or new drug candidates;
- potential drug candidates may be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve the safety and efficacy desired; or
- we may need to invest greater resources in identifying additional therapeutic opportunities for our drug candidates or developing suitable potential drug candidates, which would limit our ability to diversify and expand our drug portfolio.

Therefore, we may not be able to identify new drug candidates or additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs. We may invest efforts and resources in potential drug candidates or other potential programs that ultimately prove to be unsuccessful. Any of the foregoing events will have a material adverse effect on our business, results of operations and prospects.

RISKS RELATING TO REGULATORY APPROVALS AND GOVERNMENT REGULATIONS

All material aspects of the research, development and commercialization of biopharmaceutical products are heavily regulated, and the approval process is usually lengthy, costly and unpredictable. Any failure to comply with existing or future regulations and industry standards or any adverse actions by drug approval authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects.

The development and commercialization of drug candidates are heavily regulated in various jurisdictions. Although we focus on expanding our business in both the PRC and the U.S., we also seek to pursue opportunities in other jurisdictions. Authorities in various jurisdictions regulate strictly the development, approval, manufacturing, marketing, sales and distribution of biopharmaceutical products. Should we expand our business into these jurisdictions, we will face costly and time-consuming compliance burdens.

The process of obtaining regulatory approvals and maintaining compliance with applicable laws and regulations may be time-consuming and costly. Failure to comply with the

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applicable laws and regulations at any time or stage before or after receiving requisite regulatory approvals may lead to administrative penalties or judicial sanctions upon an applicant. Such penalties and sanctions may include, among others, refusal to approve pending applications, withdrawal of an approval, revocation of a license, a hold on clinical trials, voluntary or mandatory recalls of products, the seizure of products, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, and disgorgement of profits. Any of the foregoing events could materially and adversely affect our business, financial condition, results of operations and prospects.

The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and unpredictable. If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our targeted markets, our business may be subject to actual or perceived harm.

We are subject to risks associated with obtaining regulatory approvals. Granting, and the time in granting, regulatory approvals by the NMPA, the FDA and other comparable regulatory authorities are subject to various factors that are generally not within our control. It generally takes years to obtain regulatory approvals following the commencement of preclinical studies and clinical trials. In addition, regulations, approval policies and requirements for clinical data may change during the clinical development process of a drug candidate and may vary among jurisdictions. There can be no assurance that we will be able to obtain regulatory approvals for our existing drug candidates or any drug candidates we may identify, discover, develop or in-license in the future.

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

- disagreement in the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective for its proposed indication;
- failure of our clinical trial results to meet the level of statistical significance required for approvals;
- failure of our clinical trial process to meet GCP requirements;
- failure to demonstrate that a drug candidate's efficiency and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;

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- insufficient data collected from the clinical trials of our drug candidates to support the NDA, or other submissions or regulatory approvals;
- changes in regulations or approval policies that render our preclinical and clinical data insufficient for approval;
- failure of our manufacturing facilities or those of third-party contract manufacturers to pass GMP inspections during the regulatory review process or across the production cycle of our drug;
- failure of our clinical sites to pass audits carried out by the NMPA, the FDA or other comparable regulatory authorities, resulting in a potential invalidation of our research data;
- findings by the NMPA, the FDA or other comparable regulatory authorities of deficiencies related to our manufacturing processes or the manufacturing facilities of third-party manufacturers from whom we procure clinical and commercial supplies; and
- failure of our clinical trial process to keep abreast with any scientific or technological advancements required by regulations or approval policies.

The NMPA, the FDA or other comparable regulatory authorities may require more information to support approval, including additional preclinical, clinical or CMC data, which may result in either a delay in regulatory approval, therefore delaying our commercialization plans, or in the denial of regulatory approval. In the case where an approval is issued, regulatory authorities may approve fewer indications, including undesired indications, of our drug candidates than the indications we applied for, or grant approvals contingent on the performance of post-marketing clinical trials.

Failure to obtain regulatory approvals as expected in a timely and cost-effective manner, or at all, or failure to obtain regulatory approvals with an ideal scope of indications could have a negative impact on the commercial prospects of our drug candidates, and may cause reputational damage.

We may seek approvals from the NMPA, the FDA or other comparable regulatory authorities for an expedited review process for our drug candidates or for the use of data from registrational trials through accelerated development pathways; failure to obtain such approvals may have a material adverse effect on our business, financial condition, results of operations and prospects.

The NMPA, the FDA and the comparable regulatory authorities in other jurisdictions may allow the use of data from a registrational trial in connection with an applicable expedited review program for innovative drug candidates which may treat a serious or life-threatening

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condition, or may provide meaningful therapeutic benefit over therapies then available on the market upon a determination that the drug candidate demonstrates an effect on a surrogate endpoint or intermediate clinical endpoint which is reasonably likely to predict clinical benefit. For example, a drug candidate might receive an innovative drug designation from the NMPA if such drug or drug candidate has a novel and clearly defined structure and pharmacological property, and apparent clinical value and has not been marketed anywhere in the world; the FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity, or mortality.

There can be no assurance that any regulatory authority will consider our existing or future candidates as innovative drug applications or agree with our surrogate endpoints or intermediate clinical endpoints. In addition, there can be no assurance that any regulatory authority will grant an application for expedited approval. Even if an expedited review program exists, we may elect not to submit our candidates for review in that program. Even if we do make an application for expedited review, there can be no assurance that, after receiving feedback from the regulatory authorities, we will continue to pursue expedited review and approval. Furthermore, for any submission of an application for accelerated approval or another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing, or that any expedited review or approval will be granted on a timely basis, or at all.

Any failure to obtain accelerated approval or any other form of expedited review or approval for our drug candidates may result in a longer review period which may delay the commercialization of such drug candidate, increase the development expenses for such drug candidate and have a material adverse impact on our competitive position in the market and our business, financial condition, and results of operations.

In addition, if we obtain accelerated approval of a drug candidate based on a surrogate endpoint, we will likely be required to conduct a post-approval clinical outcome trial to confirm the clinical benefit of the drug candidate. If the post-approval trial is not successful, we may not be able to continue to market the drug for the relevant indication. Any delay or suspension of our ability to market a drug previously approved would have a material adverse effect on our business, financial condition and results of operations.

Adverse drug reactions and negative results from off-label use of our products could materially harm our business reputation, product brand name and financial condition.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with approved usage and labeling. Even though the NMPA, the FDA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, and even though we do not promote off-label use,

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there remains the risk that our product is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our products less effective or entirely ineffective and may cause adverse drug reactions. These may expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition.

Our drug candidates may cause undesirable AEs or have other properties that could delay or affect the granting of regulatory approvals, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval.

AEs caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a more restrictive label, delay in or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or a significant change in our clinical protocol or our development plan. Our trial results could reveal a high level of severity or prevalence of certain AEs. In such an event, our trials could be suspended or terminated and the NMPA, the FDA or other comparable regulatory authorities could deny approvals of, or order us to cease further development of, our drug candidates for any or all targeted indications. AEs related to our drug candidates may affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition, results of operations and prospects.

Additionally, undesirable side effects caused by any of our drug candidates after they receive regulatory approvals may lead to material and adverse effects, including the following:

- suspension of marketing of the drug candidate;
- withdraw of regulatory approvals or revocation of licenses for the drug candidate;
- additional warnings to be added to the label;
- regulatory authorities may require us to implement a risk evaluation and mitigation strategy program, or restrict distribution of our drugs or otherwise impose burdensome implementation requirements on us;
- we may be required to conduct specific post-marketing studies; and
- we could be subject to litigation and held liable for harm caused to patients, and our reputation may suffer.

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Any of the foregoing events could prevent us from achieving or maintaining market acceptance of any drug candidate that is approved and could materially and adversely affect our business, financial condition, results of operations and prospects.

After we receive regulatory approvals for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses and penalties for noncompliance.

Our drug candidates that have received regulatory approvals may be subject to conditions of approval or limitations on the approved indicated uses for which the drug may be marketed, or we may be required to perform post-marketing testing or continuously monitor the safety and efficacy of the drug candidate, which could adversely affect the drug's commercial potential. The NMPA, the FDA or other comparable regulatory authorities may also require a risk evaluation and mitigation strategy program as a condition of approval of our drug candidates or following approval. If the NMPA, the FDA or other comparable regulatory authorities approve our drug candidates, we will have to comply with requirements, including submissions of safety and other post-marketing information and reports, and registration, as well as continued compliance with GMPs and GCPs, for commercialized products as well as any clinical trials that we conduct post approval.

In addition, if any of our drug candidates receives regulatory approval in the future, it will be subject to changing and additional regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information.

We are required to maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business pursuant to relevant laws and regulations. Any failure to maintain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities to take remedial actions, suspension of our operations fines and penalties or other potential civil and criminal consequences which could materially and adversely affect our business, financial condition and results of operations. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain additional approvals, permits, licenses or certificates and there can be no assurance that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and, in turn, adversely affect our results of operations and prospects.

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In addition, after a drug is approved by the NMPA, the FDA or a comparable regulatory authority for marketing, there may be a subsequent discovery of problems with respect to our drug products which had not been identified previously, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. Such problems may result in, among others:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on our clinical trials;
- refusal by the NMPA, the FDA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us;
- suspension or revocation of existing drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

The NMPA, the FDA and comparable regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, the FDA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of patients enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in strengthened public scrutiny, elevated levels of

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enforcement and sanctions, and increased costs of compliance. Compliance with applicable laws, regulations, standards and obligations relating to data privacy, security and transfers may cause us to incur substantial operational costs or require us to change our data processing processes. Noncompliance with such laws or regulations could result in enforcement action against us, including fines, imprisonment of our management personnel, public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their respective personnel to protect the privacy of their enrolled patients and prohibit unauthorized disclosure of personal information. If such sponsors, operators or personnel divulge patients' private or medical records without their consent, they will be held liable for damage caused thereby. We have taken measures to maintain the confidentiality of the medical records and personal data we collect on patients enrolled in our clinical trials. However, such measures may not be always effective. For example, our 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. 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, which would be otherwise permissible prior to the new legislation becoming effective. Any failure to protect patients' medical records and personal data could have a material adverse effect on our business, financial condition and results of operations.

In addition, our clinical trials frequently involve professionals from third-party institutions who are working on-site with our staff and enrolled patients. There can be no assurance that such persons will always comply with applicable data privacy laws and restrictions on the use of genetic information or patients' personally identifiable information. Physicians, CROs, and other entities with whom we do business may be subject to laws or regulations of the PRC, the U.S. or other jurisdictions that restrict the use or disclosure of genetic information or other individually identifiable health information. A third party's failure to comply with those laws may affect our ability to use the individually identifiable health information and other personal information we receive from others. If the past or present operations of these third parties with whom we do business are found to violate applicable laws or regulations, they may be subject to exclusion from state or federal government programs or may be subject to other sanctions, which could also affect our reputation, our ability to apply for government programs, and our ability to conduct clinical trials. Any curtailment or restructuring of our operations could have a material adverse effect on our business, financial condition and results of operations.

The laws regulating the use of genetic information and patients' personally identifiable information are novel, complex and dynamic. We may not be able to respond to regulatory, legislative and other developments quickly and effectively or as well as our competitors, and

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these regulatory changes may in turn impair our ability to offer our existing or planned drug candidates or increase our operational costs. In addition, if our practices are not consistent, or deemed as not consistent, with legal and regulatory requirements, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges and severe criminal or civil sanctions. Any of the foregoing events could have a material and adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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 in the PRC, the U.S. and other jurisdictions, which could, in the event of noncompliance, expose us to administrative sanctions, criminal sanctions, civil penalties, contractual damages, reputational damage and diminished profits and future earnings.

Healthcare providers, including physicians and others, play a primary role in the recommendation and prescription of products for which we may seek regulatory approval. If we obtain NMPA or FDA approval for any of our drug candidates and if we then begin to market those drugs in the PRC or in the U.S., our operations may be subject to PRC and U.S. federal and state fraud and abuse laws, including the PRC Anti-Unfair Competition Law (反不當競爭法), the PRC Drug Administration Law (藥品管理法) and its implementing regulations, the PRC Criminal Law (刑法), the U.S. Federal Anti-Kickback Statute (AKS) and the U.S. Federal False Claims Act, as well as physician payment transparency laws and regulations, including the U.S. Federal Physician Payment Act (Sunshine Act). Our current and future operations also may be subject to regulation by U.S. federal, state and local authorities including, among others, the Centers for Medicare and Medicaid Services (CMS) and other divisions within the U.S. Department of Health and Human Services (HHS) such as the Office of the Inspector General and the Office for Civil Rights. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. There are ambiguities as to what is required to comply with any of these requirements, and if we fail to comply with any such requirements, we could be subject to applicable penalties.

Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. Regulatory authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational damage, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a material adverse effect on our business and results of operations.

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If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business.

We are subject to registration, review and other requirements of the PRC and the U.S. governments for cross-border sales or licensing of technology as well as operations related to genetics and data safety.

China imposes controls on the import and export of technology and software products. Under the Regulations on Administration of Imports and Exports of Technologies (技術進出口管理條例) promulgated by the State Council, which were amended in November 2020, technology import and export is defined to include, among others, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approvals by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts (技術進出口合同登記管理辦法), issued by the MOFCOM in February 2009, specify registration requirements related to the import and export of technology. We have entered into and may enter into agreements with CROs in the U.S. and the PRC for their technical support to assist us with the development of individual drug candidates, which may be deemed to constitute the import of technology under the regulations. As a result, such transfers are required to be registered with applicable governmental authorities. Although there are no explicit penalties set forth in these regulations for lack of such registration, failure to register an agreement where such registration is required may result in restrictions concerning foreign exchange, banking and taxation matters relating to such agreements. In addition, according to the Administration of Human Genetic Resources (《人類遺傳資源管理條例》) promulgated in May 2019 and the PRC Biosecurity Law (《生物安全法》) promulgated in October 2020, 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.

We are also subject to export control and import laws and regulations in the U.S., including the U.S. Export Administration Regulations, U.S. Customs regulations, economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. The U.S. Department of Commerce Bureau of Industry and Security (BIS) regulates the export of certain biological and chemical agents, and an export license may be required for the exchange of certain equipment and information we need to operate our business. Approval of such export license applications is based on the technology involved, the destination, and current U.S. foreign policy. Although we have not

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received any notification from any U.S. governmental authority regarding our exports, there can be no assurance that we will be able to obtain any such approval in a timely manner, or at all, if one is later needed.

As of the Latest Practicable Date, our agreements in effect with CROs in the PRC were signed by our PRC subsidiaries, while our agreements with CROs outside the PRC (including in the U.S) were not signed by our PRC subsidiaries. Therefore, our PRC Legal Advisor is of the view that the relevant agreements with CROs in the PRC in effect as of the Latest Practicable Date did not constitute the import or export of technology and were not subject to the Administrative Regulations of the People's Republic of China on Technology Import and Export, and were not required to be registered with competent authorities. Our legal counsel advisor in the U.S. also advised that our agreements with CROs in the U.S. in effect as of the Latest Practicable Date, which U.S. Legal Advisor has reviewed, did not involve the export of technology subject to the export license requirements imposed by the U.S. Department of Commerce Bureau of Industry and Security. To the extent that our technology is or becomes subject to U.S. export restrictions, we will comply with the applicable laws and regulations. Further, as advised by our U.S. Legal Advisor, they are not aware of any violation of U.S. import law with respect to our inbound technology transfers.

RISKS RELATING TO MANUFACTURING OF OUR DRUG CANDIDATES

We are exposed to various supply chain risks as we depend on a stable, adequate and quality supply of raw materials, technical services, equipment and infrastructure construction services, and any price increases or interruptions of such supply may have a material adverse effect on our business.

Our business and operations are exposed to various supply chain risks. We require a substantial amount of raw materials, such as packaging materials, reagents, consumables and clinical trial drugs, as well as technical services, equipment and infrastructure construction services. During the Track Record Period, we relied on third parties to supply certain materials. We expect to continue to rely on third parties to supply such materials and equipment for the research, development, manufacturing and commercialization of our drug candidates. See "Business – Procurement."

Currently, the materials and equipment are supplied by multiple source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. However, if supplies are interrupted, we may not be able to find alternative supplies in a timely and commercially reasonable manner, or at all. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates.

Moreover, we require a stable supply of materials for our drug candidates in the course of our research and development activities, and such needs are expected to increase significantly

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once we enter commercial production of drugs upon receipt of marketing approvals. However, there can be no assurance that current suppliers have the capacity to meet our demand. Any delay in receiving such materials in the quantities and of the quality that we need could delay the completion of our clinical trials, regulatory approvals of our drug candidates or our ability to timely meet market demand for our commercialized products, as applicable. Our suppliers may not be able to cater to our growing demands or may reduce or cease their supply of materials to us at any time. We are also exposed to the possibility of price increases, which we may not be able to pass on to customers and may, in turn, lower our profitability.

Our suppliers may also fail to maintain adequate quality of the materials and equipment we need. Although we implement quality inspection on the materials, there can be no assurance that we will be able to identify all of the quality issues. Suboptimal or even deficient supplies of materials and equipment may hinder the research and development of our drug candidates, subject us to product liability claims or otherwise have a material adverse effect on our operations.

In addition, there can be no assurance that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which, in turn, may result in shortages of the materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or the recall of our products. The noncompliance of these third parties may also subject us to potential product liability claims, cause us to fail to comply with continuing regulatory requirements, and result in us incurring significant costs to rectify such incidents of noncompliance, which may have a material and adverse effect on our business, financial condition and results of operation.

If we are unable to meet the increasing demand for our existing drug candidates and future drug products by ensuring that we have adequate manufacturing capacity, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business and financial condition would be materially and adversely affected.

Biopharmaceutical manufacturers often encounter difficulties in production, particularly in scaling up or out, validating the production process and assuring the high reliability of the manufacturing process. If our manufacturing facilities encounter unanticipated delays and expenses as a result of any of these difficulties, or if construction, regulatory evaluation and/or approvals of our new manufacturing facilities are delayed, we may not be able to manufacture sufficient quantities of our drug candidates, which would limit our development and commercialization activities.

Our current manufacturing capacity is sufficient to support currently planned scale clinical trials and short-term commercialization needs. If such needs grow significantly, we will need to expand our manufacturing capacity, mainly through the construction of new manufacturing facilities and upgrading our production process in a timely manner. However,

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the timing and success of these plans are subject to significant uncertainty. Moreover, such plans are capital-intensive and require considerable upfront investment, and there can be no assurance that we will be able to timely obtain such financing, if at all.

Given the size of our new manufacturing facilities, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence operation. During the construction and ramp-up period, there may be significant changes in the biopharmaceutical industry, including, among others, market demand, product and supply pricing, and customer preferences. Any adverse trends in these respects could result in operational inefficiency and excess capacity in our manufacturing facilities. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, such as:

- unforeseen delays due to construction, land use rights or regulatory issues, which could result in loss of business opportunities;
- construction cost overruns, which may require diverting resources and management's attention from other projects; and
- difficulty in finding sufficient numbers of trained and qualified staff.

The success of our business expansion also depends on our ability to advance drug candidates through the development, regulatory approval and commercialization stages. Any delay, suspension or termination in such respects would harm our ability to generate satisfactory returns on our investment in manufacturing expansion, if at all, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

We have no experience in manufacturing biopharmaceutical products on a large commercial scale and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.

As of the Latest Practicable Date, as we have not commercialized any products, we mainly produce drugs that are used for clinical trials. See "Business— Our Drug Candidates." We have limited experience in managing the manufacturing process. The manufacture of biopharmaceutical products is complex, in part due to strict regulatory requirements. If we are unable to identify an appropriate production site or a suitable partner to develop the manufacturing infrastructure, or fail to do so in a timely manner, it may lead to significant delays in the manufacturing of our drug candidates after we have obtained regulatory and marketing approvals. Investments in constructing or leasing new RNA therapeutics manufacturing facilities which are in compliance with GMP regulations may result in significant cost for us and in turn would have a material adverse effect on our commercialization plans. We may also fail to attract and retain personnel with the requisite skills and experience for drug manufacturing.

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In addition, problems may arise during the manufacturing process for reasons including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays in the construction of new manufacturing facilities or expansion of any future manufacturing facilities, changes in manufacturing production sites or limits to manufacturing capacity due to regulatory requirements, changes in the type of products produced, physical limitations that could inhibit continuous supply, and the occurrence of natural disasters. If problems arise during the production process of certain future products, a batch or even several related batches of such product may have to be discarded and cause production delays, cost increases, lost revenue and damage to customer relationships and our reputation. If problems have not been discovered before the relevant products are released to the market, we may incur additional costs in connection with product recalls and product liability.

Changes in U.S. and international trade policies, particularly with regard to China, may cause significant disruptions to our drug candidate manufacturing and other operations.

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. In January 2020, the “Phase One” agreement was signed between the U.S. and China on trade matters and went into effect on February 14, 2020, under which China agreed to expand purchases of certain U.S. goods and services by a combined US\$200 billion over 2020 and 2021 from 2017 levels. It remains unclear what additional actions, if any, will be taken by the U.S. or other governments with respect to other future international trade agreements, the imposition of tariffs on goods imported into the U.S., tax policies related to international commerce, or other trade matters. It is unknown whether new tariffs or new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. Although we have not started commercialization of drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the import or export of raw materials and directly disrupt our drug development and the manufacture of our drug candidates. Such unfavorable policies may also negatively impact the hiring of scientists and other research and development personnel, the demand for our drug products or the competitive position of our drug products, or prevent us from selling our drug products in certain countries. If any new tariffs, policies, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to recent U.S.-China trade tensions, such changes could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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RISKS RELATING TO COMMERCIALIZATION AND BUSINESS DEVELOPMENT OF OUR DRUG CANDIDATES

We have no experience in launching and marketing drug candidates. If we are unable to effectively build and manage our sales network or benefit from the sales networks of third-party collaborators, we may be unable to generate any revenue.

We currently have no sales, marketing or commercial product distribution capabilities and have no experience in marketing drugs. We intend to develop an in-house marketing team and sales force, which requires significant capital expenditure, management resources and time. We expect to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities, we will likely pursue collaborative arrangements with third parties regarding the sales and marketing of our drugs. 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 such arrangements will provide sufficient and effective sales support. Any revenue we receive will depend on the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in the search for third parties to assist us with the sales and marketing efforts of our drug candidates.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and, as a result, we may not be able to generate product sales revenue.

Our drug candidates may fail to achieve the degree of market acceptance by doctors, patients, third-party payers, hospitals, and others in the medical community that is necessary for commercial success.

Even if our drug candidates receive regulatory approvals, they may nonetheless fail to achieve satisfactory market acceptance by doctors, patients, third-party payers, hospitals or others in the medical community. Doctors and patients may prefer other drugs or drug candidates to ours. If our drug candidates do not achieve an adequate level of acceptance, the commercialization of such drug candidates may become less successful or profitable than we had expected.

The degree of market acceptance of our drug candidates, if and when they are approved for commercial sale, will depend on a number of factors, such as:

- product labeling or packaging requirements of the NMPA, the FDA or other comparable regulatory authorities, including the clinical indications for which our drug candidates are approved, and limitations or warnings contained in the labeling;

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- doctors, hospitals and patients considering our drug candidates to be safe and effective;
- whether our drug candidates have achieved first-in-class or best-in-class status and the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- timing of the launch of our drug candidates as well as of competitive drugs;
- cost of treatment in relation to alternative treatments;
- availability of adequate coverage and reimbursement under the NRDL and provincial reimbursement drug lists in the PRC, or from third-party payers and government authorities in other jurisdictions;
- willingness of patients to pay any out-of-pocket expenses in the absence of coverage and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration, including as compared with alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our drug candidates are approved but fail to achieve market acceptance among doctors, patients, third-party payers, hospitals or others in the medical community, we will not be able to generate significant revenue or become profitable. Even if our drugs achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced which are more favorably received or more cost-effective than our drugs or render our drugs obsolete.

We face intense competition and rapid technological change and the possibility that our competitors may develop products and therapies that are similar, more advanced, or more effective than ours, or launch biosimilar products and therapies ahead of us, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.

The biopharmaceutical industry in which we operate is highly competitive and rapidly changing. While our principal focus is to develop drug candidates with the potential to become novel or highly differentiated drugs, we face competition with respect to our current drug candidates and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future. Large multinational biopharmaceutical companies, well-established biopharmaceutical companies, specialty biopharmaceutical companies,

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universities and other research institutions have commercialized, are in the process of commercialization, or are pursuing the development of drugs for the treatment of cancers or other indications for which we are developing our drug candidates. For example, in recent years an increasing number of technology companies have joined the competition in the research and development of RNA therapeutics, with large biopharmaceutical companies leading the competition and small biotechnology companies making frequent breakthroughs. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. As such, our market share forecasted by CIC on our product candidates for RNAi therapeutics may change if any competitor drug candidate obtained market approvals from competent authorities or is accepted into the list in relation to reimbursement or procurement in China. See “Business – Our Core Drug Candidate.” Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Even if successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, our drug candidates may still face competition in various aspects, including safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status. Many of our competitors have substantially greater financial, technical and other resources, such as more advanced commercial infrastructure, more drug candidates in late-stage clinical development, more seasoned research and development staff and well-established marketing and manufacturing teams than us. Smaller or 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 biopharmaceutical industry may result in even more resources being concentrated in our competitors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or achieve better acceptance in the markets in which we operate or have established a competitive position. For example, the NMPA has recently accelerated market approvals of drugs for diseases with medical needs and the NMPA may review and approve drugs that have gained regulatory market approvals in the U.S., the EU or Japan in the past ten years without requiring further clinical trials in the PRC. This may lead to potential increased competition from drugs that have already obtained approvals in other jurisdictions.

Competition may further intensify as a result of advances in the commercial applicability of technologies and great availability of capital for investment in the industry. Our competitors may succeed in developing, acquiring, or licensing, on an exclusive basis, products that are more effective with a lower cost than our drug candidates, or achieve earlier patent protection, regulatory approvals, product commercialization and market penetration than we do. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability or safety in order to overcome price competition and to be commercially successful. Furthermore, disruptive technologies and

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medical breakthroughs may further intensify the competition and render our drug candidates obsolete or noncompetitive. Technologies developed by our competitors may render our potential drug candidates uneconomical or obsolete, and we may not be successful in marketing our drug candidates against competitors.

Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or not immediately available in the PRC, the U.S. or other countries for our drug candidates, and we may be subject to unfavorable pricing regulations, which may affect our profitability.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approvals of the sale price of a drug before marketing. In many countries, the pricing review period commences after marketing or licensing approvals are granted. In some markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approvals are granted. In addition, drug pricing policies are constantly changing in many countries. As a result, we might obtain regulatory approvals for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approvals.

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

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the indications and purposes for which the drug candidates are approved by the NMPA, the FDA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development,

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

The commercialization and business development of our drug candidates might not be in our full control.

Our strategic partners may own or co-own the right to commercialize our drug candidates because we may seek to in-license or out-license our drug candidates from time to time. In such cases, we would not have the exclusive right to commercialize our drug candidates. For example, we entered into a license agreement with Walvax in April 2021 pursuant to which we granted to Walvax the exclusive rights in the relevant target drug in mainland China, Hong Kong, Macau and Taiwan, including but not limited to clinical development, registration, manufacturing, and commercialization. See “Business – Collaboration and Licensing Arrangements – Licensing Arrangement with Walvax.” We may be subject to the following risks under this arrangement:

- Walvax may not pursue development and commercialization of the relevant target drug or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in its strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; and
- Walvax may not commit sufficient resources to the marketing and distribution of the relevant target drug.

In the future, we cannot assure you that if we decide to out-license other drug candidates, we will successfully be able to do so, or that any such partner will be able to successfully develop or commercialize products licensed from us, which in turn could adversely affect the licensing fees that we may receive from such arrangement. If we are unable to successfully identify a licensee partner for a particular drug candidate and are not able to further develop such drug candidate in-house, we may not be able to recover our investment in that product. Also, we cannot assure you that if we decide to in-license any drug candidates in the future, we will be successful in identifying favorable candidates or that the prospective licensor would agree to license such products to us at favorable commercial terms or at all. Even if we

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are able to in-license the drugs or drug candidates that we target, we cannot assure you that the products will be successfully commercialized. Even after we successfully in-license or out-license drug candidates, we cannot assure you that our licensors or licensees will not breach the relevant license agreements, whether inadvertently or otherwise. Alternatively, our licensors or licensees might conclude that we have materially breached our license agreements. In either case, the license agreements may be terminated, thereby removing our ability to develop and commercialize the drug candidates we in-license or generate licensing fees and royalties from the drug candidates we out-license.

Guidelines, recommendations and studies published by various organizations could disfavor our product candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' product candidates. Any such guidelines, recommendations or studies that reflect negatively on our product candidates, either directly or relative to our competitive product candidates, could result in current or potential decreased use, sales of, and revenue from one or more of our product candidates. Furthermore, our success depends in part on our and our partners' ability to educate healthcare providers and patients about our product candidates, and these education efforts could be rendered ineffective by, among other things, third-party guidelines, recommendations or studies.

Lack of third-party combination drugs may materially and adversely affect demand for our drugs.

Our drug candidates may be administered in combination with drugs of other biopharmaceutical companies as one regimen. We may also use third-party drugs in our development and clinical trials as controls for our studies. As a result, both the results of our clinical trials and the sales of our drugs may be affected by the availability of these third-party drugs. We generally have no influence over the availability and pricing of such drugs. If other biopharmaceutical companies discontinue these combination drugs, or if these drugs become prohibitively expensive, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs in a timely manner and on commercially reasonable terms, or at all. As a result, demand for our drugs may be lowered, which would in turn materially and adversely affect our business, financial condition, results of operations and prospects.

Illegal and parallel imports and counterfeit biopharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The illegal importation of similar or competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect

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our sales and profitability in the PRC and the U.S. and other countries where we commercialize our products. Unauthorized foreign imports of prescription drugs are illegal under the current laws of the PRC. However, illegal imports have occurred and may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets into higher-priced markets, which are known as parallel imports, could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers' ability to import lower-priced biopharmaceutical products of our future approved products or competing products from outside China or other countries in which we operate, conduct our clinical trials and perform our contractual obligations. Any future legislation or regulations that increase consumer access to lower priced drugs from outside China or other countries in which we operate, conduct our clinical trials and perform our contractual obligations could have a material adverse effect on our business.

Certain drug products distributed or sold may be manufactured without proper licenses or approvals or be fraudulently mislabeled with respect to their contents or manufacturers. These products are generally referred to as counterfeit biopharmaceutical products. Relevant governmental authorities may be unable to timely prevent counterfeit biopharmaceutical products imitating our products. As counterfeit biopharmaceutical products in many cases resemble the authentic biopharmaceutical products, yet are generally sold at lower prices, any counterfeiting of our products could reduce the demand for our future approved drug candidates. Counterfeit biopharmaceutical products are unlikely to meet our or our collaborators' rigorous manufacturing and testing standards, and may even cause health damage to patients. Our reputation and business could suffer harm as a result of counterfeit biopharmaceutical products.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We incurred net losses during the Track Record Period and anticipate that we will continue to incur net losses for the foreseeable future.

Investment in the development of biopharmaceutical products is highly speculative and involves significant risks that a drug candidate may fail to demonstrate efficacy or safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we financed our operating activities primarily through private equity financing. While we have other sources of income including government grants, interest income from restricted bank deposits and bank balances and consultancy income, we did not generate any revenue from commercialization of our drug products during the Track Record Period, and incurred, and will continue to incur, significant research and development expenses and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred net losses during the Track Record Period. In 2019, 2020 and nine months ended September 30, 2021, we had net loss of US\$17.1 million, US\$46.4 million and

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US\$50.0 million, respectively. Substantially all of our net losses resulted from our research and development expenses, changes in fair value of financial liabilities at fair value through profit or loss and administrative expenses.

We expect to continue to have net losses in the foreseeable future taking into consideration below activities relating to our development:

- conducting preclinical and clinical trials of our drug candidates;
- manufacturing clinical trial materials in or outside China;
- seeking regulatory approvals for our drug candidates;
- commercializing our drug candidates for which we have obtained marketing approvals;
- hiring additional clinical, operational, financial, quality control and scientific personnel;
- seeking to identify additional drug candidates;
- obtaining, maintaining, expanding and protecting our intellectual property portfolio;
- enforcing and defending any intellectual property-related claims; and
- acquiring or in-licensing other drug candidates, intellectual property and technologies.

Typically, it takes many years to develop one new drug from the time of its discovery to the time when it becomes available for treating patients. During the process, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown events that may have an adverse effect on our business, financial condition and results of operations. The size of our future losses will depend partially on our ability to generate revenue and control our expenses. If any of our drug candidates fails during clinical trials or does not obtain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and shareholders' equity.

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We had net cash outflow from operating activities since our inception. Even if we consummate the Global Offering, we may need to obtain additional financing to fund our operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our major drug candidates.

During the Track Record Period, our operations consumed a substantial amount of cash. Net cash used in operating activities was US\$14.4 million, US\$19.0 million and US\$36.9 million for 2019, 2020 and nine months ended September 30, 2021, respectively.

We expect our expenses to increase significantly in connection with our ongoing operating activities, particularly as we advance the research and development of our drug candidates and our platforms, initiate additional preclinical and clinical trials of, and seek regulatory approvals for, drug candidates.

In addition, if we obtain regulatory approvals for any of our drug candidates and elect to commercialize the candidates in-house, we might expect to incur significant commercialization expenses relating to product manufacturing, marketing, sales and distribution and post-approval commitments to continue monitoring the efficacy and safety data of our future products on the market. We may also incur expenses as we create additional infrastructure to support our operations as a public company.

We expect that we may continue to experience net cash outflows from our operating activities for the foreseeable future. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources. Adequate additional funding may not be available to us on commercially reasonable terms, or at all. If we are unable to raise sufficient capital in a timely manner or on commercially reasonable terms, we could be forced to delay, reduce or terminate our research and development projects or any future commercialization efforts, which could have a material adverse effect on our business, financial condition and results of operations.

We had net liabilities during the Track Record Period, and may continue to have net liabilities in the foreseeable future, which can expose us to liquidity risk

We had net liabilities of US\$49.0 million, US\$94.2 million and US\$140.3 million as of December 31, 2019 and 2020, and September 30, 2021, respectively. A net liabilities position can expose us to the risk of shortfalls in liquidity. This would require us to seek adequate financing from sources such as external debt, which may not be available on commercially reasonable terms, or at all. If we are unable to maintain adequate working capital or obtain sufficient equity or debt financing to meet our capital needs, we may be unable to continue our operations according to our plans and be forced to scale back our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

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We had indebtedness as of September 30, 2021 and may incur additional indebtedness in the future, which may materially and adversely affect our financial condition and results of operations.

We had certain borrowings to finance our operations during the Track Record Period. We had bank borrowings of nil, US\$1.1 million and US\$1.4 million as of December 31, 2019 and 2020, and September 30, 2021, respectively. We had lease liabilities of US\$2.0 million, US\$1.7 million and US\$3.4 million as of December 31, 2019 and 2020 and September 30, 2021, respectively. As of December 31, 2019 and 2020 and September 30, 2021, the carrying amounts of our financial liabilities at fair value through profit or loss (excluding the Series A Preferred Shares, SAFE and series seed preferred shares which were without redemption rights) were US\$66.0 million, US\$188.6 million and US\$306.1 million, respectively, which were unsecured and unguaranteed. See “Financial Information – Indebtedness.” We may incur additional indebtedness in the future, and may not be able to generate sufficient cash to satisfy our existing and future debt obligations.

Our indebtedness could have a material adverse effect on us by, among others, increasing our vulnerability to adverse developments in general economic or industry conditions, such as significant increases in interest rates, and limiting our flexibility in making changes in our business and operations. Our borrowings may subject us to certain restrictive covenants, which may restrict or otherwise adversely affect our operations. These covenants may restrict our ability to, among others, incur additional debt, provide loans or guarantees, provide security and quasi-security, incur liens, dispose of material assets through sale, lease or other methods, pay dividends or distributions on certain of our subsidiaries’ capital stock, repay or transfer certain indebtedness, reduce registered capital, make investments and acquisitions, establish joint ventures, conduct mergers, consolidation and other change-of-control transactions, and file for bankruptcy or dissolution.

In the event that we are unable to comply with the restrictions and covenants imposed by the loan agreements in our future debt obligations, banks could terminate their commitments to us, accelerate the payments and declare all amounts borrowed due and payable, enforce the security or terminate the loan agreements. If any of the foregoing events occurs, there can be no assurance that our assets and cash flow will be sufficient to repay all of our debts as they become due, or that we will be able to obtain alternative financing on commercially reasonable terms. Furthermore, if the banks enforce any security over our assets, our business, financial condition, results of operations and prospects would be materially and adversely affected.

Investments in structured deposits as financial assets at fair value through profit or loss are subject to uncertainties which may affect our financial performance.

The fair value change in our financial assets may significantly affect our financial position and results of operations. We had structured deposits of US\$9.9 million as of December 31, 2019. We did not have structured deposits as of December 31, 2020 and September 30, 2021, but may continue to invest in structured deposits after Listing, subject to

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business needs. We had changes in fair value of structure deposits of US\$0.4 million, US\$0.4 million in 2019 and 2020, respectively, and US\$0.2 million and US\$0.3 million in the nine months ended September 30, 2020 and 2021, respectively. Fair value estimation is made based on certain judgments, estimates and assumptions which are subject to various inherent uncertainties. Factors beyond our control can significantly influence and cause adverse changes to the estimates we use and thereby affect the fair value of such assets. These factors include, but are not limited to, general economic conditions, changes in market interest rates and the stability of the capital markets. Any of these factors, as well as others, could cause our estimates to vary from actual results. In addition, when determining whether an impairment of a financial asset is other than temporary, the process usually requires complex and subjective judgments. All of these could materially and adversely affect our financial condition and results of operations.

The determination of the fair value changes in financial liabilities is subject to uncertainties, which may affect our financial condition and results of operation, and may continue to affect our financial performance upon Listing.

We have issued a series of preferred shares, SAFE and convertible loans and Series C and Series D warrants over a subsidiary's registered capital to a group of investors prior to and during the Track Record Period, which are recognized as financial liabilities at fair value through profit or loss for which no quoted prices in an active market exist. The fair value change in our financial liabilities may significantly affect our financial position and results of operations. We had changes in fair value of financial liabilities at fair value through profit or loss of US\$2.6 million and US\$17.6 million in 2019 and 2020, respectively, and US\$19.8 million and US\$13.1 million in the nine months ended September 30, 2020 and 2021, respectively. The valuation of fair value changes in financial liabilities involves various parameters and inputs, as well as management estimates and assumptions which are subject to uncertainties. For details of valuation techniques, see Note 5 of Appendix I to this Prospectus. Despite our efforts to use valuation techniques for which sufficient data are available to measure fair value and to maximize the use of relevant observable inputs, factors beyond our control can significantly influence or cause adverse changes to the estimates we use and thereby affect the fair value of such liabilities. These factors include general economic conditions, changes in market interest rates and the stability of the capital markets. Any of these factors, as well as others, could cause our estimates to vary from actual results. Certain financial liabilities at fair value through profit or loss such as certain preferred shares will be converted into ordinary shares upon Listing, and changes in their fair value will continue to affect our performance until converted into ordinary shares. All of these could materially and adversely affect our financial condition and results of operations.

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Potential acquisition or strategic partnership we engage in may entail various risks and we face intense competition in identifying suitable acquisition targets in the RNAi therapeutic field.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail various risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of additional equity securities and hence the dilution of our existing shareholders;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel, or failure to otherwise achieve intended synergies in the combined operations;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the assimilation of operations, corporate culture and personnel of the acquired business;
- risks associated with the acquisition of intangible assets which are subject to amortization and impairment assessment;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and its existing drugs or drug candidates and regulatory approvals;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- changes in accounting principles relating to the recognition and measurement of our investments that may have a significant impact on our financial results.

Moreover, as there may be fierce competition in identifying suitable acquisition targets in the RNAi therapeutic field, we may not be able to locate suitable opportunities for acquisitions and strategic partnerships, which may limit our ability to grow or obtain access to technology or products that may be important to the development of our business.

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Raising additional capital may cause dilution to the interests of our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the value of shareholders' investments in our Shares will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could give rise to increased fixed payment obligations and also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline.

In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party our rights to technologies or drug candidates on unfavorable terms, which we would have otherwise sought to develop or commercialize ourselves or reserve for future potential arrangements when we are more likely to achieve more favorable terms.

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a development-stage biopharmaceutical company with a relatively short operating history. Our operations to date have focused on the preclinical studies and clinical trials of drug candidates in RNA therapeutics. However, we have not yet successfully advanced any drug candidates from research and development to commercial sale and have not generated revenue from product sales or any licensing arrangements. We also have limited experience in commercial-scale manufacturing and sales and marketing of drugs. For these reasons, particularly in light of the rapidly evolving biopharmaceutical industry, it may be difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.

We are subject to risks associated with foreign exchange rate fluctuations.

We have operations in the PRC and the U.S. Our financial information is presented in U.S. dollars and our consolidated financial results are affected by currency exchange rate fluctuations. In connection with the preparation of our financial information, the results of operations of subsidiaries, which are initially prepared in their respective local functional currencies, such as Renminbi, are translated into U.S. dollars. As a result, changes in the

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exchange rate between our functional currencies, particularly, Renminbi as one of our major operating currencies, and the U.S. dollars, could materially impact our reported results of operations and distort period to period comparisons. In particular, exchange differences arising on the settlement of monetary items, and on the retranslation of monetary items, are recognized in profit or loss in the period in which they arise. See Note 4 of Appendix I to this prospectus. During the Track Record Period, we had net foreign exchange losses of US\$0.038 million and US\$0.5 million in the nine months ended September 30, 2020 and the nine months ended September 30, 2021, respectively, and had net foreign exchange gains of US\$0.006 million in 2019 and net foreign exchange losses of US\$0.1 million in 2020. As a result of such foreign currency fluctuations, it could be more difficult to detect underlying trends in our business and results of operations.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

If we are unable to obtain and maintain patent and other intellectual property protection for our drug candidates, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected.

Our commercial success depends, to a certain extent, on our ability to protect our proprietary technology and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. See “Business – Intellectual Property Rights.” We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in the PRC, the U.S. and other countries or regions, relying on a combination of trade secrets relating to our technology and drug candidates as well as additional regulatory protection methods such as market and data exclusivities. This process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications in all jurisdictions in a timely manner at a reasonable cost or the patent applications that we own may fail to result in issued patents with claims that cover our current and future drug candidates in China, the U.S. or elsewhere. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our licensors may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been frequently litigated. The issuance, scope, validity, enforceability and commercial value of our patent rights are

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highly uncertain. Our pending and future patent applications may not be granted with approvals that effectively prevent third parties from commercializing competitive technologies and drug candidates. The patent examination process may require us or our licensors to narrow the scope of our or our licensors' pending and future patent applications, which may then limit the scope of patent protection that could be obtained. There can be no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being granted with a patent. Moreover, if there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable.

Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. We may also be subject to a third-party pre-issuance submission of prior art to the competent government authorities or become involved in interference, *inter partes* review, post-grant review, *ex parte* reexamination, derivation, opposition or similar proceedings challenging our patent rights or third-party patent rights. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. In addition, our competitors may develop competing drug products using the same specific mechanism directed by our patents. We may not be able to identify such infringement, or at all. Consequently, we do not know whether any of our technologies and drug candidates will be protectable or remain protected by valid and enforceable patents.

Our competitors may also be able to circumvent our patent issuance by developing similar or alternative technologies or drug candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in any jurisdictions. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates.

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Changes in either the patent laws or interpretation of the patent laws in the PRC, the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, after March 2013, under the Leahy-Smith America Invents Act, the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases are not published at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Even if we are able to obtain patent protection for our drug candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, which would have a material adverse effect on our ability to successfully commercialize any product or technology.

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years for inventions in the PRC 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. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors, which may have an adverse effect on our business, financial condition, results of operations and prospects.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our owned and licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO in the U.S., and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and

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such authorities may refuse to grant extensions to our patents, or may grant more limited extensions than we request. For example, depending upon the timing, duration and specifics of any FDA marketing approval of any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it, may be extended. Similarly, the October 2020 Amendment to the PRC Patent Law 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. 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. 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 are, and 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. In addition, 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. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We enjoy only limited geographical protection and patent terms with respect to certain patents and may not be able to protect our intellectual property rights throughout the world, including in the PRC or the U.S.

Filing and prosecuting patent applications and defending patents covering our drug candidates in all countries across the world could be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions in which we have not obtained patent protection to develop their own drug candidates and may export otherwise infringing drug candidates to territories, where we and our licensors have patent protection, given that the levels of law enforcement vary across jurisdictions. These drug candidates may compete with our drug candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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The laws of some jurisdictions, including the PRC, do not protect intellectual property rights to the same extent as the laws or rules and regulations in the U.S. and Europe, and many companies have encountered significant difficulties in registering, protecting and defending such rights in the relevant jurisdictions, including China. For example, we may not be able to register our exclusive licenses for our in-licensed products in China. While this does not impact our contractual rights under our licensing agreements, we may experience difficulties enforcing our exclusive rights against third parties if our licensors were to breach the licensing agreements and license such parties to use those products in China. In addition, under the PRC patent law, if an applicant applies for a patent in a jurisdiction outside of China for an invention or utility model invented within China, such applicants must concurrently report to the China National Intellectual Property Administration, or the CNIPA, for confidential examination of such invention or utility model. If an applicant fails to make such reporting but files a patent application in China for the same invention or utility model at a later time, a patent will not be granted to such applicant. Furthermore, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to prevent the infringement of our patents or marketing of competing drug candidates in violation of our proprietary rights. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, there can be no assurance that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may expect to market our drug candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have a material adverse effect on our ability to successfully commercialize our drug candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are, or any of our licensors is, forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

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In addition, given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates or our proprietary technology may expire before such candidates are commercialized. As a result, our owned and licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products that are similar or identical to ours. Moreover, some of our patents and patent applications are, and 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. Our competitors could then market competing products and technology. In addition, 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. For example, some of our licensed patents which are directed to and protect our PNP delivery platform expired in September 2021. When these patents expire before new patents that can protect our PNP delivery platform are granted to us, competitors or other third parties may use the PNP delivery platform for their own products without needing a license. Without being able to assert such patent rights against such competitors and exclude others, our competitive position may be impaired which may have an adverse effect on our business.

Our owned and in-licensed patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, or to modify or cease the development, manufacture and commercialization of one or more of the drug candidates we may develop, which could have a material adverse effect on our business, financial condition and results of operations.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property as an inventor or co-inventor. If we or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed, or our owned or licensed patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as the exclusive ownership of, or exclusive right to use, our owned or in-licensed patents. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, 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 nonexclusive. If we are unable to obtain and maintain such licenses, we may need to modify or cease the development, manufacture, and commercialization of one or more of our drug candidates. Any of our licensors may also grant licenses to others in breach of its exclusive license granted to us, enabling others to engage in the development, manufacture and commercialization of competing drug candidates, which

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may have a material adverse effect on the commercial prospect of our drug candidates. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing events could result in a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

We may also engage third-party contractors, such as CROs to assist us with the research and development of our drug candidates. There can be no assurance that such contractors will not transfer the drug candidates to other third parties without our permission. Such unauthorized transfer may also result in the loss or restriction of our intellectual property rights and therefore limit our ability to develop, manufacture and commercialize the drug candidates.

Claims that our drug candidates or the sale or use of our future products infringe, misappropriate or otherwise violate the patents or other intellectual property rights of third parties could result in substantial legal costs. Intellectual property litigation may lead to unfavorable publicity which may harm our reputation, and any unfavorable outcome of such litigation could limit our research and development activities and our ability to commercialize our drug candidates.

The field of RNA therapeutics is still in its infancy, and only a few product candidates have reached the market. Due to the intense research and development that is being undertaken in this field by several companies, including us and our competitors, the intellectual property landscape may remain uncertain for the coming years.

There can be no assurance that our drug candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. There has been extensive patenting activity in the field of RNA therapeutics, and pharmaceutical companies, biotechnology companies, and academic institutions are competing with us or are expected to compete with us in this field and file patent applications potentially relevant to our business. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, or with respect to the use or manufacture of the compounds we have developed or are developing. Litigation relating to patents and other intellectual property rights in the biopharmaceutical industry is common, including patent infringement lawsuits. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Some claimants may have substantially greater resources than us and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. Third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

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It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties having claims that cover our drug candidates. Based on the freedom-to-operate (FTO) analysis on our core product (STP705), we are not aware of any issued patents that may affect our rights to conduct research and development or commercialize that product in China or the U.S. FTO analysis is a patent investigation, based on a search of patent databases, that is commonly used to determine whether any existing patents cover a company's product, and whether that product would infringe any existing patents. However, the potential scope of an FTO investigation can be immense and all patent databases used in such investigations have limitations. Publication of discoveries in the scientific or patent literature often lags behind actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that any of our drug candidates may infringe, or which such third parties claim to be infringed by our technologies. Therefore, we cannot guarantee that our FTO search and analysis have exhaustively reviewed all the existing and future patents that potentially cover our products. As the RNA therapeutics field expands and more patents are issued, the risk increases that our proprietary technology and drug candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of therapeutics, products or their methods of use or manufacture. Because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our drug candidates, technologies or methods.

Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications on our drug candidates or for their uses, or that our drug candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our drug candidates or a similar invention, our patent application may be regarded as a competing application and may not be eventually approved. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

If a third party were to assert claims of patent infringement against us, even if we believe such third-party claims are without merit, a court of competent jurisdiction could hold that such third-party patent is valid, enforceable and infringed, and the holders of any such patent may be able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patent, or until such patent expires or is finally determined to be invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention, or use, the holder of any such patent may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such

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claims would cause us to incur substantial expenses and could cause us to pay substantial damages, if we are found to be infringing third-party patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. To avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a drug candidate, or be forced, by court order or otherwise, to modify or cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant damages as a result of claims of intellectual property infringement.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time-consuming, regardless of the outcome. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements, or the announcement of the litigation, as negative, the perceived value of our drug candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the market price of our Shares may decline. Such announcements could substantially increase our operating losses as well as harm our reputation or the market for our drug candidates, which could have a material adverse effect on our business. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, in-license required technology, or enter into strategic partnerships that would help us bring our drug candidates to market.

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We may also initiate lawsuits to protect or enforce our patents and other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents, trade secrets or other intellectual property rights when seeking approval to market their own products similar to ours, or otherwise compete with our products. In these circumstances, we may need to defend and/or assert our patents, by filing lawsuits alleging patent infringement. To counter or defend against infringement, misappropriation, violation or unauthorized use, we may be required to file claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringed, misappropriated or otherwise violated their patents, trade secrets or other intellectual property. In addition, in a patent infringement proceeding, there is the risk that the court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the technology at issue. There is also the risk that, even if the validity of such patent is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse outcome in litigation or proceedings involving our patents could limit our ability to assert our patents against those parties or other competitors, could put one or more of our owned patents at risk of being invalidated or interpreted narrowly or may curtail or preclude our ability to exclude third parties from making and selling similar or competing products.

If we initiate legal proceedings against a third party to enforce a patent covering our technologies or a drug candidate we may develop, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise challenges to the validity of certain of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technologies or drug candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of

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the patent protection on our technologies or drug candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business.

Conversely, we may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). We may also in the future choose to challenge, third-party patents in patent opposition proceedings in the CNIPA, EPO or another foreign patent office. Even if successful, the costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, CNIPA, EPO or other patent office, we may be exposed to litigation by a third party alleging that the patent may be infringed by our drug candidates or proprietary technologies. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, the USPTO and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The CNIPA, the USPTO and other governmental patent agencies also require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. We rely on our outside counsel and other professionals to help us comply, and are dependent on our licensors to take the necessary action to comply, with these requirements with respect to our licensed intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include the failure to respond to official actions within prescribed time limits, nonpayment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Changes in patent laws of the PRC, the U.S. or other jurisdictions could reduce the value of patents in general, thereby impairing our ability to protect our drug candidates and future drugs.

Our success depends on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity and obtaining and enforcing

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biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in the PRC, the U.S. or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend and enforce our intellectual property rights and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

In the PRC, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection. For example, the new PRC Patent Law (專利法) was amended on October 17, 2020 and became effective on June 1, 2021. The new PRC Patent Law introduces patent extensions to eligible innovative drug patents, and the patents owned by third parties may be extended, which may in turn affect our ability to commercialize our drug products. The new PRC Patent Law enables the patent owners to apply for a patent term extension. The compensation period shall not exceed five years, and the total validity period of patent rights for a new drug shall not exceed 14 years after the new drug is approved for marketing. In addition, the patents owned by third parties may be eligible for patent term extension, which may in turn affect our ability to commercialize our drug candidates (if approved) without facing infringement risks. The precise length of any such extension by a third party is uncertain, though the extended length has a maximum of five years. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our products noncompetitive. There can be no assurance that any other changes to PRC intellectual property laws would not have an adverse effect on our intellectual property protection.

Recently enacted U.S. laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, enable third-party submission of prior art to the USPTO during patent prosecution, and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Assuming that other requirements for patentability were met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. See “– Risks Relating to Our Intellectual Property Rights – If we are unable to obtain and maintain patent and other intellectual property protection for our drug candidates, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly

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against us, and our ability to successfully commercialize any product or technology may be adversely affected.” As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications in the U.S. and the enforcement or defense of our issued patents, each of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Recent U.S. Supreme Court rulings have also changed the law surrounding patent eligibility, narrowing the scope of patent protection available in certain circumstances and weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. For example, in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that claims to certain naturally occurring DNA molecules are not patentable. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights, all of which could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

If we are unable to protect our trade secrets, confidential information or other intellectual properties, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, and we may be subject to claims asserting ownership of what we regard as our own intellectual property.

In addition to our issued patents and pending patent applications, we rely on a combination of trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties that have access to them. However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized use and disclosure is difficult and we do not know whether the steps we have taken to protect our proprietary rights will be effective. Any of the foregoing parties may breach or violate the terms of their agreements with us and may

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disclose our proprietary information or otherwise infringe our rights, and we may not be able to obtain adequate remedies for any such breach or violation. We could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, there can be no assurance that we have entered into all necessary agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Moreover, some courts in the United States as well as other countries are sometimes less willing or unwilling to protect trade secrets. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully.

Moreover, our competitors or other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors or other third parties could purchase our products and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third parties, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third parties, our competitive position would be harmed.

Many of our employees, including our senior management, may have been previously employed at other pharmaceutical or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer or, in the case of consultants and advisors, other companies for which they currently work. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to

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paying damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms, or at all. An inability to incorporate such intellectual property rights would harm our business and may prevent us from successfully commercializing our drug candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may have an adverse effect on our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates and technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees.

Moreover, while we typically require our employees, consultants and contractors who are engaged in the development of intellectual property to execute agreements assigning the ownership of intellectual property to us, we may be unsuccessful in executing such an agreement with any other party who in fact develops intellectual property that we believe we own. Furthermore, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. In addition, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

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

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If our trademarks and trade names are not adequately protected, we may not be able to build brand recognition in our markets of interest which may have an adverse effect on our business.

We conduct business under the brand name of “Sirnaomics”. As of the Latest Practicable Date, we had one pending trademark application. Any of our pending trademark applications may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same.

There can be no assurance that any currently pending trademark applications or any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and, although we are given an opportunity to respond to those rejections, may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially and adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and, as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, it may have a material adverse effect on our business.

Our trademarks, trade names or logos may be challenged, infringed, circumvented or declared generic or determined to be infringing other trademarks, trade names or logos. We may not be able to protect our rights to these trademarks, trade names and logos, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trademarks, trade names or logos similar to ours, thereby impeding our ability to build brand identity, possibly leading to market confusion. In addition, there could be potential trademark, trade name or logo infringement claims or unfair competition claims brought by owners of other registered trademarks, trade names or logos that incorporate variations of our registered or unregistered trademarks, trade names or logos. For example, as of the Latest Practicable Date, we had not registered a trademark bearing the Chinese transliteration of our brand name “Sirnaomics” which carries two Chinese characters that appear in certain trademarks already registered in China. Our use of the Chinese transliteration in the PRC may subject us to trademark infringement claims or unfair competition claims, and we may then be subject to fines and other penalties and be required to discontinue infringing activities. These could have a material and adverse effect on our reputation and brand recognition in the PRC, and we may then not be able to compete effectively in the PRC. According to our PRC Legal Advisors, since we had not commercialized any product and did not generate any revenue from product

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sales under the Chinese transliteration of “Sirnaomics” as of the Latest Practicable Date, even if we were found to have infringed trademarks of third parties or conducted unfair competition by using the Chinese transliteration of “Sirnaomics” the risk of us being ordered by competent governmental authorities to confiscate or destroy infringing product, or pay for fines of certain times of revenue according to applicable laws or regulations, is remote. We are currently evaluating other Chinese brand name for purpose of trademark application in the PRC.

In addition, any proprietary name we propose to use with our clinical-stage drug candidates or any other drug candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. The National Medical Products Administration in China, or the NMPA, may also object to our proposed proprietary product name that infringes the existing rights of third parties.

If our trademarks, trade names and logos are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names and logos, 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, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay damages or could lose license rights that are important to our business.

We may in the future enter into license agreements with third parties providing us with rights to various third-party intellectual property, including rights in patents, patent applications and copyrights. These license agreements may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our business. Termination of the licenses provided for under these agreements or the reduction or elimination of our rights under these agreements may result in our having to

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negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under such agreements to important intellectual property or technology or our rights to develop and commercialize our drug candidates. In addition, such an event may cause us to experience significant delays in the development and commercialization of our drug candidates or incur liability for damages. If any such license is terminated, our competitors or other third parties could have the freedom to seek regulatory approvals of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain drug candidates.

In addition, we may need to obtain additional licenses from licensors and others to advance our research or allow commercialization of drug candidates we may develop. In connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our drug candidates and technology. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. We may therefore be required to expend significant time and resources to redesign our drug candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other issues related to interpretation;
- our or our licensors' obligation to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, drug candidates and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other intellectual property rights under our license agreements;
- our diligence, financial or other obligations under the license agreement and which activities satisfy those diligence obligations;

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- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are, and any such future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to several interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our diligence, financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed or any other dispute described above related to our license agreements prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing, misappropriating or otherwise violating the licensor's rights. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to seek alternative options, such as developing new drug candidates with design-around technologies, which may require more time and investment, or abandon development of the relevant research programs or drug candidates and our business, financial condition, results of operations and prospects could suffer.

Intellectual property rights do not necessarily protect us from all potential threats.

The degree of protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any drug candidates we may develop or utilize similar technology that is not covered by the claims of the patents that we own or license now or in the future;
- we, our licensors or current or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;

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- we, our licensors or current or future collaborators might not have been the first to file patent applications covering certain of our, or their, inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may not provide us with a competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- the claims of our patent applications, if and when issued, may not cover our drug candidates;
- our competitors or other third parties might conduct research and development 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;
- the inventors of our patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of license partners or current or future collaborators to the same extent as the laws of the United States;
- the validity and scope of any claims relating to our patents or other intellectual property may involve complex legal and factual questions and analysis and, as a result, the outcome may be highly uncertain;
- we engage in scientific collaborations and will continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- any drug candidates we develop may be covered by third parties' patents or other exclusive rights;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and

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- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We work with various third parties to develop our drug candidates and may have limited control over them. 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 drug candidates, 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 parties on our ongoing preclinical and clinical programs. 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 NMPA, the FDA and other comparable regulatory authorities for all of our drugs in clinical development. If we or 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 NMPA, the FDA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with products produced under GMP regulations. Any failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminates, 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 deadlines, 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. Any of the foregoing events may cause cost increases, restrict our ability to generate revenue and have a material adverse effect on our business and prospects.

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Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approvals. Our arrangements with collaborators will be critical to the successful commercialization of our drug candidates and future products. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process, and to assist with our commercialization efforts. We do not control our collaborators, and therefore there can be no assurance that these third parties will adequately and timely perform all of their obligations under their agreements with us. If they fail to complete the remaining studies successfully, or at all, it could delay or adversely affect the obtaining of regulatory approvals. There can be no assurance of the satisfactory performance of any of our collaborators, and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed product which could materially and adversely affect our business, financial condition, cash flows and results of operations. In addition, we may rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately carried out and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on us until deficiencies are remedied.

More generally, supply chain risks associated with the foregoing third-party service providers and our other suppliers may have a material adverse effect on our business, financial condition, results of operations and prospects. See “– Risks Relating to Manufacturing of Our Drug Candidates – We are exposed to various supply chain risks as we depend on a stable, adequate and quality supply of raw materials, technical services, equipment and infrastructure construction services, and any price increases or interruptions of such supply may have a material adverse effect on our business.”

We have entered into collaborations with our partners and may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing arrangements, and disputes may arise between us and our current or future collaboration partners.

We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. We have a strong track record of collaboration with biopharmaceutical and biotechnology companies as well as academic research institutions in China and the U.S. We are collaborating with Innovent and Shanghai Junshi on the development of combination therapies using STP705 and immune checkpoint inhibitors. We entered an agreement with Walvax to co-develop anti-influenza therapeutics, which includes an out-license for certain rights in mainland China, Hong Kong, Macau and Taiwan. We also benefit from our collaborations with renowned universities, including the University of Maryland on the

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enhancement of our technology and Boston University on preclinical research and development. See “Business – Collaboration and Licensing Agreements.” Any of these relationships may require us to incur nonrecurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

Our strategic collaboration with partners involves various risks, including that we may not achieve the revenue and cost synergies expected from the transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and beyond our control. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that expected synergies will be achieved in due course, or at all.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early 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 viability.

Disputes may arise between us and our current or future collaboration partners. Such disputes may cause delays in or termination of the research, development or commercialization of our drug candidates, or may result in costly litigation or arbitration that diverts management’s attention and resources.

Global markets are an important component of our growth strategy. We have retained rights for the development and commercialization of certain of our drug candidates globally. If we fail to obtain licenses or enter into collaboration arrangements with third parties in other markets, or if any third-party collaborator is not successful, our revenue-generating growth potential will be adversely affected.

Moreover, international business relationships subject us to additional risks that may materially and adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management’s attention from the acquisition or development of drug candidates;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;

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- third parties obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;
- unexpected changes in or imposition of trade restrictions, such as tariffs, sanctions or other trade controls, and similar regulatory requirements;
- economic weakness, including inflation;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest;
- failure of our employees and contracted third parties to comply with the U.S. Department of the Treasury’s Office of Foreign Assets Control rules and regulations, the U.S. Foreign Corrupt Practices Act of 1977, as amended (“FCPA”) and other applicable laws and regulations; and
- business interruptions resulting from geopolitical actions, including war and acts of terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

We may rely on third parties to manufacture a portion of our drug candidates for clinical development and commercial sales. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices.

We currently work with qualified CMOs to manufacture product candidates for preclinical and clinical supply. In addition, we procure equipment for the development and manufacturing of our product candidates from reputable manufacturers and suppliers. We also procure technical services, including CRO and CDMO services and consulting services that support our clinical trials and preclinical studies. See “Business – Procurement.”

Reliance on third-party manufacturers would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited and the NMPA, the FDA or other

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comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates;

- 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, if any;
- manufacturers are subject to ongoing periodic unannounced inspection and other government regulations by the NMPA, the FDA or other comparable regulatory authorities to ensure strict compliance with GMP. We do not have control over third-party manufacturers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- manufacturers may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or adversely impact commercialization of our future approved drug candidates.

Our rights to develop and commercialize our drug candidates are subject to the terms and conditions of licenses and sublicenses granted to us by third parties.

We rely on licenses and sublicenses to certain patent rights and other intellectual property from third parties that are important or necessary for the development of our drug candidates. Our licensors and sublicensors may also provide us with clinical data required for NDA filings in our licensed or sublicensed territories pursuant to these licenses, among other methods of

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support. However, the licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use and in all territories in which we may expect to develop or commercialize our drug products and the underlying patents may fail to provide the intended exclusivity. As a result, we may not be able to prevent competitors from developing and commercializing competitive drug products in the markets that we expect to address. In addition, our licenses may not include rights to all intellectual property relevant to our drug candidates, and therefore we may need to obtain additional licenses from our existing licensors, which may not be available on an exclusive basis, commercially reasonable terms, or at all, or expend significant time and resources to redesign our drug candidates or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. Moreover, we do not own the underlying intellectual property related to these drug candidates, and our rights are continuously subject to the terms of the underlying agreements. If our licensors breach our license agreements, we may not be able to enforce such agreements or obtain sufficient or adequate remedies. If these in-licenses are terminated, competitors may develop, seek regulatory approval of, and market, products identical to ours.

Our license agreements may not grant us the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering our drugs. Moreover, we have not had, and do not have, primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sublicensees. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our current or future licensing or collaboration partners fail to prosecute, maintain (including by failing to pay the relevant fees), enforce and defend patents licensed to us that are material to our business, the exclusivity associated with the relevant drug candidate may be reduced or eliminated, and our ability to prevent competitors from developing or commercializing biosimilar drugs could be adversely affected. Even if we have the right to control patent prosecution and maintenance of patents and patent applications licensed to us, we may still be adversely affected or prejudiced by actions or inactions of our sublicensees, our licensors, the inventors, third-party collaborators and each of their respective counsel that took place either before or after the date upon which we assumed that control.

In addition, our licensors may have relied on third-party consultants or collaborators or on funds, resources or expertise from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market biosimilar products and technologies. In addition, if our licensors have not obtained adequate rights and licenses from these third parties, we may need to obtain additional rights from these third parties or we could be prevented from developing and commercializing the relevant drug candidates or encounter direct competition. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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Over time, we may seek additional rights to intellectual property from our licensors and, in connection with the related negotiations, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including enabling third parties to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

RISKS RELATING TO OUR OPERATIONS

The loss of any key members of our senior management team or our inability to attract, retain and motivate highly qualified management, clinical and scientific personnel could delay or prevent the successful development of our drug candidates and result in a material and adverse effect on our business and results of operations.

Our success depends, in part, on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as other key clinical and scientific personnel, and other employees and consultants. The loss of the services of any of these individuals could delay or prevent the successful development of our drug candidates and our business operations would be impaired.

Although we have not historically experienced difficulties in attracting and retaining qualified employees, we may experience such problems in the future. Competition for qualified employees in the biopharmaceutical industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain, experienced management or key clinical and scientific personnel in the future. The departure of one or more of our management or key clinical and scientific personnel, regardless of whether or not they join a competitor or form a competing company, may subject us to risks relating to replacing them in a timely manner, or at all, which may disrupt our drug development progress and have a material and adverse effect on our business and results of operations. In addition, we will need to hire additional employees as we expand our commercialization team. We may not be able to attract and retain qualified employees on commercially reasonable terms, or at all.

We are subject to the risks of doing business in multiple jurisdictions.

As we operate in the PRC, the U.S. and other countries, our business is subject to risks associated with doing business in multiple jurisdictions. Our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;

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- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic stagnation or downturn in certain jurisdictions, including those caused by inflation or political instability;
- the burden of complying with a variety of foreign laws, including difficulties in enforcement of contractual provisions;
- inadequate intellectual property protection in certain jurisdictions;
- enforcement of anti-corruption and anti-bribery laws;
- trade-protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;
- the effects of applicable local tax regimes and potentially adverse tax consequences; and
- significant adverse changes in local currency exchange rates.

We may pursue partnerships with entities in foreign countries and regions, in particular in the U.S. In the event that China or the countries from which we import raw materials impose import tariffs, trade restrictions or other trade barriers affecting the importation of such components or raw materials, we may not be able to obtain a stable supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected. We may also sell our products to certain foreign countries in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. It is notable that the U.S. government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs, which have led to other countries, including China and members of the EU, imposing tariffs against the U.S. in response. See “– Risks Relating to Manufacturing of Our Drug Candidates – Changes in U.S. and international trade policies, particularly with regard to China, may cause significant disruptions to our drug candidate manufacturing and other operations.” These trade disputes may escalate and may result in certain types of goods, such as advanced research and development equipment and materials,

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becoming significantly more expensive to procure from overseas suppliers or even illegal to export. Furthermore, there can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Tensions and political concerns between China and the relevant foreign countries or regions may therefore adversely affect our business, financial condition, results of operations and prospects.

In addition, we are subject to general geopolitical risks in foreign countries where we operate, such as political and economic instability and changes in diplomatic and trade relationships. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially and adversely affect our business and results of operations.

Investments in our business, or our future potential investments may be materially and adversely affected by regulatory or governmental scrutiny in relevant countries such as the U.S.

Investments in our business, or our future potential investments, may be subject to stringent regulatory or governmental scrutiny imposed by relevant authorities. For example, foreign investments in U.S. companies and exports of technology and technical data from the U.S. (including disclosures of technology and technical data to foreign persons in the U.S.) are potentially subject to significant restrictions under the U.S. laws and regulations. Statutory changes in the U.S., such as the enactment of the Foreign Investment Risk Review Modernization Act of 2018 (“FIRRMA”), have broadened the authorities of the President of the United States and various regulatory regimes, including the Committee on Foreign Investment in the United States (“CFIUS”), to regulate trade and investment activity in the U.S.

CFIUS has the authority to determine whether foreign investments in U.S. businesses may present a threat to U.S. national security, and to impose conditions on, or effectively suspend or prohibit such investments. Certain investments are subject to pre-closing filing requirements with CFIUS and are subject to potential penalties for failing to make required filings, in addition to the potential for conditions on the investment or forced divestment. Investments in companies that are not subject to pre-closing filing requirements may nevertheless be subject to CFIUS jurisdiction and may result in adverse actions such as operating conditions on the company, conditions on the investment, blocking of the investment, or forced divestment.

Accordingly, with respect to past investments in our business by foreign persons, and to the extent our business in the future takes, investments from foreign persons, or if our potential acquisition or investment targets involve U.S. businesses, such investments could be subject to CFIUS jurisdiction or other regulatory requirements. For instance, we received an inquiry from CFIUS on April 12, 2021, in relation to an investor’s participation in our Series

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C financing, and we have been cooperating with CFIUS to provide the requested information. If an investment that triggers CFIUS jurisdiction raises U.S. national security concerns, our business may be subject to adverse action by CFIUS, such as requirements to accept operating conditions, conditions on the investment or even to facilitate divestment by a prior investor. Any such event may detrimentally affect our capability to invest or attract investments or otherwise operate our business, which may materially and adversely affect our business, financial condition and results of operations.

Other jurisdictions such as the PRC, the United Kingdom, Japan and European Union, may also revise their foreign direct investment review processes and related regulatory processes from time to time. To the extent our current or future operations or investments relate to such jurisdictions, the changes in relevant laws or regulations may materially and adversely affect our business, financial condition and results of operations.

If we fail to comply with anti-bribery laws, our reputation may be damaged, and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to the anti-bribery laws of various jurisdictions. As our business has expanded, we may be subject to an increasing range of applicable anti-bribery laws. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, such as the FCPA, or if any of the doctors or other providers or entities we do business with are found to be not in compliance with applicable laws, our reputation could be damaged and we may face civil, administrative or criminal penalties or incur significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations and prospects.

Product and professional liability claims or lawsuits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

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

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liability claims may result in a decrease in demand for our drug candidates, reputational damage, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations by regulators, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients, product recalls, withdrawals, restrictive labeling and marketing or promotional restrictions.

It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a product liability claim or a series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations may be impaired. Should any of the foregoing events occur, our business, financial condition and results of operations would be materially and adversely affected.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

We are subject to laws and regulations governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials. Our operations involve the use of hazardous materials, including chemicals, and may produce hazardous waste products. We cannot eliminate the risks of contamination or personal injury from these materials.

We do not maintain work injury insurance for injuries to our employees resulting from the use of hazardous materials. We also do not maintain insurance for environmental liability claims that may be asserted against us in connection with our storage or disposal of hazardous materials. In the event of contamination or personal injury resulting from our use of hazardous materials or our or third parties' disposal of hazardous materials, we could be held liable for any resulting damages. We may also incur significant costs associated with civil, administrative or criminal fines and penalties.

We may incur substantial costs in order to comply with current or future laws and regulations on the use of hazardous materials. These current or future laws and regulations may impose restrictions on our research, development or production activities. Failure to comply with these laws and regulations may also result in substantial fines, penalties or other sanctions.

We may be subject to intellectual property infringement claims, which may be expensive to defend and may disrupt our business and operations.

We cannot be certain that our operations or any aspects of our business do not or will not infringe or otherwise violate patents, copyrights or other intellectual property rights held by third parties. We may therefore be subject to legal proceedings and claims relating to the

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intellectual property rights of others. We cannot assure you that holders of intellectual property rights purportedly relating to some aspect of our business, if any such holders exist, would not seek to enforce such rights against us. Further, the application and interpretation of China's patent laws and the procedures and standards for granting patents in China are still evolving and are uncertain, and we cannot assure you that PRC courts or regulatory authorities would agree with our analysis. If we are found to have violated the intellectual property rights of others, we may be subject to liability for our infringement activities or may be prohibited from using such intellectual property, and we may incur licensing fees or be forced to develop alternatives of our own. In addition, we may incur significant expenses, and may be forced to divert management's time and other resources from our business and operations to defend against these third-party infringement claims, regardless of their merits. Successful infringement or licensing claims made against us may result in significant monetary liabilities and may have a material adverse effect on our business, results of operations and reputation.

We may be subject to disasters, health epidemics such as COVID-19, acts of war, terrorism, business disruptions and other force majeure events, which may have a material adverse effect on our business, financial condition and results of operations.

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 research institution 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 in the PRC or elsewhere in the world could materially disrupt our business and operations. For example, the outbreak of COVID-19 has caused illness in, and killed, many people in and outside China, caused temporary suspension of production and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy. The spread of COVID-19 continues to affect the mainland China. Since late July in 2021, there is a recurrence of the COVID-19 pandemic in several provinces in China. The exacerbation, continuance or reoccurrence of COVID-19 has already caused, and may continue to cause, an adverse and prolonged impact on the economy and social conditions in the PRC and other affected countries. The existing clinical trials and the commencement of new clinical trials could be substantially delayed or prevented by any delay or failure in patient recruitment or enrollment in our or our collaborators' trials as a result of the outbreak of COVID-19. These factors could cause the delay of clinical trials, regulatory submissions, and required approvals of our drug candidates, and could cause us to incur

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additional costs. If our employees or employees of our suppliers and other business partners are suspected of being infected with an epidemic disease, our operations may be disrupted because we or our business partners must quarantine some or all of the affected employees or disinfect relevant facilities. If we are not able to effectively develop and commercialize our drug candidates as a result of protracted clinical trials of enrolled patients, elevated public health safety measures, or failure to recruit and conduct patient follow-up, we may not be able to generate revenue from sales of our drug candidates as planned.

Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. We partially rely on our third-party research institution collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or funding withdrawals. The occurrence of any of the foregoing events could seriously harm our operations and financial condition and could increase our costs and expenses. We also partially rely on third-party manufacturers to produce and process supplies of our drugs and drug candidates. Our ability to obtain supplies of our drugs and drug candidates could be disrupted if the operations of these suppliers are affected by disasters, epidemics, business interruptions and other force majeure events. Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, disaster, epidemics, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. Our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. Acts of war or terrorism may also injure our employees, disrupt our business network and destroy our markets. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition and results of operations.

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 that are required under PRC and U.S. laws and regulations as well as based on our assessment of our operational needs and risks and industry practice. See “Business – Insurance.” However, our insurance coverage may be insufficient to cover all claims or losses which may arise. Further, we may find that we cannot insure some risks or we may find that we are underinsured for some risks. We cannot guarantee that we can insure against all risks of loss from our business. Insurance we purchase may exclude these risks or may insufficiently cover these risks due to the terms and conditions of the policies or based on the allegations made. Any liability or damage to, or caused by, our manufacturing facilities or our personnel beyond our insurance coverage may result in substantial costs and a diversion of resources and may adversely affect our drug development and overall operations. Failure to be adequately insured for any risk of loss may materially and adversely affect our business and financial condition.

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Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, and insider trading.

We may be exposed to fraud, bribery or other misconduct committed by our employees, principal investigators, consultants and commercial partners that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period, we were not aware of any instances of fraud, bribery or other misconduct involving employees and other third parties that had any material and adverse impact on our business and results of operations.

However, there can be no assurance that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such instances of misconduct committed against our interests, including undetected past acts and future acts, may have a material adverse effect on our business and results of operations.

We are subject to risks associated with leasing properties.

We lease some of our offices, laboratories, manufacturing facilities and storage space in the PRC and the U.S. The lessors of the leased properties may not have valid title or have the legal rights to such leased properties or may not have complied with all the necessary procedures. In addition, as our leases expire, we may fail to negotiate renewals, either on commercially acceptable terms, or at all, which could require us to close such offices, laboratories or manufacturing facilities and storage space. 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.

Pursuant to PRC law, lease agreements must be filed with the local branch of the Ministry of Housing and Urban-Rural Development. The filing of such leases will require the cooperation of the lessors. Any failure to register lease agreements as required under PRC law will not affect the validity and enforceability of the lease agreements, but may subject us to a fine for non-registration which may range from RMB1,000 to RMB10,000 for each non-registered agreement, which may negatively affect our ability to operate our business covered under those leases.

RISKS RELATING TO OUR DOING BUSINESS IN THE PRC

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

We have historically benefited from government grants. We recorded government grants of US\$0.2 million, US\$0.5 million and US\$0.02 million in 2019, 2020 and the nine months

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ended September 30, 2021, respectively. Our government grants may vary from period to period, going forward, and our business and results of operations may be affected as a result. Our eligibility to receive these financial incentives in the future depends on our ability to maintain the relevant qualifications. The incentives are subject to the discretion of the central government or relevant local government authorities, which could determine to reduce the amount of, or cease to provide, the grants or incentives at any time, generally with prospective effect. In addition, the policies according to which we historically received government grants may be lifted or withdrawn by the relevant government authorities at their sole discretion. There can be no assurance that we will continue to receive such government grants or receive a similar level of government grants, or at all, in the future. The discontinuation or reduction of financial incentives currently available to us could have a material adverse effect on our business, financial condition and results of operations.

The biopharmaceutical industry in the PRC is highly regulated and such regulations are subject to change, which may affect approvals and commercialization of our drug candidates.

Our research operations and manufacturing facilities are mainly conducted or located in the PRC. The biopharmaceutical industry in the PRC is subject to comprehensive government regulation and supervision, encompassing the research and development, trials, approval, registration, manufacturing, packaging, licensing and marketing of new drugs and various other aspects of the operation of biopharmaceutical companies. Any violation of the relevant laws, rules and regulations may subject us to disputes, administrative sanctions, criminal sanctions and other legal proceedings. See “Regulatory Overview.” In recent years, the regulatory framework in the PRC regarding the biopharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in, or prevent the successful development or commercialization of, our drug candidates in the PRC and reduce the current benefits we believe are available to us from developing and manufacturing drugs in the PRC. PRC authorities have become increasingly vigilant in enforcing laws in the biopharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in the PRC. We believe our strategy and approach are consistent with the PRC government’s policies, but there can be no assurance that our strategy and approach will remain consistent therewith.

There are uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations.

Most of our operations are conducted in the PRC through our PRC subsidiaries, and are governed by PRC laws, rules and regulations. Our PRC subsidiaries are subject to laws, rules and regulations applicable to foreign investment in the PRC. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

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In 1979, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in the PRC. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in the PRC or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the nonbinding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is based, in part, on government policies and internal rules, some of which are not published on a timely basis, or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Specifically, the NMPA's recent reform of the drug-approval system may face implementation challenges. The timing and full impact of such reforms are uncertain and could prevent us from commercializing our drug candidates in a timely manner.

In addition, any administrative and court proceedings in the PRC may be protracted, resulting in substantial costs and diversion of resources and management's attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than would be the case in more developed legal systems. These uncertainties may prevent us from enforcing the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

Changes in the political and economic policies of the Chinese government may materially and adversely affect our business, financial condition, results of operations and prospects and may result in our inability to sustain our growth and expansion strategies.

Due to our extensive operations in the PRC, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in the PRC. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or

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changes in tax regulations that are currently applicable to us. In addition, in the past, the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in the PRC, which may adversely affect our business and results of operations. More generally, if the business environment in the PRC deteriorates from the perspective of domestic or international investment, our business in the PRC may also be adversely affected.

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 the PRC 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. As of the Latest Practicable Date, we have not acquired any scientific data in the PRC nor transferred any such data abroad. We expect to primarily collect data of trial subjects enrolled in clinical studies and generally do not involve state secret or national security in the future. However, as advised by our PRC Legal Advisor, given that the term “state secret” is currently not clearly defined, if the scientific data are deemed involving “state secret,” we shall define the category, scope and purpose of such data to be used, and report the case to the competent department for approval according to established procedures for confidentiality management. There can be no assurance that we can always obtain relevant approvals for sending scientific data including the results of our preclinical studies or clinical trials conducted within the PRC abroad or to our foreign partners in the PRC. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, financial condition, results of operations and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders.

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside of the PRC with “de facto management body” within China is considered a “resident enterprise” and will be subject to the enterprise income tax on its global income at the rate of 25%. The implementation rules define the term “de facto management body” as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, the State

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Administration of Taxation (the “SAT”) issued the Circular of the State Administration of Taxation on Issues Relating to Identification of PRC-Controlled Overseas Registered Enterprises as Resident Enterprises in Accordance With the De Facto Standards of Organizational Management (the “Circular 82”), which provides certain specific criteria for determining whether the “de facto management body” of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this Circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT’s general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. According to Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its “de facto management body” in China and will be subject to PRC enterprise income tax on its global income if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in China; (ii) decisions relating to the enterprise’s financial and human resource matters are made or are subject to approval by organizations or personnel in China; (iii) the enterprise’s primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and (iv) at least 50% of voting board members or senior executives habitually reside in China.

If the PRC tax authorities determine that we are a PRC resident enterprise for enterprise income tax purposes, we could be subject to PRC tax at a rate of 25% on our worldwide income, which could materially reduce our net income, and we may be required to withhold a 10% withholding tax from dividends we pay to our shareholders that are non-resident enterprises. In addition, non-resident enterprise shareholders may be subject to PRC tax at a rate of 10% on gains realized on the sale or other disposition of our Shares, if such income is treated as sourced from within China. Furthermore, if we are deemed a PRC resident enterprise, dividends payable to our non-PRC individual shareholders and any gain realized on the transfer of our Shares by such shareholders may be subject to PRC tax at a rate of 20% in the case of non-PRC individuals (which, in the case of dividends, may be withheld at source) unless a reduced rate is available under an applicable tax treaty. It is unclear whether non-PRC shareholders of our company would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. Any such tax may reduce the returns on the investment in our Shares.

We have granted, and may continue to grant, options and other types of awards under our share incentive plan, which may result in increased share-based compensation expenses.

We have adopted the Pre-IPO Equity Plan to, among others, attract and retain outstanding individuals to serve as directors, officers, employees, consultants, and advisors to the Company. We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based compensation to employees in the future. As a result, our expenses associated with

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share-based compensation may increase, which may have an adverse effect on our results of operations. We had share-based payment expenses of US\$0.6 million and US\$1.0 million in 2019 and 2020, respectively, and US\$0.5 million and US\$1.4 million, respectively in the nine months ended September 30, 2020 and 2021. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the grants under our currently effective share incentive plans and any subsequently adopted share incentive plans from time to time. If we choose to do so, we may experience substantial change in our share-based compensation charges in the reporting periods following the Global Offering.

Any failure to comply with PRC regulations regarding our employee equity incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

In February 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (“SAFE Circular 7”), replacing the previous rules issued by SAFE in March 2007. Under SAFE Circular 7 and other relevant rules and regulations, PRC residents who participate in a stock incentive plan in an overseas publicly listed company are required to register with SAFE or its local branches and complete certain other procedures. Participants in a stock incentive plan who are PRC residents must retain a qualified PRC agent, which could be a PRC subsidiary of the overseas publicly listed company or another qualified institution selected by the PRC subsidiary, to conduct the SAFE registration and other procedures with respect to the stock incentive plan on behalf of its participants. The participants must also retain an overseas entrusted institution to handle matters in connection with their exercise of stock options, the purchase and sale of corresponding stocks or interests and fund transfers. In addition, the PRC agent is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan, the PRC agent or the overseas entrusted institution or other material changes. Also, SAFE Circular 37 stipulates that PRC residents who participate in a share incentive plan of an overseas non-publicly listed special purpose company may register with SAFE or its local branches before they exercise the share options. We and our PRC employees who have been granted share options will be subject to these regulations upon the completion of this Global Offering. Failure of our PRC share option holders to complete their SAFE registrations may subject these PRC residents to fines of up to RMB300,000 for entities and up to RMB50,000 for individuals, and legal sanctions and may also limit our ability to contribute additional capital into our PRC subsidiaries, limit our PRC subsidiaries’ ability to distribute dividends to us, or otherwise materially and adversely affect our business.

The STA has also issued relevant rules and regulations concerning employee share incentives. Under these rules and regulations, our employees working in the PRC will be subject to PRC individual income tax upon exercise of the share options. Our PRC subsidiaries have obligations to file documents with respect to the granted share options or restricted shares with relevant tax authorities and to withhold individual income taxes for their employees upon exercise of the share options or grant of the restricted shares. If our

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employees fail to pay or we fail to withhold their individual income taxes according to relevant rules and regulations, we may face sanctions imposed by the competent governmental authorities.

PRC regulations relating to offshore investment activities by PRC residents may limit our PRC subsidiaries' ability to change their registered capital or distribute profits to us or otherwise expose us or our PRC resident beneficial owners to liability and penalties under PRC laws.

In July 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment Through Special Purpose Vehicles (“**SAFE Circular 37**”). SAFE Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities as well as foreign individuals that are deemed as PRC residents for foreign exchange administration purposes) to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 further requires amendment to SAFE registrations in the event of any changes with respect to the basic information of the offshore special purpose vehicle, such as changes of a PRC individual shareholder, name and operation term, or any significant changes with respect to the offshore special purpose vehicle, such as increase or decrease of capital contribution, share transfer or exchange, or mergers or divisions. SAFE Circular 37 is applicable to our shareholders who are PRC residents. If our shareholders who are PRC residents fail to make the required registration or to update the previously filed registration, our PRC subsidiaries may be prohibited from distributing their profits or the proceeds from any capital reduction, share transfer or liquidation to us, and we may also be prohibited from making additional capital contributions into our PRC subsidiaries.

In February 2015, SAFE promulgated a Notice on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment (“**SAFE Notice 13**”), effective June 2015. Under SAFE Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound overseas direct investments, including those required under SAFE Circular 37, will be filed with qualified banks instead of SAFE. The qualified banks will directly examine the applications and accept registrations under the supervision of SAFE.

In addition, our shareholders who are PRC entities shall complete their overseas direct investment filings according to applicable laws and regulations regarding the overseas direct investment by PRC entities, including certificates, filings or registrations with the MOFCOM and NDRC or the local branch of the MOFCOM and NDRC based on the investment amount, invested industry or other factors thereof, and shall also update or apply for amendment in respect to the certificates, filings or registrations in the event of any significant changes with respect to the offshore investment. We have notified and requested all of our shareholders to comply with, or notify their beneficial owners who are PRC residents to comply with applicable PRC regulations, including the requirements of the NDRC and MOFCOM and their registration obligation under SAFE Circular 37 and other implementation rules.

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We may not be fully informed of the identities of all the PRC residents holding direct or indirect interests in our company, and we cannot provide any assurance that these PRC residents will comply with our request to make or obtain any applicable registrations or continuously comply with such requirements and obligations in a timely manner. The failure or inability of the relevant shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions, such as restrictions on our cross-border investment activities, on the ability of our wholly foreign-owned subsidiaries in China to distribute dividends and the proceeds from any reduction in capital, share transfer or liquidation to us. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits could be materially and adversely affected.

PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay or prevent us from using the proceeds of this Global Offering to make loans to our PRC subsidiaries in China, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

We are an offshore holding company conducting our operations in China through our PRC subsidiaries. We may make loans to our PRC subsidiaries subject to the approval from governmental authorities and limitation on the available loan amount, or we may make additional capital contributions to our wholly foreign-owned subsidiaries in China.

Any loans to our wholly foreign-owned subsidiaries in China, which are treated as foreign-invested enterprises under PRC law, are subject to PRC regulations and foreign exchange loan registrations. For example, loans by us to our wholly foreign-owned subsidiaries in China to finance their activities cannot exceed statutory limits and must be registered with the local counterpart of SAFE. In addition, a foreign-invested enterprise shall use its capital pursuant to the principle of authenticity and self-use within its business scope. The capital of a foreign-invested enterprise shall not be used for the following purposes: (i) directly or indirectly used for payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; (ii) directly or indirectly used for investment in securities or investments other than banks' principal-secured products unless otherwise provided by relevant laws and regulations; (iii) the granting of loans to non-affiliated enterprises, except where it is expressly permitted in the business license; and (iv) paying the expenses related to the purchase of real estate that is not for self-use (except for the foreign-invested real estate enterprises).

SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming the Administration of Foreign Exchange Settlement of Capital of Foreign-invested Enterprises ("**SAFE Circular 19**"), effective on June 1, 2015, in replacement of the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign-Invested Enterprises, the

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Notice from the State Administration of Foreign Exchange on Relevant Issues Concerning Strengthening the Administration of Foreign Exchange Businesses, and the Circular on Further Clarification and Regulation of the Issues Concerning the Administration of Certain Capital Account Foreign Exchange Businesses. According to SAFE Circular 19, the flow and use of RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company is regulated such that RMB capital may not be used for the issuance of RMB-entrusted loans, the repayment of inter-enterprise loans or the repayment of bank loans that have been transferred to a third party. Although SAFE Circular 19 allows RMB capital converted from foreign currency-denominated registered capital of a foreign-invested enterprise to be used for equity investments within China, it also reiterates the principle that RMB converted from the foreign currency-denominated capital of a foreign-invested company may not be directly or indirectly used for purposes beyond its business scope. Thus, it is unclear whether SAFE will permit such capital to be used for equity investments in China in actual practice. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (“**SAFE Circular 16**”), effective on June 9, 2016, which reiterates some of the rules set forth in SAFE Circular 19, but changes the prohibition against using RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to non-associated enterprises. Violations of SAFE Circular 19 and SAFE Circular 16 could result in administrative penalties. SAFE Circular 19 and SAFE Circular 16 may significantly limit our ability to transfer any foreign currency we hold, including the net proceeds from this Global Offering, to our PRC subsidiaries, which may adversely affect our liquidity and our ability to fund and expand our business in China.

In light of the various requirements imposed by PRC regulations on loans to and direct investment in PRC entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans to our PRC subsidiaries or future capital contributions by us to our wholly foreign-owned subsidiaries in China. As a result, uncertainties exist as to our ability to provide prompt financial support to our PRC subsidiaries when needed. If we fail to complete such registrations or obtain such approvals, our ability to use the proceeds we expect to receive from this Global Offering and to capitalize or otherwise fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

We and our shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributable to a PRC establishment of a non-PRC company.

On February 3, 2015, the SAT issued the Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises (the “**Bulletin 7**”). Pursuant to Bulletin 7, an “indirect transfer” of “PRC taxable assets,” including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a

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direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC enterprise income tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax. When determining whether there is a “reasonable commercial purpose” of the transaction arrangement, factors to be taken into consideration include: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consist of direct or indirect investment in China or if its income mainly derives from China; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have a real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. On October 17, 2017, the SAT issued the Announcement of the State Administration of Taxation on Issues Concerning the Withholding of Non-resident Enterprise Income Tax at Source (“**Bulletin 37**”), which came into effect on December 1, 2017. Bulletin 37 further clarifies the practice and procedure of the withholding of non-resident enterprise income tax.

Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors are not subject to the PRC enterprise income tax pursuant to Bulletin 7 where such shares were acquired in a transaction through a public stock exchange. However, the sale of our Shares by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC enterprise income tax under Bulletin 7.

There are uncertainties as to the application of Bulletin 7. Bulletin 7 may be determined by the tax authorities to be applicable to the sale of the shares of our offshore subsidiaries or investments where PRC taxable assets are involved. The transferors and transferees may be subject to the tax filing and withholding or tax payment obligation, while our PRC subsidiaries may be requested to assist with the filing. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with Bulletin 7 or to establish that we and our non-resident enterprises should not be taxed under Bulletin 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial condition and results of operations.

The PRC tax authorities have the discretion under Bulletin 7 to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities make adjustments to the taxable income of the transactions under Bulletin 7 or Bulletin 37, our income tax costs associated with such potential acquisitions or disposals will increase, which may have an adverse effect on our financial condition and results of operations.

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Governmental control of currency conversion, and restrictions on the remittance of Renminbi into and out of China, may adversely affect the value of the investment.

The Renminbi is not currently a freely convertible currency, as the PRC government imposes controls on the convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. A substantial majority of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency-denominated obligations.

Under China's current foreign exchange control system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approvals from SAFE, but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within the PRC that have the licenses to carry out foreign exchange business. Approvals from appropriate government authorities are 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. The PRC government may also at its discretion restrict access in the future to foreign currencies for current account transactions. Since 2015, in response to China's declining foreign currency reserves, the PRC government has placed increasingly stringent restrictions on the convertibility of Renminbi into foreign currencies. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our shareholders. Further, there can be no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of Renminbi into or out of China.

You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing original actions in the PRC against us or our management named in the documents based on Hong Kong or other foreign laws.

Most of our major operating subsidiaries are incorporated in China. Substantially all of our assets are located in the PRC. In addition, a majority of our Directors, Supervisors and senior management personnel reside within the PRC, and substantially all of their assets are located within the PRC. As a result, it may not be possible for investors to effect service of process upon us or our Directors, Supervisors and senior management personnel in the PRC. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions.

In July 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

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and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of 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 under 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 choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a PRC court is expressly selected as the court having sole jurisdiction for the dispute. Therefore, it is not possible to enforce a judgment rendered by a Hong Kong court in the PRC if the parties in dispute have not agreed to enter into a choice of court agreement in writing. Although the Arrangement became effective in August 2008, the outcome and effectiveness of any action brought under the Arrangement remain uncertain. As a result, it may be difficult or impossible for investors to effect service of process against certain of our assets or Directors in the PRC in order to seek recognition and enforcement of foreign judgments in the PRC.

RISKS RELATING TO THE GLOBAL OFFERING AND INVESTMENTS INTO OUR SHARES

There has been no prior public market for our Shares, and their liquidity and market price may be volatile.

No public market currently exists for our Shares. The initial Offer Price for our Shares to the public will be the result of negotiations between our Company and the Joint Representatives (for themselves and on behalf of the Underwriters) and the Offer Price may differ significantly from the market price of the Shares following the Global Offering. We have applied for listing of and permission to deal in our Offer Shares on the Stock Exchange. A listing on the Stock Exchange, however, does not guarantee that an active and liquid trading market for the Shares will develop, or if it does develop, that it will be sustained following the Global Offering, or that the market price of the Shares will not decline following the Global Offering.

The price and trading volume of our Shares may be volatile, which could lead to substantial losses to investors.

The price and trading volume of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and trading volume of our Shares. In addition to market and industry factors, the price and trading volume of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our drug candidates, the results of our applications for approval of our drug candidates, regulatory developments affecting the

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biopharmaceutical industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel or actions taken by competitors. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our Shares may be subject to changes in price not directly related to our performance.

There will be a gap of several days between the pricing and trading of our Shares, and the price of our Shares when trading begins could be lower than the offer price.

The Offer Price to the public of our Shares sold in the public market is expected to be determined on the Price Determination Date. However, our Shares will not commence trading on the Hong Kong Stock Exchange until they are delivered, which is expected to be not more than several business days after the Price Determination Date. As a result, investors may not be able to sell or otherwise deal in the Shares during that period. Accordingly, holders of our Shares are subject to the risk that the price of the Shares when trading begins could be lower than the indicative Offer Price range as a result of adverse market conditions or other adverse developments that may occur between the time of sale and the time trading begins.

Future sales or perceived sales of our Shares in the public market by major shareholders following the Global Offering could materially and adversely affect the price of our Shares.

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

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights as a holder of our Shares. Issuance of additional Shares, or the possibility of such issuance, may cause dilution to our shareholders if we issue additional Shares at a price which is lower than the net tangible asset value per Share prior to the issuance of such additional Shares, and may cause the market price of our Shares to decline. In addition, the incurrence of

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additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Because we do not expect to pay dividends in the foreseeable future after the Global Offering, you must rely on price appreciation of our Shares for a return on your investment.

We currently expect to retain all future earnings for use in the operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. Any future declarations and payments of dividends will be at the absolute discretion of our Directors and will depend on our actual and expected results of operations, cash flow and financial position, general business conditions and business strategies, expected working capital requirements and future expansion plans, legal, regulatory and other contractual restrictions, and other factors which our Directors consider relevant. Accordingly, the return on the investment in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the Global Offering or even maintain the price at which you purchased the Shares. You may not realize a return on your investment in our Shares and you may even lose your entire investment in our Shares.

The Company will be treated as a U.S. tax resident for U.S. federal tax purposes, and the U.S. will tax shareholders on that basis.

Although the Company is and will continue to be a Cayman Islands company, the Company is also treated as a U.S. corporation for U.S. federal tax purposes under the “inversion rules”, and is subject to U.S. federal income tax on its worldwide income.

Non-U.S. holders (as defined below) may be subject to material adverse U.S. federal tax consequences as a result of acquiring, owning and/or disposing of our Shares. Please see “Information About This Prospectus and the Global Offering—Certain U.S. Federal Income Tax Considerations.” for a discussion of some of these considerations.

In addition, we may also be treated as a PRC resident enterprise for PRC income tax purposes. See “—If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders.” If we were subject to both PRC and the U.S. income taxes on our income,

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we could be put at a disadvantage compared to companies that are only subject to one country's income taxes, which could materially reduce our net income and/or result in both the PRC and the U.S. potentially imposing withholding taxes on distribution on and/or transactions involving the Shares.

Tax laws could change, which could adversely impact the Company or a shareholder's investment in the Company.

There may be future changes in tax laws resulting from legislative, administrative or judicial decisions, global initiatives to modify tax law, and future issuance of new or modified regulations implementing existing law, any of which may have adverse tax consequences to the Company and/or a shareholder's investment in the Company. Any such change may or may not be retroactive to a time preceding its occurrence. The rules dealing with taxation are constantly under review by persons involved in the legislative, administrative and judicial processes, resulting in revisions of regulations and revised interpretations of established concepts as well as statutory changes.

We are a Cayman Islands exempted company and, because judicial precedent regarding the rights of shareholders is more limited under the laws of the Cayman Islands than other jurisdictions, you may have difficulties in protecting your shareholder rights.

Our corporate affairs are governed by our Memorandum and Articles and by the Cayman Companies Act and common law of the Cayman Islands. The rights of shareholders to take legal action against our Directors and us, actions by minority shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those established under statutes and judicial precedent in existence in the jurisdictions where minority shareholders may be located. As a result of all of the above, minority shareholders may enjoy different remedies when compared with the laws of the jurisdiction such shareholders are located in.

Facts, forecasts and statistics in this prospectus relating to the biopharmaceutical industry may not be fully reliable.

Facts, forecasts and statistics in this prospectus relating to the biopharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by China Insights that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Sole Sponsor, the Joint Representatives nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying

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economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the industry statistics in this prospectus may be inaccurate and you should not place undue reliance on them. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

Forward-looking statements contained in this prospectus are subject to risks and uncertainties.

This prospectus contains certain statements and information that are forward-looking and uses forward-looking terminology such as “believe,” “expect,” “estimate,” “predict,” “aim,” “intend,” “will,” “may,” “plan,” “consider,” “anticipate,” “seek,” “should,” “could,” “would,” “continue,” and other similar expressions. You are cautioned that reliance on any forward-looking statement involves risks and uncertainties and that any or all of those assumptions could prove to be inaccurate and, as a result, the forward-looking statements based on those assumptions could also be incorrect. In light of these and other risks and uncertainties, the inclusion of forward-looking statements in this prospectus should not be regarded as representations or warranties by us that our plans and objectives will be achieved and these forward-looking statements should be considered in light of various important factors, including those set forth in this section. Subject to the requirements of the Listing Rules, we do not intend publicly to update or otherwise revise the forward-looking statements in this prospectus, whether as a result of new information, future events, or otherwise. Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements in this prospectus are qualified by reference to this cautionary statement.

You should read the entire prospectus 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 Global Offering.

Subsequent to the date of this prospectus but prior to the completion of the Global Offering, there may be press and media coverage regarding us and the Global Offering, which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the Global Offering. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this prospectus, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this prospectus only and should not rely on any other information.